National Institute of Diabetes and Digestive and Kidney Diseases

NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Advisory Council Orientation Handbook

January 2022

National Institutes of Health
U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

Orientation for New Advisory Council Members

A MESSAGE FROM THE DIRECTOR, NIDDK

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of 27 Institutes and Centers that make up the National Institutes of Health (NIH), part of the Public Health Service in the U.S. Department of Health and Human Services. The Institute conducts and supports basic and clinical research in some of the most serious, common, disabling, and costly conditions affecting the public's health. The diseases in NIDDK's research mission cut across the full spectrum of medicine and include:

- Diabetes and other endocrine diseases;
- Cystic fibrosis and other inherited diseases;
- Digestive diseases;
- Obesity;
- Nutrition;
- Diseases of the kidney, genitourinary tract, and blood.

Most arise from the complex interaction of genetic, autoimmune, neuroendocrine, metabolic, nutritional, and environmental factors. Some diseases such as diabetes, obesity, hepatitis, and kidney failure disproportionately affect minority populations. NIDDK funds research projects that relate directly to these diseases, but it also places a high priority on fundamental, untargeted research.

Training is critically important to continued progress in medical research. NIDDK supports research training and career development, with special emphasis on increasing the ranks of physician scientists and recruiting underrepresented minorities and women into biomedical research careers.

The National Diabetes and Digestive and Kidney Diseases Advisory Council's most important purpose is to make recommendations regarding the funding of grant applications, focusing primarily on the relevance to the programmatic missions and priorities of the Institute. The Council also has the responsibility to ensure the adequacy of the scientific review by the initial review groups. In addition, the Council offers advice on a wide variety of policies and programs within the Institute.

As you begin service on the National Diabetes and Digestive and Kidney Diseases Advisory Council, we hope this orientation material will help answer some of your questions and provide the information you will need in your role as a Council member. In addition, your comments on the usefulness of this material and suggestions for improvement will be appreciated.

Griffin P. Rodgers, M.D., M.A.C.P.,
Director,
National Institute of Diabetes
and Digestive
and Kidney Diseases
National Institutes of Health

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NIH Gateway Center Map

Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open Monday – Friday, 6am – 10pm
- Closed on Weekends and Observed Holidays
- After 10pm weekdays, all day weekends and holidays, pedestrian visitors enter via the Commercial Vehicle Inspection Facility (CVIF) – Building 67 (on Rockville Pike between North Drive and Wilson Drive)

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am – 10pm
  Weekends and After Hours: Closed
  After 10pm on weekdays, all day weekends and holidays, visitors in vehicles should enter campus via the CVIF – Building 67 (on Rockville Pike between North Drive and Wilson Drive)
- All vehicles and their contents will be inspected upon entering the campus.
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: $2 per hour for the first three hours, $12 maximum for entire day. Closed weekends.

Security Procedures for Entering the NIH Campus:
All visitors and patients – **please be aware**: Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.
The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gate Center. You will be asked to submit to a vehicle or personal inspection.
Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc**.** Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus – Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you. Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

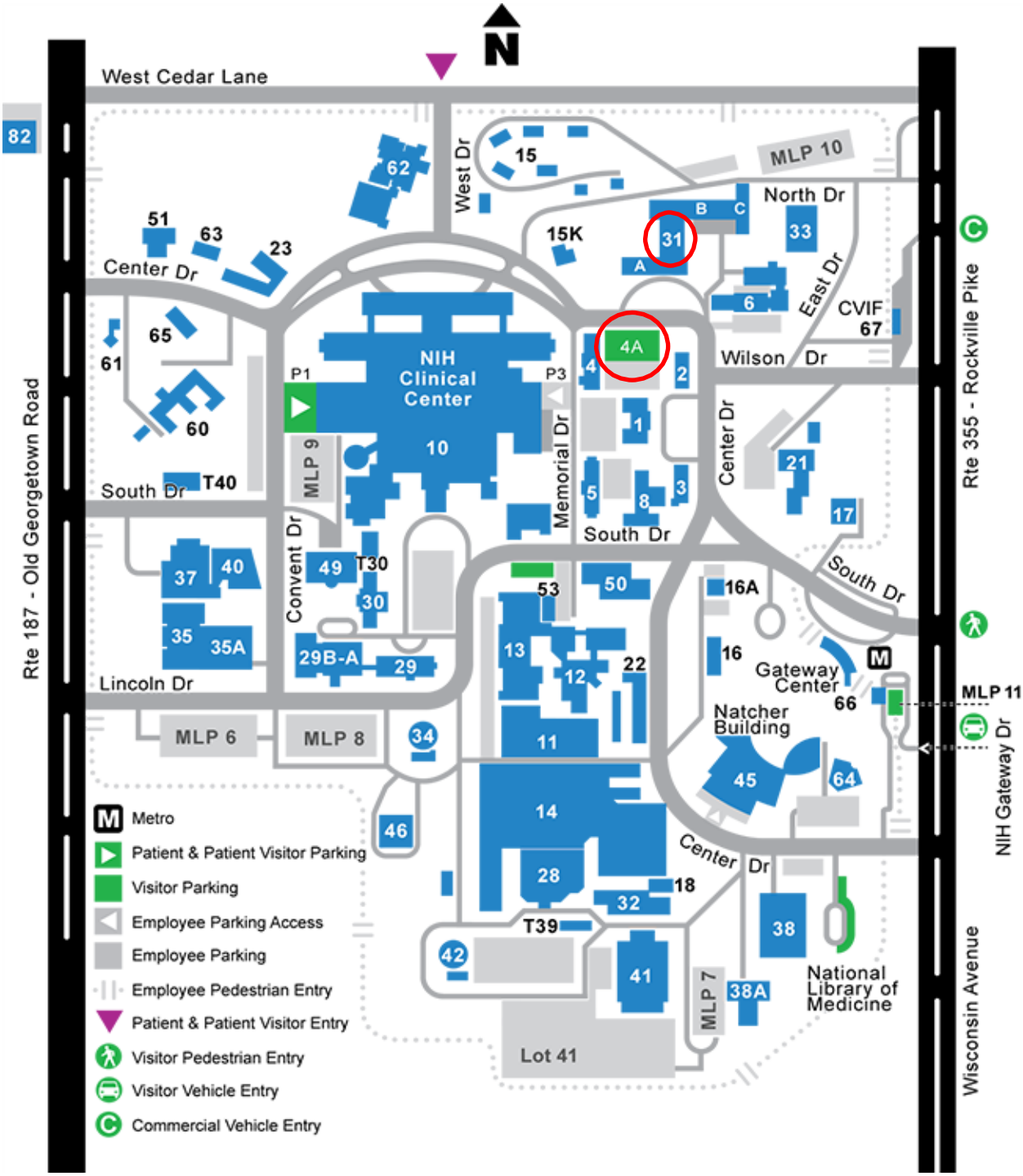
If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: http://www.nih.gov/about/visitor/index.htm.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus



Street Address:
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

See Parking on Following Page

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):
Monday – Friday, 6am – 9pm (entrance); 6am – 11pm (exit):
$2.00 per hour for the first three hours
$12.00 for the entire day

Lot 4A (between Buildings 2 and 4, across from Building 31):
Monday – Friday, 7am – 9pm (entrance and exit)

Metered parking lots:
Monday – Friday, enforced 7am – 7pm
Available in up to 2-hour increments; $2 per hour ($1.50 per hour in front of Building 31A)

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

The NIH Has implemented security measures to help ensure the safety of our patients, employees, guests, and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gateway Visitor Center. You will be asked to submit to a vehicle and personal inspection.

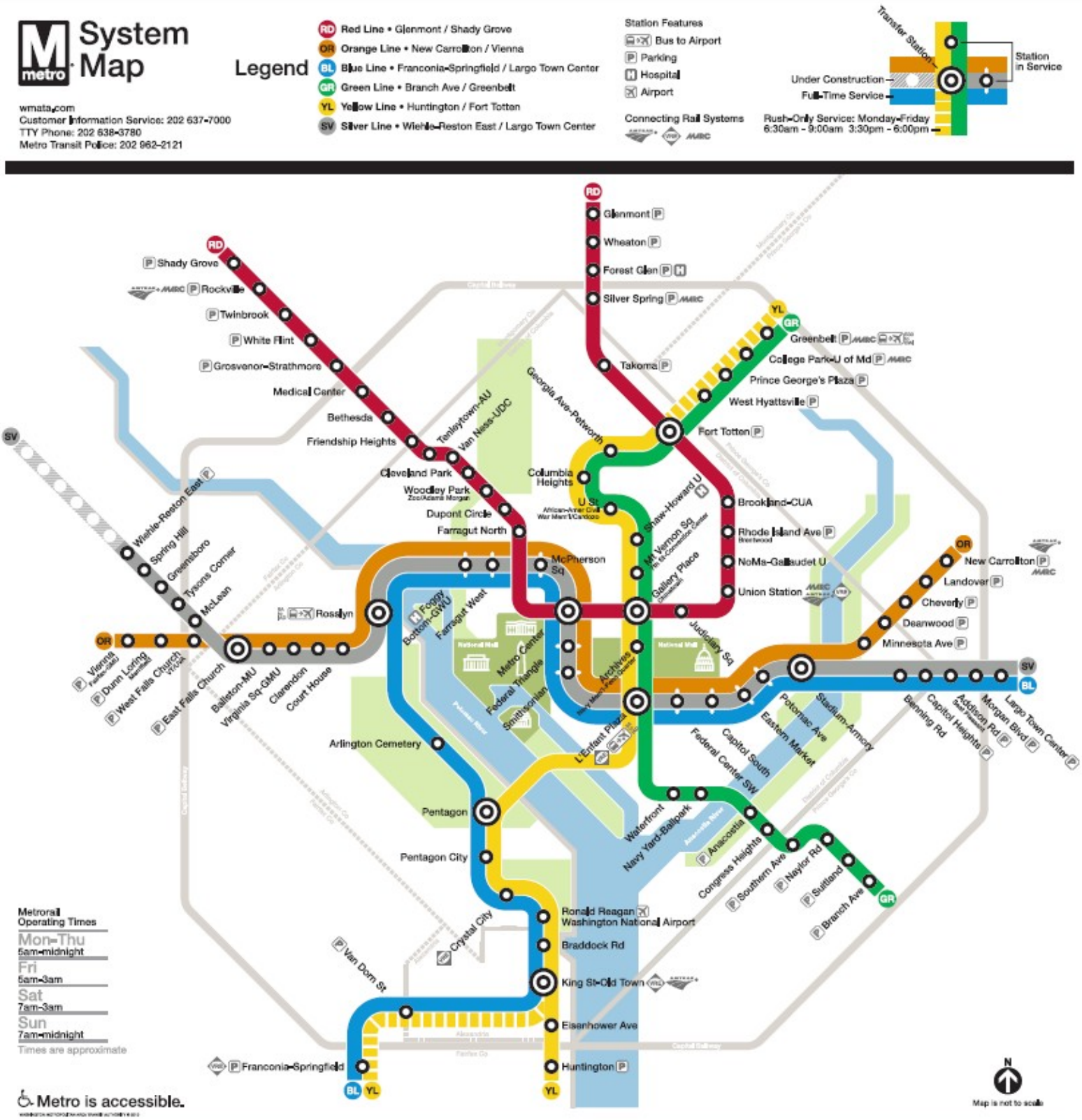
Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx. Directional signs within Building 31 will guide you to the meeting room

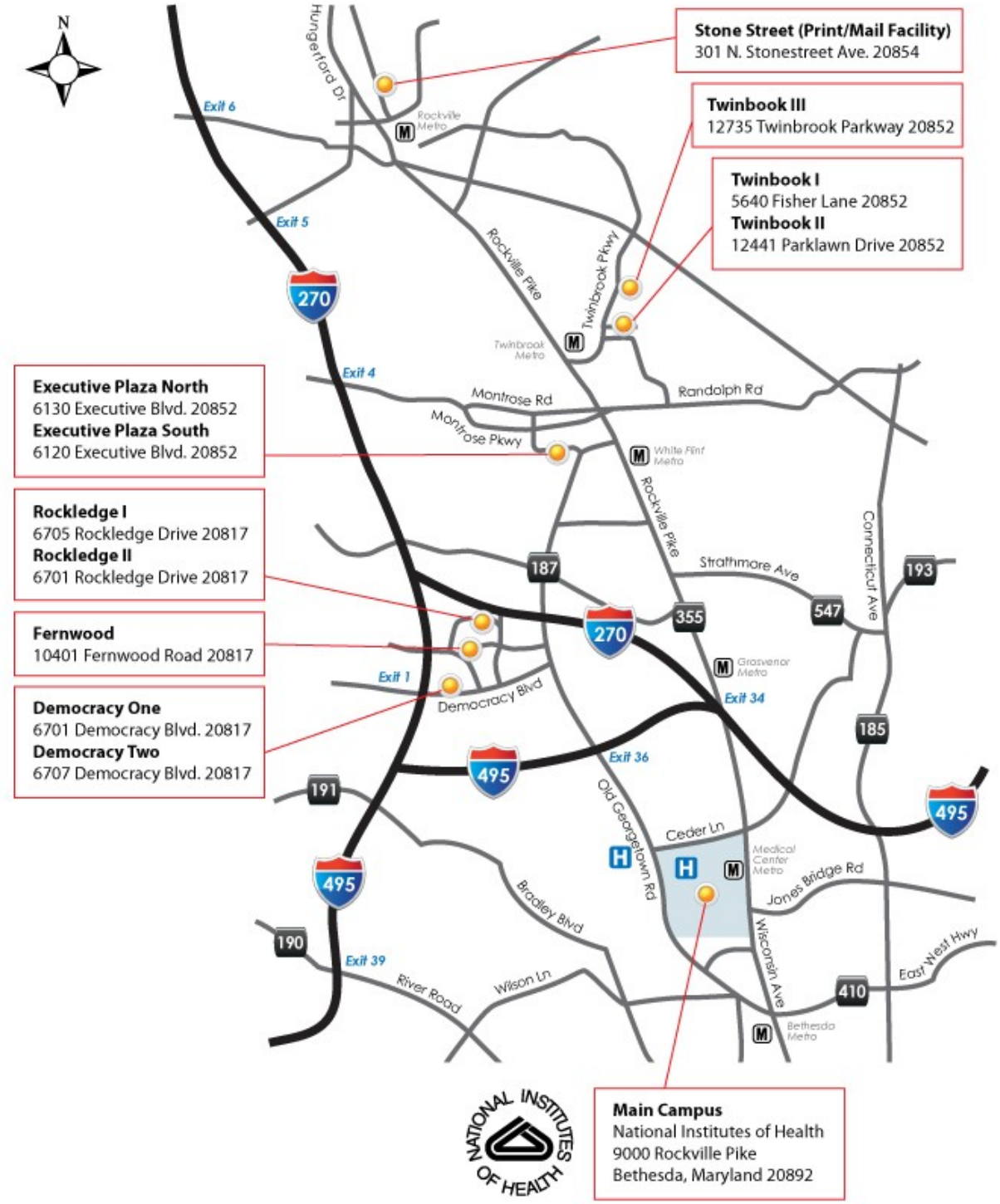
If taking a taxi directly to the meeting site: Upon entering the campus, please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges**. Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31, you and your car must first go through security procedures. Visitor parking is located directly across from Building 31 (see **circles** on map). Parking fees are $12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.


System Map
Legend
RD Red Line • Glenmont / Shady Grove
OR Orange Line • New Carrollton / Vienna
BL Blue Line • Franconia-Springfield / Largo Town Center
GR Green Line • Branch Ave / Greenbelt
YL Yellow Line • Huntington / Fort Totten
SV Silver Line • Wiehle-Reston East / Largo Town Center
Station Features
Bus to Airport
Parking
Hospital
Airport
Connecting Rail Systems
Transfer Station
Station in Service
Under Construction
Full-Time Service
Rush-Only Service: Monday-Friday 6:30am - 9:00am 3:30pm - 6:00pm
wmata.com
Customer Information Service: 202 637-7000
TTY Phone: 202 638-3780
Metro Transit Police: 202 962-2121
Shady Grove
Rockville
Twinbrook
White Flint
Grosvenor-Strathmore
Medical Center
Bethesda
Friendship Heights
Tenleytown-AU
Van Ness-UDC
Cleveland Park
Woodley Park
Dupont Circle
Farragut North
Glenmont
Wheaton
Forest Glen
Silver Spring
Takoma
Georgia Ave-Petworth
Fort Totten
Greenbelt
College Park-U of Md
Prince George's Plaza
West Hyattsville
Columbia Heights
U St
Shaw-Howard U
Brookland-CUA
Rhode Island Ave
NoMa-Gallaudet U
Union Station
Mt Vernon Sq
Gallery Place
McPherson Sq
Wiehle-Reston East
Spring Hill
Greensboro
Tysons Corner
McLean
Rosslyn
Foggy Bottom-GWU
Farragut West
Metro Center
Federal Triangle
Smithsonian
Archives
Judiciary Sq
L'Enfant Plaza
New Carrollton
Landover
Cheverly
Deanwood
Minnesota Ave
Stadium-Armory
Potomac Ave
Eastern Market
Capitol South
Federal Center SW
Capitol Heights
Addison Rd
Morgan Blvd
Largo Town Center
Benning Rd
Vienna
Dunn Loring
West Falls Church
East Falls Church
Ballston-MU
Virginia Sq-GMU
Clarendon
Court House
Arlington Cemetery
Pentagon
Pentagon City
Waterfront
Navy Yard-Ballpark
Anacostia
Congress Heights
Southern Ave
Naylor Rd
Suitland
Branch Ave
Crystal City
Ronald Reagan Washington National Airport
Braddock Rd
King St-Old Town
Eisenhower Ave
Van Dorn St
Franconia-Springfield
Huntington
Metrorail Operating Times
Mon-Thu 5am-midnight
Fri 5am-3am
Sat 7am-3am
Sun 7am-midnight
Times are approximate
Metro is accessible.
Map is not to scale
No Smoking
No Eating or Drinking
No Animals (except service animals)
No Audio (without earphones)
No Littering or Spitting
No Dangerous or Flammable Items

Bethesda Area Map Showing NIH Campus and Off-Campus Facilities



Glossary of Terms

For extensive list of grant terms see http://grants.nih.gov/grants/glossary.htm

A

Accession Number – Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition – Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant – A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code – A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C – The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement – Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) – Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application – A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers – The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing continuation; Type 7. Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation.

Appropriation – Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget – The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award – The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office – The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement – A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) – Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation – The yearly amount given to a Government Agency by Congress.

Budget Period – The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) – Award supporting Ph.D.'s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure – The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research – Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial – A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g., 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out – Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-Funding – Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator – An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered "key personnel." The designation of a co-investigator, if applicable, does not affect the PI's roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term "co-PI."

Commitment Base – Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications – Either new or re-competing applications that must undergo initial peer review.

Competing Continuation – Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range – Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept – The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts may be brought before the Advisory Council

for concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest – Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement – Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars – Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) – Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer – Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) – Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory – National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round – At NIH, there are typically three council rounds each fiscal year: September. January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

CR (Continuing Resolution) – An Act of Congress to fund or partially fund government operations for a limited period of time, in the absence of an appropriations.

Critique – An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars – Actual dollars awarded, without adjustment for inflation.

D

Direct Costs – Costs that can be specifically identified with a particular project or activity.

Direct Operations – Funds for salary and other administrative costs.

Dual Assignments – Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System – Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

E

Early Stage Investigator (ESI) – A New Investigator (*see* definition under N) who is within 10 years of completing a terminal research degree or within 10 years of completing medical residency. Between 1980 and 2001, the duration of postdoctoral training increased and the average age at which an investigator first obtained R01 funding increased by more than 5 years. Under the ESI program NOT-OD-17-101, New Investigators identified as ESIs will have their career stage considered at the time of review and award of R01 applications. By providing this advantage to ESIs, NIH can directly encourage earlier application for NIH research grant support. In some cases there may have been one or more lapses in the period of research or research training after the terminal degree or completion of medical residency. NIH Guide Notice NOT-OD-19-125, describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions can be considered.

Electronic Research Administration (eRA) – NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data – Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment – An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds $5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons – A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date – The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research – Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement.

F

Facilities and Administrative Costs (F&A) – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) – Laws regulating government contracting.

Federal Advisory Committee Act (FACA) – A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register – An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) – Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee – An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) – The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2022 – Started October 1, 2021 and ends September 30, 2022.

Full-Time Appointment – Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Opportunity Announcement (FOA) – *See* Initiative.

G

Gender – Human subject term indicating a classification of research subjects into women and men.

Grant – Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals – A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period – Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date – Official date a grant award begins; same as the first day of the first budget period.

Grantee – Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) – An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) – An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov – An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to http://www.grants.gov/.

H

High Risk/High Impact (HR/HI) – A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance – A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier – Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) – A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent – Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – *Significance:* Is the topic important? Will it advance Scientific Knowledge? ***Approach:*** Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? ***Innovation:*** Does the proposal involve new ideas or methods; does it challenge existing paradigms? ***Investigator:*** Does the investigator and collaborators have the training and experience to do the work? ***Environment:*** Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations?

Initiative – A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Funding Opportunity Announcement (FOA).

Institutional Base Salary – The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) – IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interagency Agreement – Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) – A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) – Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research – Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time – Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel – The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. "Zero percent" effort or "as needed" is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing – The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

Minority Group – Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism – Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring – A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principal Investigator – Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) – Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator – New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a "New Investigator" if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant – An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) – The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Not Recommended for Further Consideration (NRFC) – A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation – Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) – NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) – HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) – NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) – Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time – Applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: When these dates fall on a weekend or a federal holiday, they are extended to the next business day.

Organization – A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code – A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK's organizational code is DK.

Other Research Grants – Research grants not classified as research projects or research centers.

Other Support – Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support – Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) – Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement – NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback – Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline – A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review – A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile – Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months – Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application – A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget – The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval – Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score – A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act – A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance – The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) – An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

Program Official (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction – The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number – Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol – Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Public Access Policy – The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states: *The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication:* Provided, *That the NIH shall implement the public access policy in a manner consistent with copyright law.*

PubMed – Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMCID, a series of numbers.

R

Rating Criteria – *See* Initial Peer Review Criteria.

Real Property – Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal – Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications – Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self-assign.

Recipient – Organizational entity or individual receiving a grant or cooperative agreement. *See* Grantee.

Recommended – Designation given by a study section advising funding of an application. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support – Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing – Grant whose term (e.g., 4 years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research – A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”

Research Grants – Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio – The cohort of grants supported by a given NIH organization.

Research Projects – Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) – Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement – Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction – Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission – Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle – Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision – Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now “resubmission” in Grants.gov.

S

Salary Cap/Limitation – A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap – Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) – Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) – The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay – The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside – Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Sex as a Biological Variable (SABV) – NIH expects that sex as a biological variable will be factored into research designs, analyses and reporting in vertebrae animals and human studies. See: Consideration of Sex as a Biological Variable in NIH-funded Research: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-102.html

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern – A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) – A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) – A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative

effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Council Review (SCR) – Advisory Council members provide additional consideration of new and renewal applications from well-supported investigators who currently receive $1 million or more in direct costs of NIH funding for RPGs. See: Notice of NIH Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html

Special Emphasis – The NIDDK's policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcommittee endorsement for funding. Each such application is then nominated for the Division Director's concurrence and approval by the Institute Director.

Special Government Employee (SGE) – A Special Government Employee is an officer or employee who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, for not more than 130 days during any period of 365 consecutive days. This category should be distinguished from other categories of individuals who serve executive branch agencies but who are not employees, such as independent contractors.

Specific Aims – A component of an application's Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) – In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) – Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) – In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These applications are generally not discussed during the study section meeting but returned to the applicant with the assigned reviewers' written comments with no priority score. *See* Unscored.

Study Section – Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward – Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base – The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement – A combination of the reviewers' written comments and the Scientific Review Administrator's (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement – A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3, application or award, a supplement can be either non-competing (administrative) if there is no change in scope or competing revision (subject to peer review) to support new or additional activities that are not identified in the current award.

T

Targeted Research – Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer – Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award – All legal requirements imposed on a grant by NIH, whether based on statue, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant – When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards – Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research – Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group – Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored – In the NIH peer review process, applications judged by a study section to be in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed, and applicants receive a summary statement.

V

Validation – The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support – A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
FIC	John E. Fogarty International Center	**TW**
NCATS	National Center for Advancing Translational Sciences	**TR**
NCCIH	National Center for Complementary and Integrative Health	**AT**
NCI	National Cancer Institute	**CA**
NEI	National Eye Institute	**EY**
NHGRI	National Human Genome Research Institute	**HG**
NHLBI	National Heart, Lung, and Blood Institute	**HL**
NIA	National Institute on Aging	**AG**
NIAAA	National Institute on Alcohol Abuse and Alcoholism	**AA**
NIAID	National Institute of Allergy and Infectious Diseases	**AI**
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	**AR**
NIBIB	National Institute of Biomedical Imaging and Bioengineering	**EB**

*** Does Not Make Extramural Awards**

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development	**HD**
NIDA	National Institute on Drug Abuse	**DA**
NIDCD	National Institute on Deafness and Other Communication Disorders	**DC**
NIDCR	National Institute of Dental and Craniofacial Research	**DE**
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	**DK**
NIEHS	National Institute of Environmental Health Sciences	**ES**
NIGMS	National Institute of General Medical Sciences	**GM**
NIH	National Institutes of Health	
NIMH	National Institute of Mental Health	**MH**
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)	**MD**
NINDS	National Institute of Neurological Disorders and Stroke	**NS**
NINR	National Institute of Nursing Research	**NR**
NLM	National Library of Medicine	**LM**
OD	Office of the Director	**OD**

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now **SAMSHA**)

ADB	Automated Data Base System
ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program

AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities
AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant

APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization
APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRA	American Recovery and Reinvestment Act of 2009
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum

ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	Buildings and Facilities
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition

BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium
BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHPr	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ (Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section

BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative
BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH

BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia
BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource

BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals

C

CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center
CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research

CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan
CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign

CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the “CFDA number.”
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease

CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia
CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer

CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program
COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee

CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)
CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award

CRTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review
CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program

Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management
DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director's Consumer Liaison Group

DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum
DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services

DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also known as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DM	Data management
DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis

DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety, Office of Research Services
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4th Edition
DSO	Division of Security Operations
DSS	Division of Support Services
DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics
ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group

EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences
ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President

EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South (6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration; responsible for IMPAC II
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration
ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
ESI	Early-Stage Investigator
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration

ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCOI	Financial Conflict of Interest
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program
FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System

FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center
FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone
GM	Grants Management
GMB	Grants Management Branch Office

GME	Graduate Medical Education
GMO	Grants Management Officer
GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract

H

HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act of 1996

HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization
HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language

I

IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract

IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system
IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination (grants data system)
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program

IRPG	Interactive Research Project Grant
IRTA	Intramural Research Training Award or Agreement
ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition
Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects

K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System

LAN	Local Area Network
LAO	Leave Approving Official
LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay

M

MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)

MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine's Database for Scientific Publications
MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA

MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet
MSPB	Merit Systems Protection Board
MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission

N

N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCIH	National Center for Complementary and Integrative Health (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center

NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability
NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics
NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCRR	National Center for Research Resources (dissolved as of December 23, 2011)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award (also NoGA) [see NOGA p 36/59]
NGO	Non-Government Organization
NGRI	Next Generation of Researchers Initiative
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center

NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee
NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	*Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)

NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology
NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance
NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award [see NoGA prior page at NGA]
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories

NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service
NTP	National Toxicology Program

O

OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)
OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)

OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities
ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEEO	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity
OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)

OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)
OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)
OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science

OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks
ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services (NIH OD OM)
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH
OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment

OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer
OUTPT	Outpatient
OWH	Office on Women's Health

P

P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)
PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator

PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria
PLC	Program Leadership Committee
PMCID	PubMed Central Identification
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships
PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database

PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record
PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program
QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant

R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)
RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RePORT	NIH Research Portfolio Online Reporting Tools
RePORTER	RePort Expenditures and Results
RFA	Request for Application (request for grant applications for a research area)
RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force

RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap
RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RPPR	Research Program Performance Report
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research

SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist
SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SCR	Special Council Review
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods
SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine

SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official
SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)
SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRA)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers

STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information
STTR	Small Business Technology Transfer
SV	Student, or Special Volunteer

T

T&A	Time and Attendance
TAIMS	Time and Attendance Information Management System
TEHIP	Toxicology and Environmental Health Program
TIA	Time Off Incentive Award
TIG	Time In Grade
TIN	Payer Identification Number Tax
TK	Timekeeper
TMA	Tissue Microarray
TMJ	Temporomandibular joint
TO	Task Order
TOD	Tour of Duty
TOXNET	Toxicology Data Network
TQM	Total Quality Management
TSC	Training Subcommittee
TSP	Thrift Savings Plan
TTB	Technology Transfer Branch
TX	Treatment

U

U.S.C.	United States Code
UMLS	Unified Medical Language System
URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center
VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade

WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations
WTO	World Trade Organization
WWW	World Wide Web
WYLBUR	Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train	Trainee Activities System

Y

YTD	Year To Date

Z

ZIP (Code)	Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission, Overview, and History

Until May 19, 1972, the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

Overview

The NIDDK supports a wide range of medical research through grants to universities and other medical research institutions across the country. The Institute also supports government scientists who conduct basic, translational, and clinical research across a broad spectrum of research topics and serious, chronic diseases and conditions related to the Institute's mission. In addition, the NIDDK supports research training for students and scientists at various stages of their careers and a range of education and outreach programs to bring science-based information to patients and their families, health care professionals, and the public.

External research funded by the NIDDK is organized into three scientific program divisions:

- Diabetes, Endocrinology, and Metabolic Diseases
- Digestive Diseases and Nutrition
- Kidney, Urologic, and Hematologic Diseases

The NIDDK's overarching principles in moving research forward include:

- maintaining a vigorous, investigator-initiated research portfolio that supports cross-cutting science that can be broadly applied to many disease-specific research areas
- supporting pivotal clinical studies and trials, with a focus on substantial participation of groups at highest risk.
- preserving a stable pool of talented new investigators
- fostering exceptional research training and mentoring opportunities
- ensuring that science-based health information reaches patients, their families, health care providers and the public through communications and outreach activities

Important Events in NIDDK History

August 15, 1950—President Harry S. Truman signed the Omnibus Medical Research Act into law, establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute, and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950—The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

1959—Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

1961—Laboratory-equipped mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1968—The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist.

November 1970—The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, and past and present Institute National Advisory Council members.

May 19, 1972—The Institute's name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD).

October 1972— Dr. Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with two other American scientists for demonstrating one of the most important simplifying concepts of molecular biology: that the three-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of the research cited by the award was performed while Anfinsen was with the NIH.

September 1973—The creation of the first Diabetes-Endocrinology Research Centers marked the beginning of the Institute’s Diabetes Centers Program.

November 1975—After nine months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations included expanding and coordinating diabetes and related research programs; creating a diabetes research and training centers program; accelerating diabetes health care, education, and control programs; and establishing a National Diabetes Advisory Board.

April 1976—The National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*. This report to Congress called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976—Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detecting and controlling viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977—The NIH director established a trans-NIH program for diabetes, with the NIAMDD taking lead responsibility.

September 1977—More than $5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977—In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate diabetes data to scientific and public health policy and planning associations.

December 1977—Institute grantees Drs. Roger C.L. Guillemin and Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist. Guillemin's and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

1978—In response to congressional language, the NIDDK created the National Diabetes Information Clearinghouse to increase knowledge and understanding about diabetes among people with these conditions and their families, health professionals, and the public.

January 1979—The National Commission on Digestive Diseases issued the report, The *National Long-Range Plan to Combat Digestive Diseases*. Recommendations to Congress included establishing a National Digestive Diseases advisory board and information clearinghouse and emphasizing digestive diseases educational programs more in medical schools.

June 1980—In response to congressional language, the NIDDK created the National Digestive Diseases Information Clearinghouse to increase knowledge and understanding about digestive diseases among people with these conditions and their families, health professionals, and the public.

September 1980—Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at the NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980—NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease." Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

1981—A report entitled *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases* was prepared by an external group of scientific experts and was submitted to the NIH and the Senate Committee on Appropriations.

June 23, 1981—The Institute was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

April 1982—U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated the NIADDK's programs to division status, creating five extramural divisions and the Division of Intramural Research.

November 1982—Dr. Elizabeth Neufeld, chief of the NIADDK's genetics and biochemistry branch, received a Lasker Foundation Award. She was cited, along with Dr. Roscoe E. Brady of the then-named National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984—Grants totaling more than $4 million were awarded to six institutions to establish the Silvio O. Conte Digestive Diseases Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986—The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

June 3, 1986—The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

1987—The NIDDK created the National Kidney and Urologic Diseases Information Clearinghouse to increase knowledge and understanding about diseases of the kidneys and urologic system among people with these conditions and their families, health care professionals, and the general public.

August 1, 1987—Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December 1987—In response to congressional language on the fiscal year (FY) 1988 appropriation for the NIDDK, the Institute established a program of cystic fibrosis research centers.

March 1990—The National Kidney and Urologic Diseases Advisory Board issued its "Long-Range Plan: Window on the 21st Century," which recommended uniting the public and private sectors in the quest to prevent these diseases; improve methods for early detection, treatment, and rehabilitation; and ultimately find cures.

September 16, 1990—The NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June 1991—The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on preventing and treating obesity and to develop statements about topics of clinical importance based on critical analyses of the scientific literature.

September 30, 1992—Three Obesity/Nutrition Research Centers were established, along with an extramural animal models core to breed genetically obese rats for obesity and diabetes research.

October 12, 1992—Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." At the time of the award, the scientists had been receiving continuous NIDDK grant support since 1951 and 1956, respectively.

October 30, 1992—In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993—The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to the NIDDK.

October 10, 1994—Drs. Martin Rodbell and Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher at the then-named NIAMD.

June 22, 1997—Led by the NIDDK, the NIH and the U.S. Centers for Disease Control and Prevention (CDC) announced the creation of the National Diabetes Education Program (NDEP). The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

July 18, 2000—The NIDDK created the National Kidney Disease Education Program to raise awareness among the public of kidney disease and its risk factors, and make resources available to consumers and health care providers.

June 2000—To reduce the disproportionate burden of many diseases in minority populations, the NIDDK initiated an Office of Minority Health Research Coordination.

November 16, 2000—The NIDDK celebrated its 50th anniversary. Professional societies in eight U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. NIDDK published *A New Century of Science*: *A New Era of Hope* was published to highlight NIDDK-supported research and jointly hosted a scientific symposium at the Society for Cell Biology's 40th anniversary meeting.

November 2002—NIDDK created the Network of Minority Health Research Investigators to help increase the number of minority health researchers who compete for NIH research support in the fields of interest to NIDDK.

October 8, 2003—NIDDK grantee Dr. Peter Agre shared the Nobel Prize in Chemistry with another scientist for studies of channels in cell membranes. Agre discovered aquaporins, proteins that move water molecules through the cell membrane.

October 4, 2004—Dr. Richard Axel, once an intramural research fellow under Dr. Gary Felsenfeld at the NIDDK, shared the Nobel Prize in Physiology or Medicine with another scientist for discovering a large family of receptors selectively expressed in cells that detect specific odors.

October 6, 2004—Long-time grantees Drs. Irwin A. Rose and Avram Hershko shared the Nobel Prize in Chemistry with another scientist for discovering ubiquitin-mediated protein degradation inside the cell.

October 2007—Institute grantee Dr. Oliver Smithies shared the Nobel Prize in Physiology or Medicine with two other scientists for discovering principles for introducing specific gene modifications in mice by using embryonic stem cells.

2010—The NIDDK celebrated its 60th anniversary. Special events included the September 21 scientific symposium "Unlocking the Secrets of Science: Building the Foundation for Future Advances" and the publication of the commemorative report *NIDDK: 60 Years of Advancing Research to Improve Health.*

September 2010—NIDDK grantee Dr. Jeffrey Friedman and former grantee Dr. Douglas Coleman won the 2010 Albert Lasker Basic Medical Research Award for discovering the hormone leptin, which plays a key role in regulating energy intake and energy expenditure.

October 3, 2011—NIDDK grantee Dr. Bruce Beutler shared the 2011 Nobel Prize in Physiology or Medicine with NIH grantee Dr. Jules Hoffman for their discoveries concerning the activation of innate immunity. NIH grantee Dr. Ralph Steinman also shared the award posthumously for his discovery of the dendritic cell and its role in adaptive immunity.

December 2011—The journal *Science* named an HIV-prevention research study led by NIDDK grantee Dr. Myron Cohen the 2011 Breakthrough of the Year. The study found that people infected with HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy.

April 29, 2012—The Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study results appeared in the New England Journal of Medicine, marking the first major comparative effectiveness trial for the treatment of type 2 diabetes in young people. The NIDDK-funded study found that combined therapy with metformin and rosiglitazone was superior to metformin alone. The rate of treatment failure with metformin alone suggested that most youth with type 2 diabetes will require combination treatment or insulin within a few years after diagnosis.

September 21, 2012—Dr. Thomas E. Starzl, a longtime NIDDK grantee, received the 2012 Lasker-DeBakey Clinical Medical Research Award – shared with Dr. Roy Calne — for his work developing liver transplantation, an intervention that has restored normal life to thousands of people with end-stage liver disease.

October 2012—Dr. Robert J. Lefkowitz, who trained at NIDDK from 1968-1970 as a clinical associate in the Clinical Endocrinology Branch, won the 2012 Nobel in chemistry for studies of protein receptors that let body cells sense and respond to outside signals.

October 2013—Dr. James Rothman, an NIDDK grantee, received the 2013 Nobel Prize in physiology or medicine, shared with fellow NIH grantees Drs. Randy W. Schekman and Thomas C. Südhof "for their discoveries of machinery regulating vesicle traffic, a major transport system in our cells," according to the Nobel organization. The researchers' work revealed how cells use small sacs, called vesicles, to import and export materials to and from cells. This transport system is a fundamental process in how cells work.

August 1, 2015—NIDDK established the Office of Nutrition Research, replacing the NIH Division of Nutrition Research Coordination. The Office is within the NIDDK Office of the Director and will assist in leading a trans-NIH group to strategically plan new initiatives for NIH nutrition research.

September 2016—NIDDK grantee, Dr. Gregg L. Semenza was awarded the 2016 Albert Lasker Basic Medical Research Award, shared with Dr. William G. Kaelin Jr. and Dr. Peter J. Ratcliffe for their "discovery of the pathway by which cells from humans and most animals sense and adapt to changes in oxygen availability- a process essential for survival," according to the organization.

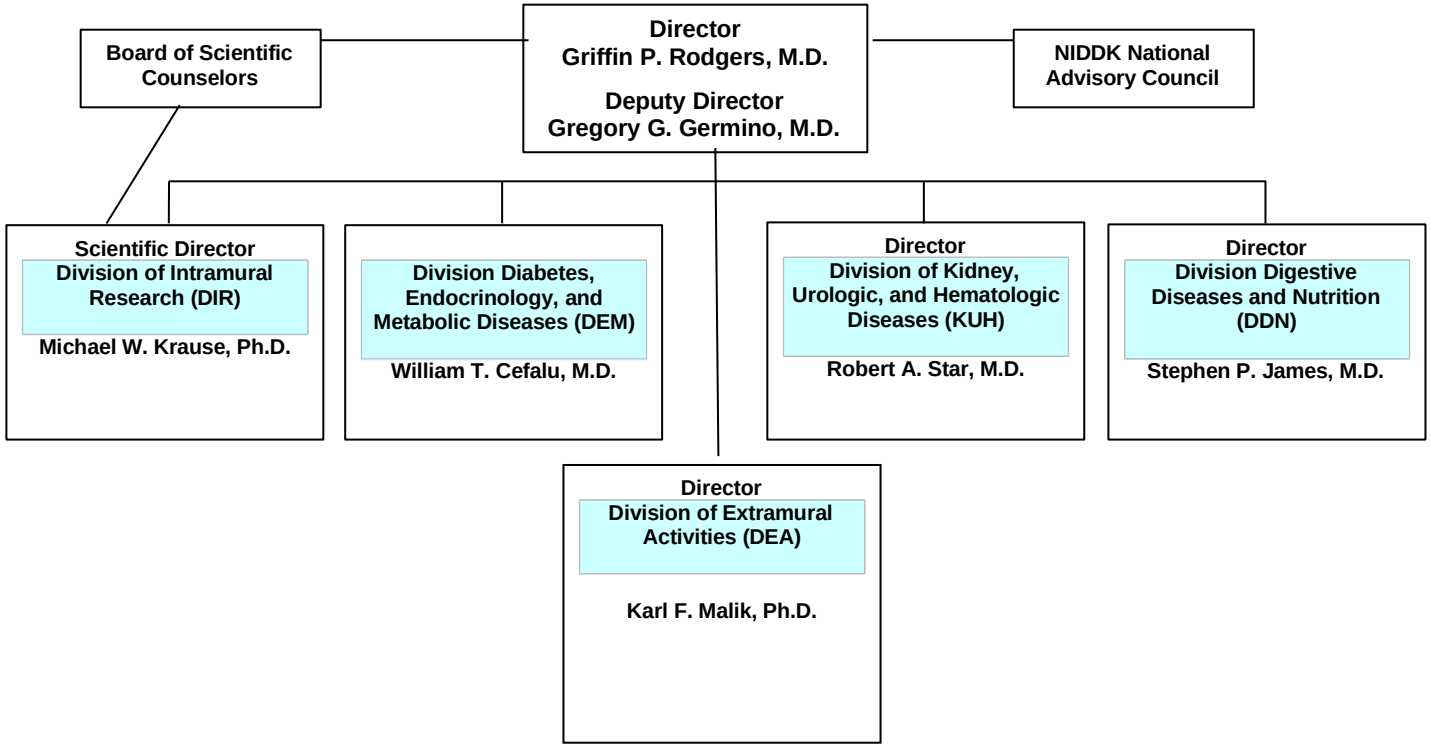
2020—The NIDDK celebrated its 70th anniversary.

January 2021—The NIDDK Office of Nutrition is relocated to the Division of Program Coordination, Planning, and Strategic Initiatives (DPCPSI) in the NIH Office of the Director.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

The Office of the Director includes the following offices:

- Biostatistics Program
- Executive Office, including administrative components:
  - — Administrative Management Branches
  - — Computer Technology Branch
  - — Ethics Office
  - — Office of Financial Management and Analysis
  - — Office of Workforce and Strategic Planning
  - — Purchasing Office
- NIDDK Central Repository
- Office of Clinical Research Support
- Office of Communications and Public Liaison
- Office of Scientific Program and Policy Analysis
- Regulatory Support Program
- Technology Advancement Office

Also, within the Office of the Director are the following research coordination offices.

The ***Office of Minority Health Research Coordination*** *(OMHRC)* addresses the burden of diseases and disorders that disproportionately impact the health of minority populations. The OMHRC helps to implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Institute of Minority Health and Health Disparities at the NIH. Dr. Lawrence Agodoa is the director of the OMHRC.

The NIDDK ***Office of Obesity Research*** (OBR) is responsible for coordination of obesity-related research within NIDDK and carries out its functions through the NIDDK Obesity Research Working Group. Drs. Karen Teff (DEM) and Susan Yanovski (DDN) are the co-directors of OBR. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch and the Office of Scientific Program and Policy Analysis (OSPPA). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

Overview of the Division of Intramural Research

The Division of Intramural Research conducts biomedical research and training related to diabetes mellitus; endocrine, bone, and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; and kidney, urologic, and hematologic diseases. The research conducted in the Intramural Research Program (IRP) spans the breadth of modern biomedical investigation, from basic science to clinical studies.

A sampling of areas under study includes:

- **biophysics** – studies of protein folding, development of optical and vibrational imaging, and theory of protein dynamics
- **cell biology** – studies of nuclear import/export, intracellular protein and lipid trafficking, cellular migration and prions
- **chemical biology and medicinal chemistry** – synthesis and characterization of novel compounds and discovery of biologically active natural products
- **developmental biology** – studies using model systems ranging from single-cell organisms to vertebrates to human cells
- **genetics, pathogenesis and novel therapies of disease** – studies of diabetes types 1 and 2, hepatitis, endocrine disorders, nephritis/nephropathy, obesity, sickle cell anemia, and gastrointestinal disorders
- **molecular biology** – studies of chromatin structure and function, transcriptional regulation and DNA recombination
- **signal transduction** – basic and human disease-oriented studies of GTP-binding proteins and GTP-binding protein-coupled receptors, tyrosine kinase receptors and nuclear hormone receptors
- **structural biology** – studies using x-ray crystallography and NMR spectroscopy

The hallmarks of the NIDDK IRP are excellence and diversity. Many of the scientists within the IRP have achieved international recognition as highly productive and innovative researchers. The program continues a tradition of excellence reflected in the several Nobel prizes and other prestigious awards that have resulted from its work. Many scientists trained in the IRP are now prominent faculty members at leading universities throughout the world.

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-intramural-research

Overview of the Division of Extramural Activities

The Division of Extramural Activities (DEA) is responsible for:

1. Coordinating the receipt, referral, and scientific review of extramural research before funding
2. The publication of Funding Opportunity Announcements in the NIH Guide for Grants and Contracts
3. The processing of awards for grants, cooperative agreements, and contracts
4. Performing quantitative and qualitative data analyses and evaluations on behalf of NIDDK's scientific program divisions and the NIDDK Office of the Director
5. Providing leadership and advice in developing, implementing, and coordinating extramural programs and policies within the NIDDK
6. Coordinating the Institute's committee management activities and meetings of the National Diabetes and Digestive and Kidney Diseases Advisory Council

Components of the DEA

- **Receipt and Referral** – logs, assigns, and internally distributes all applications received by the NIDDK
- **Grant Review Branch** – conducts scientific and technical peer review of applications
- **Grants Management Branch** – manages awards for research project grants, program project and center grants, research training and development grants, cooperative agreements, and research contracts
- **Committee Management Office** – coordinates the administrative details of all of NIDDK's meetings that operate under the Federal Advisory Committee Act. These meetings include peer review meetings to review grant applications, meetings of the NIDDK Advisory Council, and meetings of the NIDDK Board of Scientific Counselors to review components of the Intramural Research Program. Additionally, the office functions as a Service Center, overseeing all committee management tasks for the National Institute on Aging (NIA) and the National Institute of General Medical Sciences (NIGMS).
- **Office of Research Evaluation and Operations** – oversees and coordinates disease coding and reporting for the NIDDK extramural program, manages the NIH Guide publication process associated with publishing Funding Opportunity Announcements, and supports NIDDK Advisory Council activities. The office also facilitates harmonization of activities among NIDDK's four extramural divisions, and coordinates and performs special projects at the request of the NIDDK leadership.

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-extramural-activities

Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

The Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) provides research funding and support for basic and clinical research in the areas of type 1 and type 2 diabetes and other metabolic disorders, including cystic fibrosis; endocrinology and endocrine disorders; obesity, neuroendocrinology, and energy balance; and development, metabolism, and basic biology of liver, fat, and endocrine tissues. DEM also provides funding for the training and career development of individuals committed to academic and clinical research careers in these areas.

The Division of Diabetes, Endocrinology, and Metabolic Diseases supports research in:

Diabetes Research Programs

- Bioengineering, Biotechnology, and Imaging
- Clinical Research in Type 1 Diabetes
- Clinical Research in Type 2 Diabetes
- Clinical, Behavioral, and Epidemiological Obesity Research
- Diabetes and Metabolism HIV/AIDS
- Diabetes Centers
- Diabetes Genetics and Genomics
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Diabetes: Treatment, Prevention, and Complications
- Diabetic Kidney Disease
- Diabetic Urologic Disease
- Endocrine Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Kidney Genetics and Genomics
- Metabolic Pathways
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Endocrine and Metabolic Diseases Research Programs

- Bioengineering, Biotechnology, and Imaging as applied to Diabetes, Metabolic and Endocrine Diseases
- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Cystic Fibrosis
- Cystic Fibrosis Research and Translational Centers
- Diabetes and Metabolism HIV/AIDS
- Diabetes, Endocrine, and Metabolic Disease Translational Research
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Endocrinology and Hormone Signaling
- Genetic Metabolic Disease
- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity

- Nutrient Metabolism, Status, and Assessment
- Obesity, Pregnancy, and the Intrauterine Environment
- Pathophysiology of Diabetes and Metabolic Disease

Research Training and Career Development

Small Business Programs

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-diabetes-endocrinology-metabolic-diseases

Overview of the Division of Digestive Diseases and Nutrition (DDN)

The Division of Digestive Diseases and Nutrition (DDN) supports research related to digestive diseases, including the alimentary tract, liver and pancreas, nutrition and obesity. The programs include basic, translational and clinical research, research training, and career development. DDN also promotes public awareness and education about digestive diseases and related conditions and oversees several national public awareness campaigns.

The Division of Digestive Diseases and Nutrition supports basic, translational and clinical research in:

Digestive Diseases Research Programs

- Digestive Diseases Clinical Research and Epidemiology
- Digestive Diseases Genetics and Genomics
- Digestive Diseases Research Core Centers
- Gastrointestinal Immunology, Inflammation, and Inflammatory Diseases
- Gastrointestinal Microbiology and Infectious Diseases
- Gastrointestinal Neuroendocrinology
- Gastrointestinal Physiology, Development, and Epithelial Biology
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Motility and Functional Gastrointestinal Disorders
- Nutrient Metabolism, Status, and Assessment

Liver Disease Research Programs

- Digestive Diseases Research Core Centers
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Iron and Heme Metabolism, Iron Chelation
- Liver Clinical Research and Epidemiology
- Liver Diseases Genetics and Genomics
- Translational and Basic Liver Disease Research

Nutrition Research Programs

- Clinical and Epidemiological Nutrition Research
- Clinical, Behavioral, and Epidemiological Obesity Research
- Endocrinology and Hormone Signaling
- Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS
- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity
- Nutrient Metabolism, Status, and Assessment
- Nutrition and Obesity Genetics and Genomics
- Nutrition Obesity Research Centers
- Obesity Treatment and Prevention
- Obesity, Pregnancy, and the Intrauterine Environment

Obesity Research Programs

- Chronic Kidney Disease
- Clinical, Behavioral, and Epidemiological Obesity Research
- Endocrinology and Hormone Signaling

- Metabolic Pathways
- Metabolism, Energy Balance, and Obesity
- Neurobiology of Obesity
- Nutrient Metabolism, Status, and Assessment
- Nutrition and Obesity Genetics and Genomics
- Nutrition Obesity Research Centers
- Obesity Treatment and Prevention
- Obesity, Pregnancy, and the Intrauterine Environment

Pancreatic Disease Research Programs

- Acute and Chronic Pancreatitis
- Endocrine Pancreas
- Endocrine Tumors of the Pancreas
- Hereditary and Pediatric Disorders of the Pancreas
- Pancreas Basic Research and Development
- Pancreas Clinical Research and Epidemiology

Research Training and Career Development

Small Business Programs

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-digestive-diseases-nutrition

Overview of the Division of Kidney, Urologic, and Hematologic Diseases (KUH)

The Division of Kidney, Urologic, and Hematologic (KUH) Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. Areas of research include:

Kidney
Chronic kidney disease, end-stage renal disease, diabetic nephrology, polycystic kidney disease, hypertensive nephrosclerosis, acute kidney injury, kidney donation, congenital kidney disorders, IgA nephrology, hemolytic uremic syndrome, fluid and electrolyte disorders, kidney repair and regeneration, and normal and abnormal kidney development and physiology.

Urology
Benign prostatic hyperplasia, urinary incontinence, urinary tract infections, stones, erectile dysfunction, urologic chronic pelvic pain syndromes (including interstitial cystitis and chronic prostatitis), congenital urologic disorders, repair and regeneration of lower urinary tract organs, and normal and abnormal lower urinary tract development and physiology.

Hematology
Blood and blood-forming organs, hematopoiesis, hemoglobin disorders, iron metabolism, sickle cell disease, bone marrow failure, iron deficiency, Cooley's anemia (thalassemia), and hemochromatosis.

The KUH also provides funding for training and career development of persons committed to academic and clinical research in these areas.

Kidney Disease Research Programs

- Acute Kidney Injury
- Chronic Kidney Disease
- Diabetic Kidney Disease
- End-Stage Renal Disease
- Genetic Metabolic Disease
- Kidney Basic Research
- Kidney Bioengineering, Biotechnology, and Imaging
- Kidney Clinical Research and Epidemiology
- Kidney Developmental Biology and Aging
- Kidney Disease Centers
- Kidney Genetic and Genomics
- Kidney HIV/AIDS
- Kidney Inflammation and Inflammatory Diseases
- Kidney Precision Medicine Project
- Pediatric Kidney Disease
- Polycystic Kidney Disease

Urologic Disease Research Programs

- Diabetic Urologic Disease
- Genetic Metabolic Disease
- Pediatric Urology
- Urologic Disease Centers
- Urology Basic Research
- Urology Bioengineering, Biotechnology, and Imaging
- Urology Clinical Research and Epidemiology
- Urology Developmental Biology and Aging
- Urology Genetics and Genomics
- Urology HIV/AIDS
- Women's Urology

Hematologic Disease Research Programs

- Erythropoiesis and Hemoglobin
- Genetic Metabolic Disease
- Hematology HIV/AIDS
- Hematopoiesis and Hematopoietic Stem Cell Biology
- Iron and Heme Metabolism, Iron Chelation
- Molecular Hematology Centers

Website: https://www.niddk.nih.gov/about-niddk/offices-divisions/division-kidney-urologic-hematologic-diseases

Funding Mechanisms (Activity Codes) Supported by NIDDK

Brief Overview

An Activity Code is a three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). General categories include:

- F – fellowships
- K – career development awards
- N – research contracts
- P – program project and research center grants
- R – research project grants
- S – research-related programs
- T – training grants
- U – cooperative agreements
- Y – interagency agreements

Extramural research activities are divided into three main mechanisms: grants, cooperative agreements, and contracts. A mechanism is the type of funding instrument used at the NIH. In general, with grants (all activity codes other than "N" or "U"), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts ("N" series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements ("U" series), both the awarding unit and the recipient have substantial responsibility. Programs are areas within the funding mechanisms (for example, research, training, fellowships, and cooperative agreements). Activity codes identify categories applied to various mechanisms.

For NIH-wide activity codes and definitions beyond the NIDDK codes listed below, go to Types of Grant Programs page (http://grants.nih.gov/grants/funding/funding_program.htm) to search activity codes or to the comprehensive list of extramural grant and cooperative agreement activity codes for more information on selected grant programs.

Special NIH-Wide Programs

DP1 **NIH Director's Pioneer Award** (NDPA) (Roadmap program)
To support individual scientists of exceptional creativity, who propose pioneering – and possibly transforming approaches – to major challenges in biomedical and behavioral research.

DP2 **NIH Director's New Innovator Awards** (Roadmap program)
To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 **Type 1 Diabetes Targeted Research Award**
To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

DP5 **Early Independence Award**
To support the independent research project of a recent doctoral degree recipient.

Fellowship Programs

F30 **Individual Predoctoral National Research Service Award (NRSA) for M.D./Ph.D Fellowship**
To support students enrolled in MD/PhD, or equivalent combined degree programs, once they have identified a dissertation project.

F31 **Individual Predoctoral National Research Service Award (NRSA)**
To support students enrolled in a doctoral degree program (usually PhD) once they have identified a mentor and have chosen a dissertation research project.

F32 **Individual Postdoctoral National Research Service Award (NRSA)**
To support postdoctoral fellows to pursue mentored research training prior to applying for a faculty position.

Research Career Programs

K01 **Research Scientist Development Award - Research & Training**
To support basic scientists (non-clinicians) as they transition to independence and develop their careers with the support of a mentor.

K05 **Research Scientist Award**
To support a research scientist qualified to pursue independent research which would extend the research program of the sponsoring institution, or to direct an essential part of this research program.

K08 **Clinical Investigator Award (CIA)**
To support early clinician scientists who are transitioning to independence in a junior faculty position while pursuing a basic or clinical research project and developing their career.

K12 **Physician Scientist Award (Program) (PSA)**
Award to an institution to support several individuals as they transition from fellowship to faculty while pursuing a research project with the help of a mentor(s).

K23 **Mentored Patient-Oriented Research Career Development Award**
To provide support for the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research. Supports early clinician scientists who are transitioning to independence in a junior faculty position and developing their career while pursuing a clinical research project that involves direct patient contact and the support of a mentor(s).

K24 **Midcareer Investigator Award in Patient-Oriented Research**
Supports established clinician scientists to enable them to pursue their patient-oriented research while mentoring the next generation of patient-oriented researchers.

K25 **Mentored Quantitative Research Career Development Award**
To support highly productive postdoctoral fellows pursuing mentored research projects while looking for faculty appointments.

K99 **NIH Pathway to Independence Award (PI)**
R00 Supports the initial phase of a Career/Research Transition award program that provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists.

Extramural Loan Repayment Program

L30 **Loan Repayment Program for Clinical Researchers**
NIH may repay up to $35,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in clinical research.

L40 **Loan Repayment Program for Pediatric Research**
NIH may repay up to $35,000 of your qualified student loan debt per year, including most undergraduate, graduate, and medical school loans if you are actively engaged in research related to pediatric disease or disease model.

Research and Development-Related Contracts

N01 **Research and Development Contracts**
To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N02 **Resource and Support Contracts - Awarded in the ICD**
To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N41 **Small Business Technology Transfer (STTR) Contracts - Phase I**
To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N42 **Small Business Technology Transfer (STTR) Contracts - Phase II**
To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N43 **Small Business Innovation Research (SBIR) Contracts- Phase I**
To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N44 **Small Business Innovation Research (SBIR) Contracts - Phase II**
To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P01 **Research Program Projects**
For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project

is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P20 **Center Exploratory Grants**
To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P30 **Center Core Grants**
To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P50 **Specialized Center**
To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

Research Projects

R01 **Research Project Grant**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R03 **Small Research Grants**
Supports research projects that can be completed in a 2-yr time frame. NIDDK does not participate in the parent FOA for R03s, but issues FOAs for specific audiences, e.g. NIDDK-supported K01, K08, and K23 awardees.

R13 **Research Conference Grant**
To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R15 **Academic Research Enhancement Awards (AREA)**
To support small-scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to $75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R18 **Research Demonstration and Dissemination Projects**
To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R21 **Exploratory/Developmental Grants**
Supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R24 **Resource-Related Research Projects**
To support research projects that will enhance the capability of resources to serve biomedical research.

R25 **Education Projects**
For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R34 **Clinical Trial Planning Grant**
To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R41 **Small Business Technology Transfer (STTR) Grants - Phase I**
R42 To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R43 **Small Business Innovation Research (SBIR) Grants - Phase I**
R44 To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

RC2 **High Impact, Interdisciplinary Science in NIDDK Research Areas**
To support high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/ resource designed to accelerate scientific progress in the future.

Research-Related Programs

S06 **Native American Research Centers for Health (NARCH)**
Supports partnerships between American Indian/Alaska Native (AI/AN) tribes or tribally-based organizations and institutions that conduct intensive academic-level biomedical, behavioral and health services research.

SC1 **Research Enhancement Award**
Individual investigator-imitated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other extramural support (R01 or equivalent).

SC2 **Pilot Research Project**
Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

Training Programs

T32 **Institutional National Research Service Award (NRSA)**
To enable institutions to make National Research Service Awards to individuals selected by the institution, in either short-term, predoctoral, and/or postdoctoral research training in specified shortage areas.

T32 **Diversity NRSA Diversity Supplement Award**
Additional slot awarded to an existing training grant for either a specific medical student wishing to take a year off from school to pursue research training or for a pre- or post-doctoral trainee from a group underrepresented in biomedical research, when no slot is available on the training grant.

T32 **MSRT Medical Student Research Training Supplement**
Additional slot awarded to an existing training grant for either a specific medical students wishing to take a year off from school to pursue research training or for a pre- or post-doctoral trainee from a group underrepresented in biomedical research, when no slot is available on the training grant.

T35 **NRSA Short-Term Research Training**
Provides 2-3 months of support for medical students, selected by the institution, to pursue research training during off-quarters or summer periods.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U01 **Research Project Cooperative Agreement**
To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U13 **Research Conference Cooperative Agreement**
To support international, national, or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U24 **Resource – Related Research Projects – Cooperative Agreement**
Supports research projects contributing to improvement of the capability of resources to serve biomedical research.

U34 **Multi-Center Clinical Study Implementation Planning Grants**
Supports a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U54 **Specialized Center – Cooperative Agreement**
To support any part of the full range of research and development from very basic to clinical; may involve ancillary, supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These differ from program project in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes, with funding component staff helping to identify appropriate priority needs.

UC4 **High-Impact Research and Research Infrastructure Cooperative Agreements**
To support multi-year funded cooperative agreement research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the cooperative agreement companion to the RCA. It is also the multi-year funded companion to the existing UC2; thus ICs need OER prior approval to use the UC 4.

UG3 **Phase 1 Exploratory/Developmental Cooperative Agreement**
As part of a bi-phasic approach to funding exploratory and/or developmental research, the UG3 provides support for the first phase of the award. This activity code is used in lieu of the UH2 activity code when larger budgets and/or project periods are required to establish feasibility for the project.

UH2 **Exploratory/Developmental Cooperative Agreement Phase II**
UH3 To provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

X01 **Resource Access Program**
To invite eligible institutions to seek access to NIH research resources. This includes programs where institutions will request access to submit to the resource, e.g., high throughput screening assays. It also includes programs where access to a specific NIH research resource is needed to conduct certain research.

X02 **Preapplication**
A program to invite eligible institutions to submit a pre-application (also known as a “white paper” to “precis”) to facilitate certain approaches or economies, such as reducing burden on the applicant community, for a funding opportunity.

NIH Operates Under a Continuing Resolution

Notice Number:
NOT-OD-22-009

Key Dates

Release Date:
October 20, 2021

Related Announcements

None

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the Extending Government Funding and Delivering Emergency Assistance Act (Public Law 117-43) signed by President Biden on September 30, 2021. This Act (CR) continues government operations through December 3, 2021 at the FY 2021 enacted level, with no reduction.

Continuing the procedures identified under NOT-OD-21-058 and consistent with NIH practices during the CRs of FY 2006 - 2021, NIH Institutes and/or Centers may, at their discretion, issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award. Upward adjustments to awarded levels will be considered after FY 2022 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2021 (see NOT-OD-21-056) remain in effect under this CR, as well as the salary limitation set at Executive Level II of the Federal Pay Scale (see NOT-OD-21-057) and the Ruth L. Kirschstein National Research Service Award predoctoral and postdoctoral stipend levels and tuition/fees as described in NOT-OD-21-049.

Inquiries

Please direct all inquiries to:

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified in the Notice of Award.

Notice of Fiscal Policies in Effect for FY 2021

Notice Number:

NOT-OD-21-058

Key Dates

Release Date:

January 29, 2021

Related Announcements

NOT-OD-21-056 - Notice of Legislative Mandates in Effect for FY 2021

NOT-OD-21-057 - Guidance on Salary Limitation for Grants and Cooperative Agreements FY 2021

NOT-OD-21-049 - Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2021

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

This Notice provides guidance about the NIH Fiscal Operations for Fiscal Year 2021 and implements the *Consolidated Appropriations Act, 2021* (Public Law 116-260), signed into law on December 27, 2020.

The agreement provides $42.93 billion for NIH, including $404 million from the *21st Century Cures Act* (Public Law 114-255), a three percent increase above FY 2020. The agreement provides a funding increase of no less than 1.5 percent above fiscal year 2020 to every Institute and Center (IC).

The agreement appropriates funds authorized in the 21st Century Cures Act along with mandatory funding for the Type 1 Diabetes Program – which includes funding for the following initiatives:

- Cancer Research
- Brain Initiative
- All of Us Precision Medicine Initiative
- Common Fund
- Type 1 – Diabetes Program

The mandatory funding for Type 1 Diabetes provided in PL 116-260 for FY 2021 is $150 million.

The following NIH fiscal policies are instituted in FY 2021:

FY 2021 Funding Levels: Non-competing continuation awards made in FY 2021 will generally be issued at the commitment level indicated on the Notice of Award. Any exceptions will be posted at the site listed under "Additional Information," below. Subsequent budget periods are funded based on the availability of appropriations, satisfactory performance, compliance with the terms and conditions of the award, and the continued best interest of the Federal government. The NIH awarding

Institutes/Centers (ICs) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2021 funds.

Ruth L. Kirschstein National Research Service Awards (NRSA): Consistent with the recommendations of the Advisory Committee to the Director regarding the Biomedical Research Workforce, the NIH will increase NRSA stipends by approximately two percent for predocs and two percent for postdocs. The full range of stipend adjustments for FY 2021 is described in NIH Guide Notice NOT-OD-21-049.

Next Generation Researchers Initiative Policy: NIH will prioritize meritorious R01-equivalent applications from Early Stage Investigator (ESI) PD/PIs. By providing funding priority for ESIs, NIH intends to encourage funding applications that involve researchers earlier in their career in accordance with the policy established in FY 2017 and described in NIH Guide Notice NOT-OD-17-101.

Salary Limits: Section 202 of PL 116-260 restricts the amount of direct salary to Executive Level II of the Federal Executive pay scale. Effective January 3, 2021, the salary limitation for Executive Level II is $199,300. Further information is described in NIH Guide Notice NOT-OD-21-057.

Other Legislative Mandates: Other statutory requirements are described in NIH Guide Notice NOT-OD-21-056.

Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs, will be posted on the NIH Funding Strategies webpage.

Inquiries

Please direct all inquiries to:

National Institutes of Health
Office of Policy for Extramural Research Administration (OPERA)
Division of Grants Policy
Email: GrantsPolicy@nih.gov

2022 Interim Award Funding Policy

The Department of Health and Human Services (HHS), including NIH, operates under the Extending Government Funding and Delivering Emergency Assistance Act (Public Law 117-43) signed by President Biden on September 30, 2021. This Act (CR) continues government operations through December 3, 2021 at the FY 2021 enacted level, with no reduction.

NIDDK extramural research is organized into 3 programmatic divisions: 1) Diabetes, Endocrinology, and Metabolic Diseases; 2) Digestive Diseases and Nutrition; and 3) Kidney, Urologic, and Hematologic Diseases.

Until FY 2022 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). See https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-058.html *NIH external link* for details.

- NIDDK will announce additional details regarding its interim FY 2022 funding policy, including details regarding funding of competing grant applications as information becomes available.

2021 Award Funding Policy

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on many of the most serious diseases affecting public health.

NIDDK extramural research is organized into 3 programmatic divisions:

1. Diabetes, Endocrinology, and Metabolic Diseases;
2. Digestive Diseases and Nutrition; and
3. Kidney, Urologic, and Hematologic Diseases.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, cooperative agreements, career development and training awards, and contracts.

Budget Data

Current Appropriation

NIH is operating at a program level of $ 42.709 billion in FY 2021, an increase of approximately $1.3 billion over the FY 2020 final budget allocations.

NIDDK's discretionary appropriation for FY 2021 is $2.132 billion. This is an increase of about 0.8% from NIDDK's appropriation in FY 2020. This figure does not include the Special Type 1 Diabetes appropriation of $150M that NIDDK oversees on behalf of the Department of Health and Human Services.

Funding Strategy

NIDDK is committed to supporting as many meritorious competing research grant applications as possible. Consistent with NIH policy (see NIH Guide Notice NOT-OD-21-058), NIDDK will manage its portfolio in biomedical research investments in a manner that includes recognizing applications from and providing special consideration for early career investigators.

To maximize our available resources, all grant awards will continue to be subject to programmatic adjustments from the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council approved levels. These adjustments take into consideration the overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Funding Guidelines

Competing Awards

For FY 2021 NIDDK is establishing a nominal "payline" for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 16th percentile. Most R01 applications submitted to Funding Opportunity Announcements that 1) do not have a set-aside funds, 2) have a primary assignment to NIDDK, 3) request less than $500,000 direct costs per year, and 4) score at or better than the 16th percentile will receive an award. Applications that have NIDDK as a secondary assignment do not benefit from this payline.

R01 applications that do not include therapeutic clinical trials as the primary focus of the research plan requesting $500,000 or more in direct costs for any year will be held to a more stringent pay line – the 10th percentile for both Type 1 and 2 applications.

Therapeutic Clinical Trial R01 Applications

Per NOT-DK-18-012, NIDDK will not apply the more stringent pay line to R01 applications that include therapeutic clinical trials if that total direct costs (exclusive of F&A on subcontracts) for five years do not exceed $2.5 million (or $2 million for four years), even if that directs costs equal or exceed $500,000 in some years. As indicated above, the more stringent pay line will continue to be applied for all other R01 applications (i.e., all applications that do not have a therapeutic clinical trial as the primary focus of the research plan).

Consistent with NIDDK policy first established in FY2016, R01 applications received in response to Funding Opportunity Announcements (FOAs) that are PARs will not automatically be considered for funding based on payline/percentile ranking. Scores and additional programmatic factors will be weighed when considering applications received under R01 PAR FOAs for funding.

Please note the following regarding competing awards:

- NIDDK will exercise discretion and consider portfolio balance, programmatic importance and a number of other factors in determining precisely which applications are awarded.
- All grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels.
- These funding levels are applicable for applications to be paid in FY 2021. Many applications submitted in FY 2021 (e.g., those submitted in January/February/March for September/October Advisory Council consideration) will not be eligible for funding consideration until FY 2022. The funding levels for FY 2022 cannot now be reliably predicted.

Early Stage Investigators (ESIs)

Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. In FY 2021 NIDDK will place special emphasis on supporting ESIs (new investigators within 10-years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant; see ESI FAQs and NIDDK's New and Early Stage Investigators page) by establishing a nominal payline for R01 applications submitted by ESIs at the 25th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

R01s applications submitted by New Investigators who are not also ESIs will be paid up to the 16th percentile (same as the general pay line).

First Competitive Renewal Applications of R01 Grants Awarded to NIDDK ESIs

Consistent with the NIH Next Generation Researchers Initiative, NIDDK seeks to encourage the stable integration of early career researchers into the scientific research workforce. In support of this, the nominal payline for first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 award will be 19th percentile in FY 2021. Only one award per eligible investigator may be considered for this special payline. If a special payline award is made to an eligible investigator any other eligible applications from that investigator will be considered for funding based on the standard nominal payline.

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited support in selected cases. The goal is to preserve essential research resources pending the re-review of a revised application. NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These awards provide support for investigators to collect preliminary data and use these data to revise and improve their R01 applications.

Administrative Supplements

NIDDK has prioritized its budget to maintain funding of investigator-initiated grants at the highest possible level. Therefore, the institute has little flexibility to support administrative supplements. Given this prioritization, the number of successful administrative supplement applications will be extremely low and generally limited to rare, unforeseen circumstances (e.g., requests to replace key pieces of equipment following a natural disaster). In FY 2021, NIDDK does not have any special FOAs or

Notices soliciting administrative supplements to replace old equipment or to expand the scope of a project by adding funds or restoring an administratively cut year.

Duration of Grant Support

Competing awards are adjusted to achieve a 4-year average duration for research project grants. Nevertheless, applications from ESIs, MERIT extensions, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

Salaries

Section 202 of the Department of Defense and Labor, Health and Human Services, and Education Appropriations Act, 2021 prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II currently set at $199,300.

Non-competing (Continuation) Awards

Consistent with the Notice of Fiscal Policies in Effect for FY 2021 (see NOT-OD-21-058 non-competing (Type 5) continuation grants (research and non-research) issued in FY 2021 will generally be issued at the commitment level indicated on the Notice of Award. Out-year commitments for continuation awards in FY 2022 and beyond remain unchanged.

Program Project (P01), High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2), and Other Applications with Budgets Greater than $500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants, High Impact, Interdisciplinary Science in NIDDK Research Areas (RC2), and other investigator-initiated grant applications with budgets of $500,000 or more requested direct costs in any one year. Prior approval is required before submitting an application for review that requests $500,000 or more in direct costs in any one year. The request to submit such applications should be received at least three months prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the following site for information on research areas supported by NIDDK: http://www.niddk.nih.gov/research-funding/research-programs/.

New (Type 1) and Renewal (competing continuation [Type 2]) program project (P01) applications may request a maximum of $6.25 million in direct costs over five years, excluding the Facilities & Administrative (F&A) costs for subcontracts. In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the NIDDK Advisory Council approved levels.

Also, please note that any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal.

HIV/AIDS Research

HIV/AIDS related applications will receive additional consideration in the context of NIH's HIV/AIDS research priorities (see NOT-OD-20-018) as well as programmatic relevance to the NIDDK mission.

Resources for New and Early Stage Investigators

A New Investigator (NI) is an NIH research grant applicant who has not yet competed successfully for a substantial, competing NIH research grant. For a complete list of NIH grants that do not disqualify a PD/PI from being considered a New Investigator, see the NIH Definition of New Investigator.

An Early Stage Investigator (ESI) is a new investigator who has completed his or her terminal research degree or medical residency – whichever date is later – within the past 10 years and has not yet competed successfully for a substantial, competing NIH research grant.

How Are New Investigators (NIs) and Early Stage Investigators (ESIs) Identified?

Software within the eRA Commons will check first for New Investigator (NI) status based on the individual's previous award history. For individuals identified as NIs, the software will calculate the ten-year window of Early Stage Investigator (ESI) status based on the date of the terminal research degree or the residency end date entered in the investigator's Profile. To ensure that NIH recognizes your ESI status, you must update your eRA Commons profile to reflect the date of completion of your terminal research degree of the end of your residency.

Note: NIH will consider a request to extend the period of your ESI status if there has been a lapse in your post-degree training (see Form for Requesting an Extension in the Early Stage Investigator (ESI) Period).

What Benefits Are Conveyed With New Investigator (NI) or Early Stage Investigator (ESI) Status?

Peer Review – For both New Investigator (NI) and Early Stage Investigator (ESI) applications, peer reviewers are instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by established investigators. Institute staff members pay special attention to applications from NI and ESI investigators as well.

Differential payline (for ESIs) – Each year, the NIDDK sets a percentile "payline" for R01 applications based on available funds and the volume of applications. The payline for ESI applications is typically more generous than the regular payline for established investigators (see NIDDK Funding Policy). While NIDDK often makes administrative reductions in grant duration, applications from ESIs that fall within the payline are usually awarded the full requested duration.

Consideration for NIH High Priority, Short-Term Project Award (R56) – Although you cannot apply for this grant activity, NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect key preliminary data in order to submit an improved revised R01 application, but you should understand that NIDDK has only enough funds to make very few of these awards.

Mentoring Workshops – NIDDK regularly holds workshops for recently funded new investigators. In addition, when NIs or ESIs receive their first grant they are encouraged to maintain contact with their Program Official who can be an excellent resource during this critical stage of your research career.

First Competitive Renewal of R01 Applications From Former NIDDK ESIs – NIDDK seeks to encourage the stable integration of early career researchers into the scientific research workforce. In support of this, the nominal payline for first competitive renewal applications for R01 awards to researchers who were ESIs when they competed for the initial NIDDK Type 1 R01 award is typically more generous than the regular payline for established investigators (see NIDDK Funding Policy). Only one award per eligible investigator may be considered for this special payline. If a special payline award is made to an eligible investigator any other eligible applications from that investigator will be considered for funding based on the standard nominal payline.

For Information

Visit the NIH New and Early Stage Investigator Policies page, or view NIDDK Research Programs and Contacts for your scientific area of interest.

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Department of Agriculture, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/members.

What does the Council do? (For an abbreviated version see: "RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBER" at the end of this document.)

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for grant Funding Opportunity Announcements (FOAs) and contract Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific business, including the closed-session discussion of grant applications. Note that other public venues may clear concepts.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKAC. Two members are selected from each subcommittee of the NDDKAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

Expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year (which begins on October 1st).

Council meetings are scheduled for two days, but occasionally may only take one day, depending on the agenda. Council meetings may be conducted: 1) in-person on the NIH Campus in Bethesda, MD; 2) virtually using meeting software (Zoom, Webex, etc.); or 3) using a combination of in-person and virtual formats.

Typically, on the morning of the first day of the Council meeting, the full Council (Council in the Whole) meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers. ***Note: Open sessions are open to the public and members of the press may be present.***

Typically, sometime after the open session of the full Council (either in the same day or on the following day) the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and discuss any appeals and/or the funding any applications submitted by foreign institutions. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally concur with subcommittee recommendations for funding grants and concur with initial peer review regarding all remaining applications under consideration.

Note: A sample Council meeting agenda is included among the Advisory Council Logistical documents. Council meeting agendas are posted several weeks before the meetings and are available from the Council's home page (https://www.niddk.nih.gov/about-niddk/advisory-coordinating-

committees/national-diabetes-digestive-kidney-diseases-advisory-council). Minutes are also posted and available from the home page.

What is Council's role in concept clearance?

NIDDK seeks Council's advice regarding its plans for the development of Funding Opportunity Announcements (FOAs). The final decision to move forward with an initiative and publish an FOA is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

The following types of special issues are typically presented to Council.

1. **Reinstatement of Research Aims**. Applications for which the division is requesting to reinstate specific aims or research not recommended for support by the study section.

2. **Non-Peer-Reviewed Applications**. Used in some circumstances. Council performs both initial peer review and second-level review functions.

3. **Deferred Applications**. All Council-deferred applications independent of review results.

4. **Unresolved Appeals.** Formerly called rebuttals. When program staff working with a scientific review officer have been unable to resolve the applicant's concerns regarding the review process (based on at least one of the four criteria for an appeal including: bias, conflict of interest, inappropriate expertise, and/or, the DEA director reviews the appeal, and staff present it to Council.

5. **Foreign Applications**. Foreign applications (applications submitted by a foreign institution) that a division proposes to award.

6. **Human Subjects**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.

7. **Biohazards**. Applications proposed for award with unresolved concerns about biohazards.

8. **Use of Animals in Research**. Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.

9. **Minority Recruitment Plans in Institutional Training Grant Applications**. Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.

10. **Inclusion of Women and Minorities as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

11. **Inclusion of Children as Subjects in Clinical Research**. Applications a division plans to award with an unresolved inclusion issue ("U" code).

12. **Special Council Review**. Review of research applications from a Principal Investigator with more than $1,000,000 in direct costs in annual NIH support.

CHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

COMMITTEE'S OFFICAL DESIGNATION

National Diabetes and Digestive and Kidney Diseases Advisory Council

AUTHORITY

Required by 42 U.S.C. 284a, sections 406 of the Public Health Service (PHS) Act, as amended, The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as Institute) on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

DESCRIPTION OF DUTIES

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for basic and clinical study, investigation, or research on diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country as to the diseases, disorders, or other aspects of human health with respect to which the Institute was established and, with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council will prepare triennial reports describing the manner in which the Institute has complied with section 429B of the PHS Act, which sets forth requirements addressing the inclusion of women and members of minority groups as subjects in clinical research conducted or supported by NIH. Each report shall be submitted to the Director, NIDDK, for inclusion in the triennial report submitted to Congress by the

Director, NIH, pursuant to section 403 of the PHS Act. Each triennial report prepared by the Council shall include each of the following:

1. The number of women included as subjects, and the proportion of subjects that are women, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories of research area, condition, or disease, and accounting for single-sex studies.

2. The number of members of minority groups included as subjects, and the proportion of subjects that are members of minority groups, in any project of clinical research conducted during the applicable reporting period, disaggregated by categories od research area, condition, or disease and accounting for single-race and single-ethnicity studies.

3. For the applicable reporting period, the number of projects of clinical research that include women and members of minority groups and that—
   (a) Have been completed during such reporting period; and
   (b) Are being carried out during such reporting period and have not been completed.

4. The number of studies completed during the applicable reporting period for which reporting has been submitted in accordance with section 492B(c)(2)(A) of the PHS Act.

AGENCY OR OFFICIAL TO WHOM THE COMMITTEE REPORTS

The Council will advise the Secretary and the Director, NIDDK.

SUPPORT

Management and support services will be provided by the Division of Extramural Activities, NIDDK.

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is $56,170. The estimated annual person-years of staff support required is 0.7, at an estimated annual cost of $86,745.

DESIGNATED FEDERAL OFFICER

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time NIDDK employees will be assigned as DFO and carryout these duties on a temporary basis.

The DFO will approve all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any

meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH, or Director, NIDDK.

The Director, NIDDK shall designate a member of the staff of the institute to serve as the executive secretary of the Council. The DFO will also serve as the executive secretary for the Council.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held at the call of the Chair (with the DFO's approval) or upon request of the Director, NIDDK, not less than three times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b to Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing.

TERMINATION

Unless renewed by appropriate action, prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of not more than 18 members appointed by the Secretary (appointed members) and 6 nonvoting ex officio members. The nonvoting ex officio members will include the Secretary; the Director, NIH; the Director, NIDDK; the Under Secretary for Health of the Department of Veterans; the Assistant Secretary of Defense for Health Affairs; the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the appointed members, two-thirds will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NIDDK, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. One-third of the appointed members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. All appointed members must be eligible to serve as Special Government Employees (SGEs) and will serve as SGEs. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Appointed members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. The Secretary shall make appointments in such a manner as to ensure that the terms of the appointed members do not all expire in the same year. A member may serve 180 days after the expiration of that member's term if a successor has not taken office. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair will be two years.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee /working group must be deliberated by the parent advisory committee. A subcommittee/working group may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants are not members, do not count towards the quorum and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Departmental policies. Council and subcommittee records will be handled in accordance with General Records Schedule 6.2, Federal Advisory Committee Records, or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

October 31, 2020

APPROVED

Lawrence A. Tabak -S

Digitally signed by Lawrence A. Tabak -S
Date: 2020.10.19 15:45:47-04'00'

Date

Principal Deputy Director, NIH

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides secure web-based access to NIH summary statements. As an NIDDK Advisory Council member you may search, sort, and read any or all the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB nightly, so the ECB is always current.

> ***The data in the ECB, and the passwords that you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it open while unattended. Use it and then disconnect. If you are logged-in to the system but inactive (approximately one hour) the system will automatically disconnect, and you will have to log-in again.***

How do I get started?
An NIDDK staff member will provide information (USER NAME and PASSWORD) necessary for you to log-in to the ECB. Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page**:**
https://ecb.nih.gov/council/login.cfm

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. To log-in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can log-in to the ECB. To change your password, go to the ECB log-in page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please email oreo@niddk.nih.gov or call the NIDDK DEA Office of the Director (301.594.8843).
If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?
When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the "Back" button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option.** There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the "Summary of Review and Discussion" section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either "Primary and Dual Projects" or "Dual Projects only" in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic,** simply enter the appropriate term in the boxes labeled "Summary Text Contains." This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND, OR,* and *NOT*) to connect two character strings. Note: If one is searching for a topic such as "endocrine disruptors" consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principal Investigator Starts With:" For example, searching for "**Ham"** will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP)**, place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

1 New
2 Competing Continuation
3 Supplement
4 Extension
5 Noncompeting Continuation
6 Change of Institute or Division
7 Change of Grantee or Training Institution
8 Change of Institute or Division (noncompeting continuation)
9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).

- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.

- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.

- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND, OR, NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the “Clear Scores” button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2021, the entry would be 01/15/2021 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting "Greater Than or Equal To" from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box 'Foreign Grants' to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 10 to 30 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer's email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note**: Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a “Zip” file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:
Email: oreo@niddk.nih.gov; phone: 301.594.8843 (NIDDK DEA Office of the Director)

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures

A. Purpose

This documents operating procedures established annually by the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) for use of council-delegated authorities. These authorities establish program management and council review procedures for the Institute's extramural programs and establish authorities for management actions undertaken by staff.

In general, the Council makes three types of recommendations relating to second level review of scientific review group (SRG) actions: (1) the Council can concur with the SRG critique; (2) it can suggest a different budget and/or a different length of the grant period; and (3) it can advise deferral of an application for re-review. Specific procedures are given below for each of these types of actions. These procedures are meant to ensure a level of uniformity and comparability across the Council's three subcommittees, which are aligned with the Institute's programmatic divisions. Those subcommittees of Council are free to develop and utilize their own procedures with the understanding that they be consistent with the operating procedures.

B. Background

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding Institutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKAC responsibilities with regard to grant portfolio management.

C. Definitions

1) **Council Delegated Authorities**: Those actions negotiated between the NDDKAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2) ***En Bloc* Action**: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKAC for review.

3) **Staff Actions**: Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKAC. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) no-cost extensions, and (e) phase-out or interim support.

4) **Communication Letter**: A communication between an applicant and Institute staff that is included for NDDKAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKAC by approval has delegated authority to the NIDDK Director for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards

recommended by the Council. In general, these operational guidelines for administrative actions are developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, resubmission (amended) renewal, or revision (supplemental)) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Expedited *En* Bloc Concurrence

NIH, to improve the efficiency of making awards, authorized the use of an expedited *en bloc* concurrence Council review process. NIDDK makes use of an expedited concurrence of *en bloc* actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution) or need SCR, will follow a process of expedited concurrence whereby the review of applications is delegated by the Chairman of the Advisory Council to designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDKAC.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score. Typically, this will occur once each Council round, several weeks before the scheduled NDDKAC meeting, however circumstances may arise that will require an additional, earlier expedited concurrence review to allow a set of applications to be funded in a timely manner to optimize the initiation or continuation of the proposed research. In the event of an earlier expedited concurrence review the same procedures described below will be followed including the involvement of the full NDDKAC.

Electronic or written concurrence by a minimum of two members with no votes for non-concurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKAC meeting for review.

The full NDDKAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications.

Special Council Review

Each Council round the NDDKAC will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under NIH policy. For each application on the list that may be funded, NIDDK staff will provide information about that other funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

Specification of Council Action Requirements

Actions requiring NDDKAC review or advice and ***not*** eligible for expedited *en bloc* concurrence are: SCR, applications from foreign institutions, nominations for Method to Extend Research in Time (MERIT) awards and extensions, and unresolved appeals of initial peer review.

Actions not requiring NDDKAC review or advice are: (1) change of grantee institution, (2) change of principal investigator, (3) administrative supplements to provide additional support either to meet the increased cost of maintaining the level of research previously recommended, to otherwise accommodate research activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project, or (4) phase-out or interim support.

The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications. Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, facsimile or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, in rare instances the NIDDK Director may act on behalf of the Council as a whole.

NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided written justification, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, restorations will be summarized for Council information at the next regular scheduled meeting.

The NDDKAC may also advise the Institute on: The adequacy of the initial review process; and, funding of applications out of order (i.e., “Reaches”) and/or with Special Emphasis dollars.

Finally, the NDDKAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations

As circumstances require, based on programmatic considerations, the Director, NIDDK, generally after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive

Secretary of NDDKAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record and should be reported to Council at its next scheduled meeting.

F. References

1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a

2) PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf)

3) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page (http://grants.nih.gov/grants/funding/women_min/women_min.htm)

4) OER Policy & Guidance: Inclusion of Children Policy Implementation (http://grants.nih.gov/grants/funding/children/children.htm)

5) NOT-OD-12-140: Notice of Special Council Review of Research Applications from PDs/PIs with More than $1.0 Million Direct Costs in Annual NIH Support (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html)

10/31/2021

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL
(All terms end December 31)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

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NIDDK Advisory Council Meetings Dates: 2022 - 2023

2022

January 26-27 (Wednesday and Thursday)

Virtual Meeting

May 11-12 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G

September 7-8 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G

2023

January 25-26 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G

May 17-18 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G

September 13-14 (Wednesday and Thursday)

Building 31, C-Wing 6th Floor Conference Center, Conference Rooms C, D&E, and F&G

217th Meeting of the
NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

Meeting Held Virtually using Web-based Collaboration/Meeting Tools

Thursday and Friday, September 9-10, 2021

Day 1: Thursday, September 9, 2021

OPEN SESSION of the Full Council 10:00 a.m. to 2:00 p.m. EDT

I. CALL to ORDER **Dr. Griffin Rodgers**

II. CONSIDERATION of SUMMARY MINUTES of the 216th COUNCIL MEETING **Dr. Rodgers**

III. FUTURE COUNCIL DATES **Dr. Rodgers**

2022

January 26-27 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms 6, 7, and 10

May 11-12 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms 6, 7, and 10

September 7-8 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms 6, 7, and 10

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September 13-14 (Wednesday and Thursday)
Building 31, C-Wing 6th Floor Conference Center
Conference Rooms C, D&E, and F&G

IV. ANNOUNCEMENTS
Confidentiality/Conflict of Interest **Dr. Karl Malik**

V. REPORT from the NIDDK DIRECTOR **Dr. Rodgers**

VI. UPDATE: DIRECTOR, NATIONAL INSTITUTE OF BIOMEDICAL IMAGING AND BIOTECHNOLOGY **Dr. Bruce Tromberg**

VII. UPDATE: HEALTH EQUITY WORKING GROUP **Dr. Gregory Germino**

<<BREAK 12:00 noon - 12:15 p.m. EDT>>

VIII. UPDATE: NIDDK STRATEGIC PLANNING PROCESS **Dr. Germino**

IX. CONCEPT CLEARANCE **NIDDK Staff**

<<BREAK – 2:00 p.m. – 2:15 p.m. EDT>>

EXECUTIVE SESSION 2:15 p.m. EDT to 4:00 p.m. EDT

X. Intramural Research Program Update **Dr. Michael Krause**

XI. Intramural Research Program Implementation Plan to Recommendations of Blue-Ribbon Panel Review **Dr. Krause**

Day 2: Friday, September 10, 2021

XII. SUBCOMMITTEE MEETINGS Open Session
- Diabetes, Endocrinology, and Metabolic Diseases (10:00 – 10:30 a.m. EDT)
- Digestive Diseases and Nutrition (10:00-11:00 a.m. EDT)
- Kidney, Urologic, and Hematologic Diseases (10:00-11:00 a.m. EDT)

<<BREAK: DEM 10:30-10:45 a.m. EDT; DDN and KUH 11:00-11:15 a.m. EDT>>

XIII. SUBCOMITTEE MEETINGS Closed Session
- Diabetes, Endocrinology, and Metabolic Diseases (10:45 a.m. – 12:15 p.m. EDT)
- Digestive Diseases and Nutrition (11:15 a.m. – 12:15 p.m. EDT)
- Kidney, Urologic, and Hematologic Diseases (11:15 a.m. – 12:15 p.m. EDT)

<<BREAK – 12:15 p.m. – 12:30 p.m. EDT>>

CLOSED SESSION of the Full Council 12:30 p.m. to 12:45 p.m. EDT

XIV. REPORTS OF SUBCOMMITTEES: CONSIDERATION of APPLICATIONS **Dr. Malik**
- Digestive Diseases and Nutrition
- Diabetes, Endocrinology, and Metabolic Diseases
- Kidney, Urologic, and Hematologic Diseases

XV. ADJOURNMENT **Dr. Rodgers**

National Diabetes and Digestive and Kidney Diseases Advisory Council
National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health Department of Health and Human Services

I. CALL TO ORDER
Dr. Rodgers

Dr. Griffin Rodgers, Director, NIDDK, called to order the 216th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 10:00 a.m. on May 12, 2021, via Zoom videoconference. This meeting was conducted using a two-tiered webinar format. The panelist tier consisted of NIDDK's Advisory Council members and NIDDK staff members who presented during the meeting. The audience tier was available to members of the public and allowed them to view and listen to the meeting.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Ms. Tracey Brown Dr. David Penson
Dr. David D'Alessio * Ms. Ceciel Rooker
Dr. Iain Drummond Dr. Kathleen Sakamoto
Dr. Penny Gordon-Larsen Dr. Michael Snyder
Dr. Barbara Kahn Dr. Ronald Sokol
Dr. Mark Nelson Dr. Ian Stewart *
Dr. Richard Peek Ms. Lorraine Stiehl
Dr. Gary Wu
* Ex-Officio

Subject Matter Experts:
Dr. E. Dale Abel Dr. Robert Eckel
Ms. Dawn P. Edwards Dr. Keith C. Norris

Also Present:
Dr. Griffin Rodgers, Director, NIDDK and Chair of the NIDDK Advisory Council
Dr. Karl F. Malik, Executive Secretary, NIDDK Advisory Council
Dr. Matthew E. Portnoy, Deputy Director, Division of Extramural Activities
Dr. Gregory G. Germino, Deputy Director, NIDDK
Dr. William Cefalu, Director, Division of Diabetes, Endocrinology and Metabolic Diseases, NIDDK
Dr. Stephen P. James, Director, Division of Digestive Diseases and Nutrition, NIDDK
Dr. Robert A. Star, Director, Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

B. NIH and NIDDK PANELISTS/SPEAKERS
Dr. Eliseo Pérez-Stable, Director, National Institute on Minority Health and Health Disparities
Dr. Marie Bernard, Acting NIH Chief Officer for Scientific Workforce Diversity, and Deputy Director, National Institute on Aging
Dr. Robert Rivers, NIDDK

Dr. Peter Perrin, NIDDK
Dr. David Saslowsky, NIDDK
Dr. Voula Osganian, NIDDK
Dr. Olivier Blondel, NIDDK
Dr. Xujing Wang, NIDDK
Dr. Miranda Broadney, NIDDK
Dr. Lisa Spain, NIDDK
Dr. Pamela Thornton, NIDDK
Dr. Norann Zaghloul, NIDDK
Dr. Paul Kimmel, NIDDK
Dr. Katrina Serrano, NIDDK

C. ANNOUNCEMENTS

Dr. Rodgers

Dr. Rodgers began by noting this is NIDDK's fourth consecutive virtual Council meeting. NIH has decided that all advisory council meetings will be held virtually at least through September 2021, so the next NIDDK Advisory Council meeting will again take place in a virtual format on September 9 and 10. He expected that the January 2022 meeting will take place in person.

Council Member News

Dr. Rodgers recognized four subject matter experts who joined the meeting:

- **E. Dale Abel, M.D., Ph.D.**, is the Francois M. Abboud Chair in Internal Medicine, John B. Stokes III Chair in Diabetes Research, Chair and Department Executive Office of the Department of Internal Medicine, Director of the Fraternal Order of Eagles Diabetes Research Center, and Professor of Medicine in Biochemistry and Biomedical Engineering at the University of Iowa Carver College of Medicine in Iowa City, Iowa.
- **Robert Eckel, M.D.**, is a Professor of Medicine, Emeritus, in the Division of Endocrinology, Metabolism, and Diabetes and the Division of Cardiology at the University of Colorado, Anschutz Medical Center in Morrison, Colorado.
- **Dawn P. Edwards** is a Patient Advocate and Wellness Ambassador at the Rogosin Institute and the NXStage Medical Company in Jamaica, New York.
- **Keith C. Norris, M.D., Ph.D.,** is Professor of Medicine and Executive Vice Chair for Equity Diversity and Inclusion at the University of California, Los Angeles in Los Angeles, California.

Dr. Abel and Dr. Eckel will participate in discussions within the Diabetes, Endocrinology and Metabolic Diseases (DEM) subcommittee. Ms. Edwards and Dr. Norris will participate in discussions within the Kidney, Urology, and Hematology (KUH) subcommittee.

General Announcements

Dr. Rodgers pointed out that 2021 is the 100th anniversary of the discovery of insulin, which transformed the treatment of diabetes and shifted the prognosis from almost always fatal to a manageable condition. NIDDK has played an important role in the understanding of the

pathophysiology, prevention, and management of all forms of diabetes. This includes NIDDK's landmark studies such as the Diabetes Control and Complications Trial (DCCT), the follow-up Epidemiology of Diabetes Interventions and Complications (EDIC) study, and the Diabetes Prevention Program Outcomes Study (DPPOS). NIDDK has also contributed to technological advances such as continuous glucose monitors and the artificial pancreas. To highlight these advances, NIDDK and the Canadian Institute of Health Research (CIHR) are hosting a joint symposium on June 2 and 3, 2021 with the theme: Heterogeneity of Diabetes: Beta Cells, Phenotypes and Precision Medicine. The symposium will bring together research leaders with the aim of facilitating engagement, stimulating collaboration and highlighting critical knowledge gaps and novel approaches in diabetes research.

Dr. Rodgers also recounted some recent news about former Council members:

- **Dr. Bruce Spiegelman, former member and long-time NIDDK grantee,** will receive the American Diabetes Association's Albert Renold Award, which recognizes career achievements in mentorship or creating a robust environment for diabetes research. Dr. Spiegelman focuses on the regulation of energy metabolism with a particular emphasis on gene transcription. His team at Dana-Farber Cancer Institute in Boston studies fat and muscle cell development, control of metabolic rates, and the dysregulation of glucose and lipid metabolism in disease to better understand biochemical pathways in metabolic diseases. Dr. Spiegelman has trained and mentored several dozen students and postdocs, many of whom currently have independent laboratories across the country, with numerous NIDDK-funded projects.
- **Dr. Robert W. Schrier**, renal physician and former NIDDK Advisory Council Member, died on January 23, 2021. A prolific principal investigator on NIDDK-funded grants from 1986-2014, Dr. Schrier contributed greatly to research on polycystic kidney disease, kidney failure, and the regulation, release, and action of the hormone vasopressin. His work led to more than 1,000 publications and his three volume textbook *Diseases of the Kidney and Urinary Tract* is used by clinicians and academicians around the world. He was also a great help in developing one of NIDDK's previous strategic plans. Dr. Schrier served as president of the American Society of Nephrology, the International Society of Nephrology, and the National Kidney Foundation – the only person to have served in all three roles.

NIDDK Staffing News

Dr. Rodgers made the following staffing announcements:

- **Dr. James Balow** has stepped down as the Clinical Director of the NIDDK Intramural Research Program and **Dr. Chris Koh** has stepped into the role of Acting Clinical Director. A national search to fill the Clinical Director position will commence later this month. Dr. Rodgers thanked both Dr. Balow and Dr. Koh for their service in this role.
- Dr. Rodgers had announced the retirement of **Dr. Philip Smith** at the January 2021 meeting, a move that will take place at the end of May. **Dr. Karen Teff** from the

Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) will replace Dr. Smith as co-Director of the Office of Obesity Research and on the NIH Obesity Research Task Force Senior Leadership Group. Dr. Rodgers extended best wishes to Dr. Smith on his retirement and gratitude to Dr. Teff for stepping up to these new roles.

- **Ms. Catherine Carr**, NIDDK Regulatory Officer, has left NIH for an opportunity at the Food and Drug Administration.
- **Dr. Yu-Chen Tsai** has assumed the role of NIDDK Regulatory Officer, joining. Dr. Ying Huang in the Office of Clinical Research. Dr. Tsai was formerly a regulatory specialist at Emmes, a global clinical research organization.
- **Dr. Ludmila Pawlikowska** has joined NIDDK's Division of Digestive Diseases and Nutrition (DDN) to focus on genetics and genomics of liver and digestive disorders and obesity. She received her undergraduate degree from Harvard University and her Ph.D. from the University of California San Francisco. Following post-doctoral work in genetics of biliary disorders and common and rare disease genomics, she joined the faculty at UCSF, where she advanced to the rank of Associate Professor and a Member of the Institute for Human Genetics, and conducted research in the genomics of liver disorders, aging, stroke, and vascular malformations.
- **Kaitaia Fu**, **Hubert Walters**, and **Sunshine Wilson** have all joined NIDDK as Senior Grants Management Specialists.

Dr. Rodgers also announced some additional NIDDK staff retirements:

- **Dr. Tamara Bavendam**, Program Director for the NIDDK Women's Urologic Health Program, has retired after 8 years at NIDDK. Dr. Bavendam applied her knowledge from clinical practice and work in the private sector to expand and promote the NIDDK's women's urology program. Her dedication to the NIDDK's mission and women's urologic health is recognized and valued extensively throughout the research community.
- **Dr. Deborah Hoshizaki** has retired from her position as Program Director for the Kidney and Urology Regeneration and Repair portfolio. Dr. Hoshizaki had 18 years of federal service and worked to establish the Genito-Urinary Development Molecular Anatomy Project (GUDMAP) as well as the Rebuilding a Kidney Consortium (RBK), which focuses on finding the best strategies for generating nephrons for clinical use. She worked tirelessly to increase the visibility of research results into the broader scientific community.

Dr. Rodgers also recognized "above and beyond" service taken on by some NIDDK staff. As the nation experiences a surge of unaccompanied children arriving at the southern border, HHS has asked for staff to volunteer to support the response and help ensure that the needs of these children are met while in the care of the United States. Currently, 12 NIDDK staff members have volunteered to help with these efforts that include long hours and challenging circumstances. Dr. Rodgers thanked these staff members for their empathy, sense of duty and willingness to leave friends, family, and the comforts of home to care for others in need.

Other NIDDK News

Dr. Rodgers gave a brief update on the development of the NIDDK Strategic Plan, which will complement disease-specific planning efforts. Staff have received many valuable ideas and insights from the Strategic Plan Working Group, the NIDDK Advisory Council, and a public Request for Information (RFI) released in 2020. Based on this input, NIDDK staff have been writing the first draft, which will be sent to external members of the Working Group for review. NIDDK will then post a draft of the Plan on the website this summer for public comment, before finalizing later this year.

Dr. Rodgers also highlighted recent outreach and engagement efforts on social media, including a Facebook Live event as part of National Kidney Month in March. Dr. Rodgers interviewed Dr. Jonnie Hamilton, Medical Manager, Ascension Community Health and First Vice President of Chi Eta Phi Sorority Incorporated. The discussion focused on how to help patients manage chronic kidney disease (CKD) and ways to protect kidney health. The event reached about 500 participants and had a positive reception. A second Facebook event in April focused on promising chronic kidney disease research, where Dr. Rodgers spoke with NIDDK's Drs. Robert Star and Paul Kimmel.

NIDDK has gained more than 10,000 followers on Twitter and plans a Twitter chat on June 3 to coincide with the symposium commemorating the 100th anniversary of insulin. Dr. Rodgers invited Council members and the public to join the conversation and follow NIDDK on Twitter, Facebook, YouTube, and Instagram.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 215th COUNCIL MEETING

Dr. Rodgers

The Council approved, by voice vote, the Summary Minutes of the 215th Council meeting, which had been sent to them in advance for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

In order to save time, Dr. Rodgers did not review all planned Advisory Council meeting dates. Updates will be posted on the Council website.

IV. ANNOUNCEMENTS

Dr. Malik

Confidentiality

Dr. Karl Malik reminded Council members that material furnished for review purposes and discussion during the closed portion of the meeting is considered confidential. The

content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Dr. Malik reminded Council members that advisors and consultants serving as members of public advisory committees, such as the NIDDK Advisory Council, may not participate in situations in which any violation of conflict of interest laws and regulations may occur.
Responsible NIDDK staff shall assist Council members to help ensure that a member does not participate in, and is not present during, the review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, or partner (including close professional associates), or an organization with which the member is connected.
To ensure that a member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr.
Malik directed each Council member to a statement in his or her meeting folder regarding the conflict of interest in review of applications. He asked each Council member to read it carefully, sign it, and return it to NIDDK before leaving the meeting.

Dr. Malik pointed out that when the Council reviews applications in groups without discussion
—also called "*en bloc*" actions—all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict.

Regarding multi-campus institutions of higher education, Dr. Malik said that an employee at one campus may participate in any particular matter affecting another campus, if the employee's financial interest is solely at one campus and the employee has no multi-campus responsibilities.

V. REPORT FROM THE NIDDK DIRECTOR
Dr. Rodgers

Budget Update

Dr. Rodgers gave an update on the status of the budget appropriation process for NIH for Fiscal Year 2022. He reminded members that the Fiscal Year 2021 Omnibus Appropriations Package was signed into law just before the Council's January 2021 meeting. This bill included $42.7 billion for the NIH, a 3 percent increase over FY2020, including funding for targeted programs such as the BRAIN Initiative, Alzheimer's disease research, and opioid research. NIDDK received $2.132 billion in the 2021 appropriations, an $18 million (0.8 percent) increase.

Dr. Rodgers explained that a change in administration typically delays the budget process, which starts with the President's Budget Request. President Biden released a Fiscal Year 2022 discretionary request, which only provides high-level budget guidance. This is sometimes called the "skinny" budget.

Dr. Rodgers shared a few details about the President's discretionary budget, which includes $51 billion for the NIH, an increase of $9 billion over FY2021 funding. This amount includes$6.5 billion for a new entity at NIH called the Advanced Research Projects Agency for Health (ARPA-H). The idea behind this is to promote high-risk/high-reward innovative research for health, similar to DARPA at the Department of Defense and ARPA-E at the Department of Energy. Few details are available at this point, but the administration noted an initial focus that includes "cancer and other diseases such as diabetes and Alzheimer's."

The skinny budget also mentions several areas of interest to NIH, including ending the opioid crisis, the HIV/AIDS epidemic, health inequities, racial disparities, and the health impact of climate change. Dr. Rodgers said that the full budget should be released soon, and he will provide additional information about the process at the September 2021 Council meeting.

Congressional Activities

Dr. Rodgers reported on Congressional activities by NIDDK staff over the past months, including three virtual congressional briefings on different aspects of NIDDK research.

- On March 31, the Endocrine Society organized a briefing on diabetes and COVID-19. Representative Kim Schrier of Washington State, a pediatrician who has type 1 diabetes, provided opening remarks. Dr. Rodgers gave a presentation on NIDDK research, and Dr. Will Cefalu, DEM Director, also participated.
- On April 14, the Friends of NIDDK organized a briefing focused on the NIDDK annual report titled *NIDDK Recent Advances & Emerging Opportunities*. Directors of NIDDK's three extramural divisions and Dr. Rodgers talked about research advances and emerging opportunities described within the report. Former council member Ms. Pamela Taylor gave a moving and informative talk about her experience with diabetes and her participation in the Diabetes Prevention Program and the Diabetes Prevention Program Outcomes Study. Dr. Rodgers took time to thank Council members for their constructive feedback on the report, which was released at the January Council meeting.
- On May 7, Dr. Rodgers, along with several other NIH Institute Directors, met virtually with the clerks of the Senate Appropriations Labor-HHS Subcommittee to talk about autoimmune disease research. Dr. Rodgers spoke about NIDDK research in this area, with a focus on type 1 diabetes.

Council Questions and Discussion

Comment from Council: *The NIH is limited to a certain number of Institutes and Centers. Has there been any discussion of how the ARPA-H would be structured within the NIH overall governance?*

Dr. Rodgers answered that the idea is in the early stages. Dr. Collins and his staff are eager to learn more about what the President envisions and the level of support from appropriate congressional leadership. Congressional input is required to add or subtract from the current 27 institutes. At the moment, the premise would be that ARPA-H would be an office within the director's office that would then work with the various ICs; this would not require the creation of a new institute.

Dr. Rodgers also mentioned that despite only receiving a 0.8 percent increase in the NIDDK budget last year, the Institute was able to maintain a robust payline, both for established investigators and early-stage investigators, as well as launch a few new initiatives. He noted, however, that the increase hasn't provided much flexibility for dealing with the COVID crisis and the financial implications of restarting lab and clinical research activities. Many of the disorders and comorbidities that impact the outcome of COVID-19 are in the NIDDK purview—including diabetes, obesity, and others—representing additional research opportunities.

VI. COUNCIL FORUM (PART 3)

Underrepresented Investigators and Underrepresented Science
Dr. Gregory Germino, Dr. Eliseo Pérez-Stable, Dr. Marie Bernard, Dr. Rob Rivers

Dr. Germino hosted part three of the Council Forum on Underrepresented Investigators and Underrepresented Science. He explained that this series started in September 2020 in the middle of the COVID-19 pandemic, which tested health and social systems and highlighted health inequities that result from a long history of racism and the structures that continue to deny justice and equal opportunity for all. What COVID-19 and many of the diseases in the NIDDK portfolio have in common is that their prevalence and severity are greatly impacted by the social determinants of health—zip code more than genetic code. During this time of racial reckoning, NIDDK has been challenged to look at who we hire, who we fund, what we fund, and to ask the question of whether we are doing enough to achieve racial and health equity.

The Forum kicked off with a focus on NIDDK's extramural workforce. Black applicants make up only 1 to 2.3 percent of all R01 applicants per year for NIDDK. This group receives too few awards per year to report the exact number because of privacy rules. Staff from the NIDDK Office of Minority Health Research Coordination reviewed the history of NIDDK's efforts to promote a diverse workforce, pointing out ways NIDDK could continue to help build bridges to keep trainees in its pipeline, especially through mentoring.

The Forum continued at the January 2021 Council meeting with an examination of the related issue of supporting health disparities research. Black researchers are more likely

to propose research on topics—such as health disparities—that have lower award rates. These topics tend to be funded by ICs, such as the National Institute of Minority Health and Health Disparities, that have smaller budgets and lower award rates overall.

NIDDK is making support for health equity research a cross-cutting theme of its Strategic Plan that will be ready for public comment this summer. NIDDK is also establishing a working group of Council Members to help identify opportunities in this area.

The third installment in the Forum series included three parts:

- Dr. Eliseo Pérez-Stable, Director of the National Institute of Minority Health and Health Disparities (NIMHD), presented on some of the initiatives his Institute is leading or co- leading.
- Dr. Marie Bernard, Deputy Director of the National Institute on Aging and acting NIH Chief Officer for Scientific Workforce Diversity, talked about NIH-wide efforts to promote diversity, equity, and inclusion in biomedical research.
- NIDDK's Dr. Rob Rivers provided an overview of initiatives developed by the NIH UNITE Committee.

NIMHD-Led/Co-led Initiatives

Dr. Pérez-Stable started by reviewing the populations of focus for NIMHD. These include racial and ethnic minorities as defined by the U.S. Census, people of any race with less privileged socio-economic status, underserved rural residents, and sexual and gender minorities. The first three categories are outlined in the legislation that established NIMHD; the fourth category was added in 2016.

He also reviewed concepts central to this topic:

- A health disparity is a health outcome that is worse in one population compared to a reference group.
- Discrimination, racism, and being underserved in healthcare lead to social disadvantage.
- Race, ethnicity, and socioeconomic status are fundamental factors that influence health and health outcomes.

For example, African Americans have more strokes when compared to Whites, even among those with similar systolic blood pressure readings. Most chronic diseases—including diabetes—are more common among those who are poor. Among people with diabetes, those from minority groups had fewer heart attacks but more end-stage renal disease than Whites.

He pointed out that social determinants of health (SDOH) have gotten a lot of attention recently, especially during the COVID-19 pandemic. SDOH are the conditions in which people are born, grow, live, work, and age. They include:

- Demographics, including family background
- Geographic region of resident (urban/rural)
- Cultural identity, religion
- Language proficiency, literacy, and numeracy

- Structural determinants, such access to housing, green space, broadband, economic opportunity, transportation, schools, healthy foods, and public safety.

NIMHD led an NIH-wide effort to develop the PhenX toolkit of high-quality standard SDOH measures that investigators can use in their studies. NIMHD has also developed a research framework that can help investigators identify potential research projects that look at the domains that influence health and the different levels of influence, from the individual level to interpersonal, community, and societal influences. Most research focuses on biological factors on the individual level, but NIMHD funds research that looks at all levels and domains of influence.

Racial and ethnic minorities have been disproportionately affected by the pandemic: more than 50 percent of COVID-19 cases and 45 percent of deaths have affected Latinos, American Indian/Alaskan Natives, and African Americans—groups that make up about one- third of the U.S. population. Underlying factors include long-standing disparities and disadvantages, higher proportions of public-facing jobs, and crowding in housing and communities. Higher rates of co-morbid conditions (especially diabetes) and less access to care also result in more advanced disease and higher mortality rates in all age groups within these populations. This illustrates the imperative to implement prevention and healthcare strategies to address the effects of the pandemic as well as underlying inequities.

NIH has responded with cross-cutting initiatives focused on social, behavioral, and economic issues launched through a joint effort with NIMHD and the National Institute on Mental Health, the Office of Behavioral and Social Research, and the National Institute on Aging.

So far the effort has funded 52 supplements to existing grants in Fiscal Year 2020. The initiative has also included a number of R01 grants with several application deadlines still pending. Most projects have focused on adding COVID-specific surveys to existing cohorts of populations or patients, including nursing home residents and pregnant women who gave birth. It also included developing digital and community-engagement interventions to address COVID transmission through behavioral change and evaluate the social and mental health impacts of the pandemic and analyze the excess morbidity/mortality burden. Some of these analyses have shown that life expectancy may have decreased by as much as 2 or 3 years in African Americans and Latinos, although there is some expectation that some of the deaths in these groups are underreported.

With a congressional allocation in 2020, NIH launched the Rapid Acceleration of Diagnostics, or RADx, program to enhance COVID-19 testing among underserved and vulnerable populations in the U.S. through a consortium of community-engaged research projects. The program’s goals are to strengthen available data on disparities in infection rates, disease progression, and outcomes and to identify strategies to reduce disparities in COVID-19 diagnostics.

Phase 1 of the program took place from September to November 2020 with $300 million in funding. Phase 2 will continue from early 2021 to Summer/Fall 2021 to integrate new advances and expand studies and populations with $189 million in funding. The program funded 53 testing interventions in 33 states, the District of Columbia, and Puerto Rico, as

well as 16 social and behavioral research studies and a coordination and data collection center at Duke-UNC. The goals of RADx are to:

- Accelerate COVID-19 community implementation science.
- Amplify and disseminate community best practices for successful implementation of intervention testing strategies.
- Support data collection, integration and sharing while preserving necessary data protections.

The structure of the program requires investigators to work as team members as part of the consortium. For example, researchers at Stanford are working with the Lakota Sioux in South Dakota, and researchers at Johns Hopkins are working with the White Mountain Apache and Navajo Nations. In addition, the Coordinating Center is setting up infrastructure to continue this work through NIMHD.

The most public-facing RADx activity is the Community Engagement Alliance (CEAL) against COVID-19 disparities, which started as part of an effort to ensure participation of diverse populations in the clinical trials for COVID-19 vaccines. The program is based on the principle of building partnerships between academic health centers and trusted community leaders and organizations that can deliver a science-based message. The National Medical Association, National Hispanic Medical Association, and other professional organizations as well as civil rights organizations like the NAACP and *Unidos U.S.* have gotten involved and supported the efforts.

The December appropriations bills also included funding for the Chronic Disease and Health Disparities Centers, which builds on a Fiscal Year 2020 initiative to address chronic diseases and health disparities in diabetes, kidney disease, and obesity. With this latest funding, NIMHD will work with NIDDK, NHLBI, NCI and NCATS to establish a comprehensive center initiative. NIMHD will receive $45 million to support regional multi-institutional consortia that produce collaboration, research, and translational science on a wide scale, targeting more than one chronic disease.

This has led to a new funding opportunity announcement and request for applications to support new Centers that integrate prevention, intervention testing, and management strategies for chronic and co-occurring conditions as well as co-occurring risk factors for chronic diseases that lead to health disparities. These will include efficacy studies with some observational components related to prevention and management. Each proposal will include at least two chronic diseases and involve two institutions as well as a community- engagement core. Centers will also be required to set aside a minimum amount for an investigator development core that will be an engine for diversification of the workforce.

He pointed out that race is a difficult topic that people tend to avoid, but the murder of George Floyd has brought it into the forefront and opened up conversations about racism. A 2015 survey by the Kaiser Family Foundation asked respondents if they had been treated unfairly in the past 30 days because of their racial or ethnic background in the following places or scenarios: in a store while shopping; in their place of work; in a restaurant, bar, theatre, or other entertainment place; in dealings with the police; and while getting healthcare for themselves or a family member. The study found that more

than a third of Latinos and more than half of African Americans said that they had been treated unfairly in the past 30 days because of their racial or ethnic background, as compared to only 15 percent of White Americans. In healthcare-specific scenarios, 12% of African Americans and 14% of Latinos reported being treated unfairly, relative to only 5 percent of Whites.

The majority of research on racism has focused on the interpersonal arena, and researchers have developed measures of association between racism and various outcomes, such as behavior, substance use, mental health issues, and cardiovascular reactivity. Other examples of racism as a research construct have included studies on internalized racism, perceived societal discrimination and second-hand effects of racism

Most recently, research has focused on the construct of structural racism, which is defined as the history, culture, institutions, policies, and codified practices that perpetuate inequity by promoting an ideology of inferiority. This includes organized systems that categorize, rank, devalue, disempower, and differentially allocate resources. Residential segregation—an outcome or effect of policies—is the cornerstone of these systems. NIMHD held a workshop on this topic in 2017 and has published a funding opportunity for research on Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities. The May 2021 issue of the journal Ethnicity & Disease contains an NIMHD-sponsored special supplement on this topic as well.

NIH IC Directors recently held two 3-hour sessions on racial equity as part of the UNITE Initiative (the subject of the next presentation). One of the lessons learned from this was a sociological definition of diversity and –that well-meant claims of “colorblindness” actually perpetuate the status quo. It’s not a matter of blame or guilt, but actually something more profound.

He pointed out that the number of American Indian physicians went down in the years 2013 to 2018. And while the percentage of African-American and Latino/Hispanic medical students has increased to 15 percent, it falls far short of the 33 percent these groups make up of the U.S. population. The numbers for Ph.D. recipients in STEM fields are also similar, with Blacks and Latinos in distressingly low numbers, and American Indian recipients actually declining. NIDDK and other ICs at NIH are trying to address this challenge, and the NIH Office of Scientific Workforce Diversity will play a critical role in the next several years.

NIMHD initiated in 2016 an annual week-long intensive training in minority health for early- stage investigators and postdoctoral fellows with an interest in health disparities research.

The sessions include lectures by leading scientists in this area, mock grant-review sessions using real applications, and meetings with NIMHD and other NIH scientific program staff. The program has had 270 participants over the past five years, 60 percent of whom were from underrepresented minority groups, and 20 percent physicians. Program participants have successfully applied for R01 and K awards.

The Faculty Institutional Recruitment for Sustainable Transformation (FIRST) program was established by Dr. Hannah Valantine during her tenure as Chief Diversity Officer at NIH. This is a Common Fund program designed to foster sustainable institutional culture change and inclusive excellence, encourage hiring of diverse faculty, and support faculty development, mentoring, sponsorship and promotion across NIH ICs. NIMHD will house the coordination and evaluation center while NCI will house the faculty cohort.

He also introduced the NIH-wide Minority Health and Health Disparities Strategic Plan, which charts the way forward to advance the science of minority health and health disparities research from 2021-2025. This report includes "leap" goals for 2030, two of which relate to NIDDK's mission and the higher rates of renal disease and diabetes among minority populations:

- Identify differences in factors that cause progression to end stage renal disease (ESRD), and find informative subpopulations, among African Americans or Blacks; Hispanics or Latinos; American Indians and Alaska Natives, Pacific Islanders and Asians with chronic kidney disease by 2030.
- Identify factors contributing to the disparity between Whites and African Americans or Blacks; Hispanics or Latinos; American Indian and Alaska Natives; Pacific Islanders and Asians in control of hemaglobin A1C and target those factors through rigorous clinical trials and adaptive population-based interventions by 2030.

He closed by bringing the Council's attention to a special issue of the *American Journal of Public Health* that included articles on NIMHD research strategies and their visioning process. He also explained that a new book, *The Science of Health Disparities*, has been produced by NIMHD, NIH and extramural scientists. The book is intended as a methods manual for fellows and junior faculty and others who want to get involved in this field.

Council Questions and Discussion

Comment from Council: *Will the Chronic Disease and Health Disparities Centers be looking at racial bias as it may impact ongoing complications following COVID-19 as well as to the incidence of COVID-19?*

Dr. Pérez-Stable explained that the Chronic Disease and Health Disparities Centers will look at all chronic diseases—including diabetes, kidney disease, and obesity—as they relate to health disparities. These Centers are not focused on COVID-19 specifically, although these chronic diseases do play a role in COVID outcomes.

Comment from Council: *What role does the Center for Scientific Review (CSR) and Study Sections play in enabling researchers from underrepresented groups to get funding? Are the right reviewers looking at the applications?*

Dr. Pérez-Stable agreed that this is an important question. He referenced a recent study that showed how topic choice accounts for part of the funding gap between minority and non- minority researchers and that the funding gaps originated in the CSR review process. But across the board, too few underrepresented minority investigators apply for funding.

Currently, Dr. Noni Byrnes is addressing this issue. One approach may be to have standing committees do more of the reviews. Up to 20 percent of NIH principal investigators are not involved in reviewing grants, so there is also room to expand the pool of reviewers.

Comment from Council: *Does NIMHD have plans to increase training in this area of research so that more investigators are well versed in the methods required to rigorously study and address problems of health disparities?*

Dr. Pérez-Stable explained that NIMHD currently doesn't have the plans or the budgetary flexibility to do more in this area. UCSF developed a course for clinical research training that included an elective on health disparities research methods as well as qualitative research and population health methods, which is a model that could be generalized through the existing networks of CTSA.

Comment from Council: *This problem requires more "groundwater" solutions that focus on the way society is structured and how that flows through all our institutions, rather than "fish-level" solutions that focus on the individual or "lake-level" solutions that focus on systems. How do we drive progress toward groundwater solutions?*

Dr. Pérez-Stable admitted that this is a challenge. The general paradigm in public health science was that disparities are based on social class, and if we decrease economic inequality, these differences will go away. We've moved away from that to understanding more about the roles that race, ethnicity, and cultural identity play in variances. It will take multi-sector interventions and the collaboration of health scientists with people in the housing, planning, food delivery, and environmental areas. So much of disparity is generated through chronic disease management. We have just begun these efforts to address structural racism. We plan to do more in Fiscal Year 2023.

Comment from Council: *A lot of institutions are doing great work in methods training for researchers into health disparities and minority health. What training is provided to reviewers to ensure that they are not continuing to look at race and ethnicity through the same indoctrinated lens of white supremacy?*

Dr. Pérez-Stable acknowledged the issue and assured Council that the director of CSR and others are doing their best to address it directly. Pointing out egregious examples is one way to move the needle further. Reviewers have certain expertise in different areas of research— clinical research, molecular biology, population science—and research methods. It may not be necessary to have a demonstrated expertise to be able to recognize the potential impact of a topic to be an effective reviewer.

Comment from Council: *Underrepresented minorities—particularly African Americans— are actually overrepresented in military populations. Is there a role for data from the Department of Defense to answer some of these questions? When we control for access to care, it mitigates some of the health disparities but does not completely remove the effect.*

Dr. Pérez-Stable said that the DoD is interested in this area, and there is a military representative on the NIMHD Council. Looking at data from the U.S. Department of Veterans Affairs (VA), African Americans have better outcomes than both non-veteran African Americans and White Americans served by the VA. Dr. Pérez-Stable provided the caveat that some of this data may be confounded by the demographics and circumstances of those who enlist.

Comment from Council: *Studies of cardiovascular outcomes and mortality, as well as kidney disease, by the VA have shown improved outcomes under the military healthcare system, which is a more "universal" system than standard American healthcare.*

NIH UNITE Initiative

After a brief recess, Dr. Germino introduced Dr. Marie Bernard, Deputy Director of the National Institute of Aging and Acting NIH Chief Officer for Scientific Workforce

Diversity to report on NIH efforts to promote diversity, equity and inclusion in biomedical research.

Dr. Bernard explained that the UNITE Initiative, presented at a special meeting of the Advisory Committee to the Director of NIH in February 2021, is the result of a lot of thought and deliberation. The events of 2020 brought into sharp focus the ongoing reality of racial injustice in our country and the responsibility of all of us to address it. The directors of the NIH Institutes and Centers had a series of intense meetings from June 2020 onward at which these issues were identify and discussed. Two self-assembled affinity groups at NIH—Eight Concepts for Racial Equity (8CRE) and African-American and Black Senior Scientists (AA/B Scientists), as well as the Anti-Harassment Steering Committee, gave candid input and informed next steps.

The directors agreed that NIH must address structural racism and must ensure that biomedical research and the administrative system that supports it are devoid of hostility grounded in race, sex, or other federally protected characteristics. With the UNITE initiative, NIH commits to delineate elements that may perpetuate structural racism in biomedical research both within NIH and the extramural community and lead to a lack of personnel inclusivity, equity, and diversity. The group committed to give all ideas equal and fair review without regard to current dogma, precedents, or who presents the data. As COVID-19 made clear, health disparities and inequities continue to contribute to morbidity and mortality in our country, and we must redress fundamental causes and identify effective interventions.

The UNITE Initiative unveiled on February 26, 2021 represents five interacting committees:

- U: Understanding stakeholder experiences through listening and learning
- N: New research on health disparities/minority health/ health equity
- I: Improving the NIH culture and structure for equity, inclusion, and excellence
- T: Transparency, communication, and accountability with our internal and external stakeholders

- E: Extramural research ecosystem: Changing policy, culture, and structure to promote workforce diversity

Dr. Bernard then elaborated on the charge and projects of each of the committees. For example, the **U Committee** will perform a broad, systematic self-evaluation to delineate elements that perpetuate structural racism and lead to a lack of diversity, equity, and inclusion within the research community. This committee has already published a request for input on ways to improve racial and ethnic inclusivity and diversity in research environments. They have also embarked on a project to collect qualitative data through a comprehensive assessment across stakeholders in listening sessions, focus groups, town halls and anonymous submissions. This evaluation is expected to be completed sometime in summer 2021.

The **N Committee** will address long-standing health disparities and issues related to minority health to advance health equity and ensure transparency, accountability, and sustainability of resources in this area. Dr. Rob Rivers, Program Director in the NIDDK's Office of Minority Health Research Coordination (OMHRC), is co-chair of this committee. Their foundational efforts include a concept approved on February 26 to use Common Fund resources to fund innovative and transformative health disparities research. Funding opportunity announcements for this were published in March. They also plan to examine the portfolios of NIH stakeholders to take a full inventory of existing efforts in this area. The current tracking system cannot track these research topics automatically, so this must be done manually.

The **I Committee** is looking at the racial and ethnic demographics of NIH's total workforce of 44,000 individuals—comprised of 18,000 federal employees, as well as contractors and trainees—relative to the breakdown by job classifications: overall, scientific, health and research, and infrastructure. Dr. Bernard noted differences in diversity between direct support roles and infrastructure roles; among senior leadership particularly, there is a clear need for more racial diversity. This committee is looking at expanding recruitment efforts for NIH investigators from underrepresented groups, setting up an anti-racism steering committee to coordinate with Institute-level anti-racism plans, and establishing a campaign to make NIH staff aware of options for reporting racist actions. They will also work with NIH senior leadership to appoint a diversity, equity, and inclusion officer in every IC, with direct access to the IC director to track, advance, and coordinate IC-specific diversity, equity and inclusion efforts and actively participate in NIH-wide diversity efforts.

The **E Committee** is charged with evaluating NIH extramural policies and processes to identify and change practices and structures that perpetuate a lack of diversity and inclusion. This committee is focused on race and ethnicity data about applicants and funding rates. Dr. Bernard noted that after a 2011 paper found significant disparities in application and success rates for African-American/Black scientists applying for R01 equivalent grants, her position of Chief Officer for Scientific Workforce Diversity was established to address those findings. By 2020, the identified trend is improving—almost double the number and success rate of African American and Black applicants—but there is still a lot of work to do. This committee is looking at more

transparency with grant demographic data as well as career pathways, institutional culture, NIH processes, and collaboration with minority- serving institutions.

She explained the **T Committee** last, noting that it focuses on transparency and accountability and has the following responsibilities:

- Maintaining the committee's website (nih.gov/endingstructuralracism)
- Raising awareness both within NIH and with the public
- Working to diversify the portraiture around NIH to reflect the Institutes' goal for recruitment and retention.

The T committee is also committed to identify and correct any NIH policies or practices that may have helped to perpetuate structural racism and continue to implement approaches to enhance portfolio diversity. The committee will also launch a multi-phased, -tiered, and - integrated Common Fund initiative focused on transformative health disparities research initiatives to reduce health disparities/inequities and ensure an NIH-wide commitment to the NIMHD structural racism funding opportunity announcement described by Dr. Pérez- Stable. Furthermore, the committee will also develop a sustainable process of gathering and publicizing demographic data on the NIH workforce and implement policy changes that promote anti-racism and remove barriers to professional growth for staff from diverse backgrounds. Another effort will focus on expanding the NIH intramural Distinguished Scholars program that has led to greater diversity among tenure-track investigators.

Dr. Bernard then reported on progress toward the goals set out by the committee:

- As a sign of NIH's commitment to this issue, NIH Director Dr. Francis Collins issued a public apology "to those individuals in the biomedical research enterprise who have endured disadvantages due to structural racism."
- NIH has committed $24 million to the two FOAs issued—one for transformative research to address health disparities and the other focusing on minority-serving institutions. Other funding devoted to these efforts include $60 million of Common Fund resources and $30.8 million from 25 NIH ICOs.
- The NIH BRAIN Initiative has published the first FOA that considers diversity in its review process—each applicant must explain the diversity plan for their project.
- The Office of Extramural Research published an update to their databook that now includes grantee data by race, ethnicity and disability status. The NIH Office of Equity, Diversity, and Inclusion is preparing to publish internal NIH staffing data by race, ethnicity, and other parameters.
- The Anti-Racism Steering Committee has held its first meeting and total membership is now above 460 individuals.

Dr. Bernard closed by acknowledging the efforts of the more than 80 members of the UNITE Initiative. In addition to Dr. Rivers, co-chair of the N committee, she also credited Dr. Larry Tabak, NIH Principal Deputy Director, and Dr. Alfred Johnson, NIH Deputy Director for Management, who serve with her as co-chairs of the overall UNITE Initiative.

Council Questions and Comments

Before opening up the floor to questions and comments from the Council, Dr. Germino pointed out that the actions of the UNITE Initiative align well with NIDDK's actions both in terms of funding initiatives and also internal evaluation of the workforce dynamic.

Comment from Council: *How rigorous do you feel the metrics are for evaluating the success of these initiatives? Will you be able to measure success?*

Dr. Bernard answered that this initiative is a marathon—maybe an ultramarathon—and the mile markers along the way will inevitably change as we get a clearer sense of the journey. For this first part, metrics include deadlines for accomplishing certain tasks and regular progress reports. The Advisory Committee to the Director already has a working group on diversity and that group has been consulted and has made recommendations. The NIH community has also made it clear that they will be watching and expecting progress.

Comment from Council: *What are we offering in terms of leadership development opportunities, especially for people from underserved populations?*

Dr. Bernard agreed that leadership opportunities are important and acknowledged that she has benefitted from training programs in this area. She agreed that broader dissemination of these programs may hold some benefit.

Comment from Council: *Institutional racism is rooted in maintenance of power by the privileged. How can we use both negative and positive reinforcements to force some unwilling people to give up power or to share it?*

Dr. Bernard agreed that this is an important point to consider. If NIH is going to continue as the global leader in science, it must take advantage of diverse perspectives. The future workforce is a diverse workforce. Some approaches may include the Faculty Institutional Recruitment for Sustainable Transformation funding opportunity that was released before UNITE was unveiled. Ten institutions will receive funding to recruit cohorts of underrepresented faculty and develop a program of mentoring, networking, and additional training. Institutional culture will be measured by how welcoming it is for people from underrepresented groups. Early data from the intramural Distinguished Scholars Program was impressive enough that NIH committed $250 million over the next 9 years from the Common Fund to replicate it. Additionally, every IC must have a diversity plan and approach in place, and the directors' performance evaluations will be tied to those metrics. She also noted that the IC directors are on board with the effort.

Comment from Council: *We all have a role to play in this by being willing to get uncomfortable and get closer to race and racism and how deeply embedded and rooted it is. We all have a part to play in dismantling the power structure this society is built on.*

Comment from Council: *Will the UNITE Initiative, especially the E committee, include efforts to recruit diverse populations into science, medicine, and research?*

Dr. Bernard credited Dr. Collins and Dr. Tabak for the thoughtful configuration of the UNITE Initiative, especially in terms of the co-chairs of each committee. One of the chairs of the E committee is Dr. Jon Lorsch, Director of the National Institute of General Medical Sciences (NIGMS). NIGMS funds many training opportunities at NIH, and they want to provide pathways by which underrepresented groups can join the scientific workforce, as well as offer solutions to help keep people on those pathways (i.e., to remove barriers).
They will present their ideas at the January meeting of the Advisory Committee to the Director.

Comment from Council: *What efforts have been made to seek research mechanisms and accountability tools to force institutions to look at the painful reality of racism?*

Dr. Bernard responded that she would like to have more money to put towards these types of efforts, but she believed that as the project goes forward successful strategies will emerge, so that their principles can be applied in other areas.

UNITE Common Fund Concepts

Dr. Rivers gave an update on the Common Fund initiatives aimed at transformative research to address health disparities and advance health equity. He thanked the Council members for their active interest in this area of research.

Dr. Rivers explained that the Common Fund is funded by the Office of the Director to support trans-NIH scientific programs and foster innovative ideas that have potential to transform and benefit the broader biomedical research community. The idea is to move the NIH mission of improved health for all people forward faster by supporting bold programs that catalyze discovery. As part of the UNITE Initiative, the Common Fund is working both within NIH and across the country to rethink cultural and societal structures and focus on how certain thoughts and ideologies in the biological sciences have dehumanized others and lead to poor health outcomes.

To that end, the Common Fund is supporting two funding opportunity announcements with the goal to develop, implement, and disseminate innovative and effective interventions and strategies that prevent, reduce, or eliminate health disparities and increase health equity.
One of the initiatives, RFA-RM-21-021, is open to the entire research community. The companion initiative, RFA-RM-21-022 is designed specifically to spur increased investigation and resources for minority-serving institutions. Projects eligible for this funding must:

- Include an intervention component to make sure ideas are placed into action.
- Reflect transformative ideas that differ from what has been done for the past 20-30 years.
- Focus on one or more of the NIH-designated populations that experience health disparities.
- Document or demonstrate meaningful collaborations and partnerships with local community-engaged leaders.

He explained that the goal is for the community to actively participate in the research and contribute ideas based on their experiences and first-hand knowledge. Projects are encouraged to include community-prioritized research questions and address cross-cutting issues such as determinants of health and priorities of multiple NIH ICs. For example, a research opportunity that investigates metabolic disorders and obesity—which are focus areas for both NHLBI and NIDDK—would be prioritized because they address issues that crosscut several institutes and involve multilevel interventions and real transdisciplinary intersectional collaborations.

Dr. Rivers shared the project's website (https://commonfund.nih.gov/healthdisparitiestransformation) and email address (CFHealthDisparities@mail.nih.gov) for more information. Before turning to new questions, Dr. Rivers responded to a previous question from a Council member about pathway programs to encourage biological and biomedical research. He pointed out that at the January 2021 Council meeting he presented a program called STEP-UP (http://stepup.niddk.nih.gov/), which provides research opportunities for juniors and seniors in high school as well as undergraduates.

Comment from Council: *In nephrology and medicine in general, when we consider clinical algorithms and race and research race and ethnicity as they relate to outcomes, there is the potential to conclude we can look at a person and tell their biology, to assume that race and biology are related, when actually gene prevalences are extremely variable and interact with their environment. We need a better understanding of these aspects and the differences between minority health and health disparities.*

Dr. Pérez-Stable agreed with the comment. Race and ethnicity are social constructs that are self-identified but have biological components. There has been a backlash against that, with some saying that adjusting glomerular filtration rate (GFR) by race is racist. Some clinical systems have now abandoned that practice. Studying whether metabolic or biological measures differ by the self-identified construct of race or ethnicity are part of discovery science and the multi-faceted nature of health and health outcomes. He pointed out that racism and differences among various groups also present issues in other countries, even if people there deny that race plays a role in health separate from social class and don't collect racial and ethnic data.

Comment from Council: *What is NIH's experience in sustaining relationships with local communities when grant cycles end? Researchers can spend a lot of time and energy assembling investigators and building community relationships with people outside biomedical research and then those relationships dissolve when you run out of funds. Are there ways to encourage commitments that extend beyond the usual five-year cycle?*

Dr. Rivers agreed this is a concern and an area where NIH and NIDDK are open to innovative solutions and creative ways that universities and other institutions can increase support for community engagement beyond the study cycle.

Comment from Council: *A recommendation to extend grant cycles to 7 years with certain funds tied to the continuation of the community relationship as well as matching funds from the institutions involved. This kind of structure may help communities understand*

that someone beyond the institution is committed to supporting ongoing partnerships rather than letting one partnership go and starting a new one from scratch.

Comment from Council: *A suggestion that applicants should be encouraged to formally identify and involve partners within the institution and community during grant writing of the grant to help develop the project. This would help build commitment and institutional memory and develop a sustainable model.*

Comment from Council: *Could this be an area of opportunity for public-private partnerships in which NIH supports the grant for 5 years, but then industry partners step in to sustain the program? For example, the food industry may be interested in supporting access to healthy foods.*

Comment from Council*: Concerning the debate about GFR and inappropriate metrics and conversions applied generally to diverse populations, can precision medicine give us a better standard for applying medical care?*

Dr. Star said that using GFR as a population metric works only in the populations where the data came from, but not in other populations, which has led to problems. He explained that the Kidney Precision Medicine Project and other DEM and DDN projects are using a precision medicine approach to treat each individual. These projects may lead to answers in the long-term.

Dr. Germino wrapped up this last session in the series of Council Forums on underrepresented investigators and underrepresented science, but assured Council members that the discussion of this topic will continue. These are prominent themes in the NIDDK Strategic Plan currently being developed, and Council will hear from the working group on health equity some time in the next year.

VII. CONCEPT CLEARANCE

Dr. Rodgers then turned to Concept Clearance by Council, a step required before ICs can publish funding opportunity announcements, or FOAs. To streamline this process, summaries of the concepts were supplied to Council members for their review before the meeting.
Concepts for re-competitions or continuations of existing programs were shown as part of a list to save time. Cleared concepts will be made publicly available on the NIDDK website.

Division of Digestive Diseases and Nutrition Concepts
Members of the DDN staff presented three concepts on behalf of the division.

- **Support for the Development of R01 or R01 Equivalent Projects by Investigators from Underrepresented Populations in Biomedical Research:** Dr. Peter Perrin presented a new initiative, the purpose of which is to provide support for the development of innovative research projects led by faculty members from underrepresented populations in biomedical research and facilitate competitive R01or R01 equivalent applications to the NIDDK within the mission of the

Division of Digestive Diseases and Nutrition. Underrepresented populations in the U.S. biomedical, clinical, behavioral research enterprise are described in NOT-OD-20-031, "Notice of NIH's Interest in Diversity." Leveraging opportunities available through Biomedical Research Cores and Enrichment Activities at the Silvio O. Conte Digestive Diseases Research Core Centers or other appropriate Centers is a key aspect of this initiative.

- **Investigator Award to Support Mentoring of Diverse Early Career Researchers:** Dr. David Saslowsky presented this initiative, which notes that effective mentoring is critical for successful career advancement in academic biomedical research, particularly at early career stages where budding investigators begin to formulate their research focus, develop insights, and needed scientific skill sets. Researchers from underrepresented groups (URGs) typically receive less mentoring than non-minority peers (Beech et al. 2013) and augmentation of mentoring programs is needed to help overcome challenges faced by URG students, trainees, and faculty. A need for increased mentoring of early career stage URG researchers to sustain their career pathway(s) has also been highlighted at the NIH special ACD meeting on racial equity (2021), at NIDDK Advisory Council Meetings, in NIDDK Strategic Plan Working Groups, in the NIDDK Office of Minority Health and Research Coordination (OMHRC), and among thought leaders external to NIH. This new initiative would fill a current gap in NIDDK programs by supporting dedicated effort for established investigators conducting research within NIDDK's missions to provide effective mentoring for URG scholars.

- **Discovery Science Research to Improve Understanding of Risk and Causal Mechanisms for Obesity in Early Life:** Dr. Voula Osganian presented this concept, which notes that obesity in children remains a major public health problem, with the most recent prevalence among youth ages to 2-19 years estimated at 20%. Research suggests that high-risk growth trajectories emerge during infancy and early childhood and tend to persist, suggesting this is a critical period in the development and prevention of obesity. The goal of this initiative is to stimulate innovative, discovery research to better understand interindividual variability in risk and underlying causal mechanisms for accelerated weight gain and the development of obesity during infancy and early childhood. This initiative proposes to establish a diverse, prospective cohort of pregnant women early in pregnancy to systematically and intensively study mothers and their offspring. Focusing research efforts to better understand early causal determinants of pediatric obesity may yield targeted, more effective, and durable obesity prevention and treatment interventions.

Next, Dr. Stephen James presented a list of four continuing concepts:

- **Continuation of the Drug Induced Liver Injury Network (DILIN)**
- **Lymphatics in Health and Disease in the Digestive System**
- **Improving Medication Adherence in Children who had a Liver Transplant (iMALT)**
- **Bioinformatics for ChiLDReN genomics**

Dr. Rodgers then took back the floor to preside over Council questions and comments on the DDN concepts.

Council Questions and Comments

Comment from Council: *What magnitude of financial support is proposed for the R01 Development Support project?*

Dr. Perrin noted that R03 grantees could receive $50,000 per year for two years, positing that these awards are structured to give sufficient resources for an early-career researcher to be able to obtain good preliminary data and, if need be, resubmit for funding the following year.

Comment from Council: *Should the research question for the Pediatric Obesity Prevention Discovery concept be more targeted? Is the aim to examine obesity risk in the general population and look at interactions that might lead to increased risk for obesity, or is it to compare the risks between people at lower risk and people at high risk?*

Dr. Osganian assured Council members that all details will be accounted for during the planning and implementation phases if this concept is funded, and that people at both average and high risk for obesity will be included.

Division of Diabetes, Endocrinology and Metabolic Diseases Concepts

Members of the DEM staff presented a total of twelve concepts on behalf of the division, including one group of concepts from the Special Diabetes Program and another group of concepts from the division.

Special Diabetes Program

- **Characterization of Islet-derived Extracellular Vesicles for Improved Detection, Monitoring, Classification, and Treatment of Type 1 Diabetes:** Dr. Olivier Blondel presented a concept for an initiative, which will support the development of tools and experimental platforms for the purification and characterization of Extracellular Vesicles (EV) originating from the human pancreatic islet and its broader tissue environment in healthy individuals, and individuals with type 1 diabetes (T1D) or at-risk of developing the disease. It will also support the exploration of the contribution of pancreatic EV biology to islet function, dysfunction and T1D disease initiation; the development of EV-based diagnostic tools for disease monitoring and classification; and the use of pancreatic EV biology to identify novel therapeutic targets.

- **High-Resolution Exploration of the Human Islet Tissue Environment [HIRN Human**

- **Pancreas Analysis Consortium (HPAC)]:** Dr. Xujing Wang presented an initiative addressing the on-going need to support teams of investigators to propose studies that will contribute to a higher resolution understanding of the organization

of the human pancreatic tissue environment by describing the composition and function of important components of the pancreatic islet and peri-islet tissue architecture, the cell-cell relationships and means of communications used by cell types and cell subtypes within the pancreatic tissue ecosystem, and the contribution of adjacent tissues to islet cell function and dysfunction.

Successful projects will integrate the Human Pancreas Analysis Consortium (HPAC) that is part of the Human Islet Research Network or HIRN. HIRN's overall mission is to support innovative and collaborative translational research to understand how human beta cells are lost in T1D, and to find innovative strategies to protect and replace functional beta cell mass in humans. New studies should have a primary focus on increasing our understanding of human tissue structure and function, and human disease biology, as opposed to exploring the biology specific to any animal models.

- **Pilot and Feasibility Studies to Improve Technology Adoption and Reduce Health Disparities in Type 1 Diabetes Mellitus:** Dr. Miranda Broadney presented this concept, the overarching goal of which is to reduce health disparities in type 1 diabetes mellitus (T1D) through improving technology usage within individuals from minority racial and ethnic backgrounds. Significant disparities exist in both health outcomes and health technology usage within T1D. Health outcomes data indicate that T1D patients from underrepresented backgrounds have worse glycemic control and increased morbidity and acute complications from their diabetes than peers of non-underrepresented backgrounds. Furthermore, data indicate that the rate of technology use (most commonly defined as the use of insulin infusion pump and/or continuous glucose monitoring) is significantly lower within patients of underrepresented backgrounds comparatively. These disparities are likely interconnected and there is a need to develop effective interventions to improve technology adoption in minority populations. This initiative will fund investigator-initiated research proposals aimed at improving technology use in patients with T1D of underrepresented backgrounds. The goals will be to identify, develop, determine feasibility, and pilot efficacy of interventions designed to improve technology adoption, glycemia and patient reported outcomes including quality of life in individuals from underrepresented backgrounds with T1D.

- **Expansion of the National K12 Program for the Career Development of Clinician- Scientists in Diabetes Research (Diabetes-DOCS):** Dr. Lisa Spain discussed a concept for a national career development program for physician scientists, modeled on programs developed at other NIH institutes. The purpose of the Development Of Clinician-Scientists in Diabetes research (Diabetes-DOCS) Program is to support the development of physicians committed to a career in diabetes research. The Diabetes-DOCS program is intended to remedy the dearth of pediatric endocrinologists and physicians from other specialties who conduct outstanding, innovative research into the causes and consequences of diabetes. Diabetes-DOCS will be a single national program, implemented by one or more PD/PIs, together with an advisory committee composed of basic and clinical investigators who have a strong record of funded research and successful training of physician-scientists. Although there will be one national administrative center

awardee, scholars are expected to be appointed and supported at their home institutions around the country. The program will start with a focus on Type 1 Diabetes (T1D) research, with funding from the Statutory Special Diabetes Program. This expansion (based on limited competition review) will fund additional slots to support the career development of physicians whose research focuses on NIDDK emphasis areas in type 2 diabetes and metabolic diseases. The program is expected to deliver on goals to increase the diversity of physician scientists with independent research careers in the mission of NIDDK.

Next, Dr. William Cefalu briefly presented **Support for Small Business Innovation Research (SBIR) to Develop New Methods and Technologies for Assessment of Risk and for Early Diagnosis and Prognosis of Type 1 Diabetes**. As this is a continuation of an existing initiative, he limited his remarks but noted that this initiative's goal is to develop innovative technologies and biomarkers to provide early identification of T1D risk and the onset of autoimmunity.

Division of Diabetes, Endocrinology and Metabolic Diseases

- **DDEMD Stakeholder Engagement Innovation Center:** Dr. Pamela Thornton presented a concept from the DEM Stakeholder Engagement Work Group with the goal to improve health equity and health disparities research within the division. DDEMD has prioritized health equity research. A fundamental approach for tackling health disparities and promoting equity involves meaningful stakeholder engagement with individuals and communities that are 'hardly reached' yet central to research that involves them. Stakeholders may be incorporated across the research process from idea generation, design, execution, and oversight, to dissemination of results. Evidence indicates that stakeholder engagement can result in powerful outcomes such as trust building, enhanced recruitment and retention, and maximizing uptake and sustainability of successful interventions. Although engagement activities with community may require additional research time, the opportunity to promote health equity and reduce disparities outweighs this potential challenge. DDEMD investigators often lack expertise in stakeholder engaged methodologies. To accelerate this important area, strategic investments are required. Thus, this initiative will establish a novel Stakeholder Engagement Innovation Center to provide research resources to educate investigators in stakeholder and community engaged research and develop a community of diverse, multidisciplinary researchers with expertise in critically-needed methods to improve diabetes prevention and treatment interventions in health disparities populations. The proposed initiative is informed by a DDEMD 2020 seminar series and complements current NIDDK strategic planning efforts to achieve health equity.

- **Integration of Medical and Social Care Clinical Trial Interventions:** Dr. Thornton also presented a concept from the Trans-NIDDK Work Group, which notes that. exposure to health-impeding social determinants of health (SDOH) contributes to poor obesity, diabetes, and kidney disease outcomes. Adverse SDOH disproportionately affect economically disadvantaged and minority populations and contribute to the avoidable health inequities that characterize NIDDK disease areas. In the wake of the COVID 19- fueled economic crisis—and co-occurring

sociopolitical events that have driven growing awareness of systemic racism—it is critically important to accelerate strategic efforts to address SDOH and advance the science of health equity. The United States is currently experiencing a transition to value-based payment models that incentivize health settings to treat the "whole person," including SDOH and related social risks. This transition represents an opportunity to effectively address SDOH through novel healthcare delivery models that extend medical care beyond clinic walls into community contexts. However, evidence for how to address social risks via healthcare settings is lacking and current implementation strategies vary across healthcare delivery contexts. The proposed initiative would establish a NIDDK pilot program as the Institute's initial steps to systematically advance the science of medical and social care interventions to address patients' social risks through linkages with community partners. This program is complementary with existing NIDDK efforts in health equity to strategically move toward advancing the field.

- **Integrated Physiology of the Exocrine and Endocrine Compartments in Pancreatic Diseases:** Dr. Norann Zaghloul presented a trans-DK concept aimed at understanding how the exocrine and endocrine compartments of the pancreas may be interacting in the context of diseases relevant to both compartments. Islet dysfunction is a hallmark of both type 1 and type 2 diabetes. Because of this, decades of study have produced an extensive understanding of islet biology, the vast majority focusing on beta-cells specifically or on islets as independent units distinct from the exocrine pancreas in which they are embedded. The two compartments of the pancreas have traditionally been viewed as discrete non-interacting tissues, despite their shared contribution to regulation of postprandial nutrient absorption. This has resulted in a divide in the study of the pancreas between regulation of digestion (exocrine) and hormonal regulation of metabolism (endocrine) with little overlap between the two. Compelling evidence, however, has challenged this separation and supports the possibility of a greater interaction than previously appreciated. These observations suggest that achieving a more complete understanding of the pancreas as a whole will significantly advance understanding of diseases of both compartments. To target this need, this initiative proposes to solicit applications aimed specifically at characterizing interactions between exocrine and endocrine pancreas. The goal of these projects will be to: 1) elucidate the nature of cross- compartment interactions within the pancreas, 2) understand coordinated regulation of exocrine and endocrine tissues/cells, and 3) define mechanisms by which exocrine-derived cells and/or signaling molecules can contribute to islet function and vice versa.

Next, Dr. Cefalu presented a list of four continuing DEM concepts:

- **National Centers for Metabolic Phenotyping in Live Models of Obesity and Diabetes (MPMOD)**
- **Expansion of the National K12 to Include T2D Physician-Scientists**
- **Diabetic Foot Consortium**
- **Trial to Assess Chelation Therapy 2 (TACT2) <u>Council Questions and Comments</u>**

Comment from Council: *Regarding the Characterization of Islet-derived Extracellular Vesicles for Improved Detection, Monitoring, Classification, and Treatment of Type 1 Diabetes program (three questions total):*
Will there be enough islets available to support this ambitious research project?

Dr. Blondel responded that there are many existing platforms that can be used to initiate this research. Investigations should start with an examination of islet extracellular vesicles in general and then move to the differences in the pathological state. A few research groups have already started to work in that space, leading to expectations of some strong projects.

Comment from Council: *Is there a way to know from which cell type the extracellular vesicles will be derived?*

Dr. Blondel responded that there will not be a way to isolate microvesicles or extracellular vesicles from beta cells using a single protein. However, the Division has encouraging data from pilot studies that show that switching to two or three cell surface markers lets the researcher reach cell specificity. For example, one protein may be common to beta cell and kidney and heart cells. But by adding another for sorting that is not found in kidney or heart with just two proteins, the researcher can achieve a highly purified beta cell fraction.

Comment from Council: *Will this be a cooperative U mechanism, or is it a mechanism by which individual investigators would apply to access samples?*

Dr. Blondel responded that this program will award R01 grants.

Comment from Council: *Regarding Pilot and Feasibility Studies to Improve Technology Adoption and Reduce Health Disparities in Type 1 Diabetes Mellitus*:
Is the increase in incidence of T1D overall and across different racial ethnic groups thought to be a change in gene environment that's occurring differentially, or might we in fact be missing an intermediate form or variant of diabetes that has arisen due to changes in societal conditions?

Dr. Cefalu responded that there is no indication that the genes have changed. He noted that not everyone who is genetically at risk develops T1D. The Division has taken a great interest in other subtypes of diabetes, particularly since the endotypes differ in presentation in both type 1 and type 2 disease, he said. Additionally, Dr. Spain noted that scientists have recorded increases in most other autoimmune diseases.

Comment from Council: *We are seeing more cases of T1D being diagnosed in children who are overweight. This is not the classic pattern. Could something different be driving this change?*

Dr. Rodgers believe that is a correct observation. As incidence of overweight and obesity increases in the population at large, insulin resistance may play a part in what would be considered classical T1D.

Comment from Council: *Regarding the National Centers for Metabolic Phenotyping in Live Models of Obesity and Diabetes (MPMOD)*: *How will this next phase centers be structured? Will these be funded as supplements to existing centers, or will there be open competition for more smaller, discrete phenotyping?*

Dr. Cefalu responded that the centers will continue and may consolidate over time, focusing more on live models. The unique aspect of this concept is a coordinating center to help ensure that URM scientists get support and resources. DEM will institute metrics and milestones to ensure equity. **Division of Kidney, Urologic, and Hematologic Diseases Concepts**

- **Interventions to Address Structural Racism and Improve Outcomes in Kidney Disease Patients:** Dr. Paul Kimmel presented this initiative, which examined how marginalized racial and ethnic groups who have been subject to structural racism experience disparate health outcomes relative to more privileged groups. Structural racism affects access to and quality of care, as well as access to social determinants of health, contributing to poor kidney health outcomes. Chronic stress and associated elevation in allostatic load induced by perceived discrimination and navigation of adverse social determinants of health are also associated with adverse health outcomes. Relatively few interventions have been tested to address the effects of racism in the lives of chronic kidney disease (CKD) and end stage renal disease (ESRD) patients. This initiative will invite applications that will develop and implement interventions targeting aspects of structural racism and/or perceived discrimination, to improve outcomes of patients with CKD or ESRD. Successful applicants will include a multidisciplinary and diverse principal investigator team and will involve community representatives in all aspects of the study. A Coordinating Center will provide statistical, methodological, and clinical trials support and will convene awardees annually to share progress and ideas. This initiative will provide a long overdue opportunity to address important and under-addressed contributors to racial and ethnic disparities in CKD and ESRD and will help develop an emerging research area in kidney disease.

Next, Dr. Star presented the KUH renewals:

- **Chronic Kidney Disease in Children Study (CKiD) limited re-competition**
- **Pragmatic Trial of Higher vs. Lower Serum Phosphate Targets in Patients Undergoing**
- **Hemodialysis (HiLo) limited re-competition**
- **Chronic Renal Insufficiency Cohort (CRIC) Study limited re-competition**
- **Stimulating Urology Interdisciplinary Team Opportunity Research (SUITOR) expansion**
- **Predoctoral to Postdoctoral Fellow Transition Award (F99/K00) continuation**
- **Multidisciplinary Urologic Research (KURe) Career Development Program (K12 Clinical Trial optional) continuation**

Dr. Star also presented three trans-NIDDK concepts currently up for renewal:

- **CareerTrac Tracking System**
- **High-Impact, Interdisciplinary Science in NIDDK Research Areas (RC2 Clinical Trial Optional)**
- **Early-Stage Preclinical Validation of Therapeutic Leads for Diseases of Interest to the NIDDK (R01 Clinical Trial Not Allowed)**

Council Questions and Comments

Comment from Council: *Could this initiative be a model for other studies for other diseases? Do you know if a similar initiative is being planned elsewhere in NIDDK or other Institutes and Centers?*

Dr. Kimmel explained that this initiative is similar to the Common Fund initiative and may also be similar to initiatives being put forth by NIMHD. KUH wanted to focus on interventions, rather than disease pathways, and hopes that this could become a model for other institutes to follow.

Comment from Council: *Could the F99/K00 program be a trans-NIDDK initiative?*

Dr. Robert Star answered that, yes, this program could become a trans-NIDDK initiative once various challenges are met. For example, part of the program's attractiveness rests on bringing in researchers like engineers and bioethicists who have never worked on kidney disease before. That is challenging to organize and publicize so that KUH receives the desired type and caliber of proposals. Dr. Rodgers added that NIDDK often prefers to treat promising trans-NIDDK initiatives as a pilot project within the Division, then expand as success warrants it.

Comment from Council: *Will basic scientists in this program know where to reach out for preclinical support and advice on what they should do next?*

Dr. Star pointed out that this issue applies to all NIDDK research, not just a specific program. All NIDDK researchers should know and feel comfortable reaching out to their assigned program officer at any time, whether the project is going well or not, he said.

Comment from Council: *Has NIDDK considered making T99/K00 transition grants so people on T32s move on to K Awards?*

Dr. Star responded that a review of KUH and NIDDK data shows that very few investigators to date have progressed from T to F to K to R funding, unfortunately. He shared that KUH is currently formulating a replacement for the T32 program that should do a better job of providing career development and mentoring support. Details were to be shared in closed session on the following day.

Office of Minority Health Research Coordination Concepts

Evaluation of the NIH/National Medical Association (NMA) Travel Award Program and the Network of Minority Health Research Investigators (NMRI): Dr. Katrina Serrano presented a review of the NIH/National Medical Association (NMA) Travel Award Program and the Network of Minority Health Research Investigators (NMRI), two

longstanding programs within the NIDDK Office of Minority Health Research Coordination (OMHRC) that are designed to build capacity and promote outreach. Both programs are intended to diversify the scientific workforce and aim to support investigators who are underrepresented in biomedical research. Although preliminary data suggest program success, a comprehensive independent evaluation of both programs has not been conducted. This proposed contract aims to better understand the components that allow for success of the programs, as well as identify areas for improvement. Lessons learned from this evaluation can be leveraged to the NIH community as a "how-to" model for developing and sustaining programs that train and promote a steady and diverse pool of talented investigators.

Next, Dr. Serrano presented one OMHRC concept for renewal:

- **Promoting Organ and Tissue Donation Among Diverse Populations**

Dr. Rodgers acknowledged that Council members had no questions or comments about the OMHRC concepts.

VIII. ADJOURNMENT DAY ONE
Dr. Rodgers

The first day of the 216th meeting of the NIDDK Advisory Council was adjourned at 3:08 p.m. on May 12, 2021.

IX. OPEN SESSION OF SUBCOMMITTEE MEETINGS
See Minutes posted on NIDDK Council Minutes Website.

X. CLOSED SESSION OF THE SUBCOMMITTEE MEETINGS
A portion of the meeting was closed to the public in accordance with the determination that it concerned matters exempt from mandatory disclosures under Sections 552b(c)(4) and

552b(c)(6), Title 5, U.S.C. and Section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C. Appendix 2).

Members absented themselves from the meeting during discussion of and voting on applications from their own institutions, or other applications in which there was a potential conflict of interest, real or apparent. Members were asked to sign a statement to this effect.

XI. CLOSED SESSION OF THE FULL COUNCIL

This portion of the meeting was closed to the public, in accordance with the determination that it concerned matters exempt from mandatory disclosure under Sections 552(b)(c)(4) and 552(b)(c)(6), Title 5, U.S. Code and Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix).

CONSIDERATION OF REVIEW OF GRANT APPLICATIONS. A total of 1540 grant

applications (637 primary and 903 dual), requesting support of $628,464,707 were reviewed for consideration at the May 12-13, 2021, meeting. An additional 1254 Common Fund applications requesting $2,075,026,551 were presented to Council. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, 1113 applications requesting $398,445,265 received second- level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 12-13, 2021, meeting.

XII. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the Council members, presenters, and other participants. He thanked the Council members for their valuable input. There being no other business, the 216th meeting of the NIDDK Advisory Council was adjourned at 1:45 p.m. on May 13, 2021.

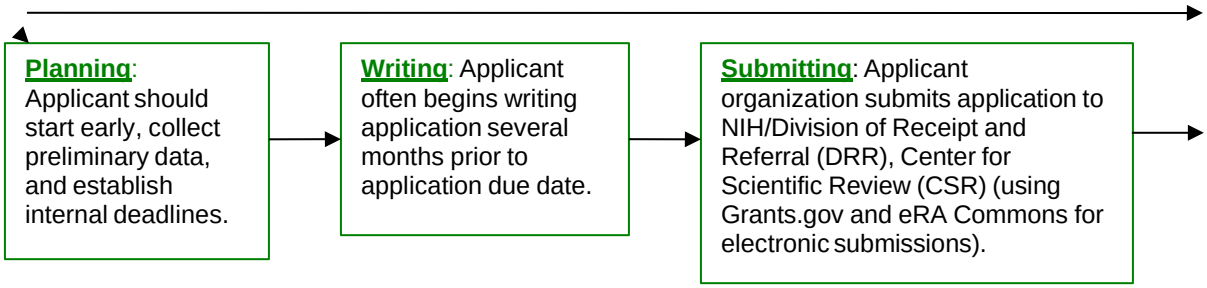
I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Grants Process At-A-Glance

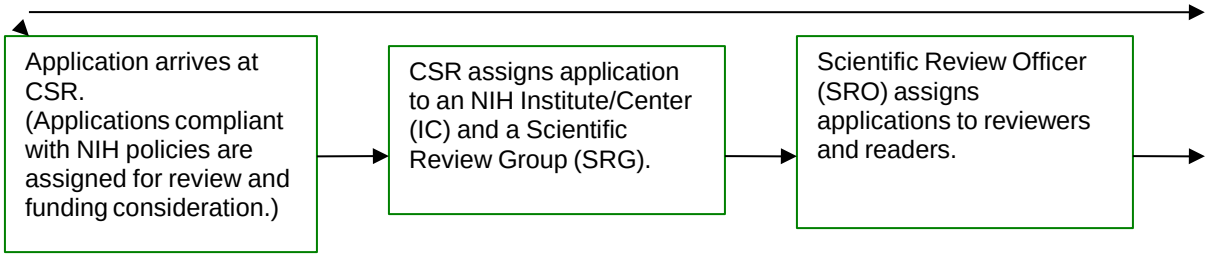
The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

Planning, Writing, Submitting



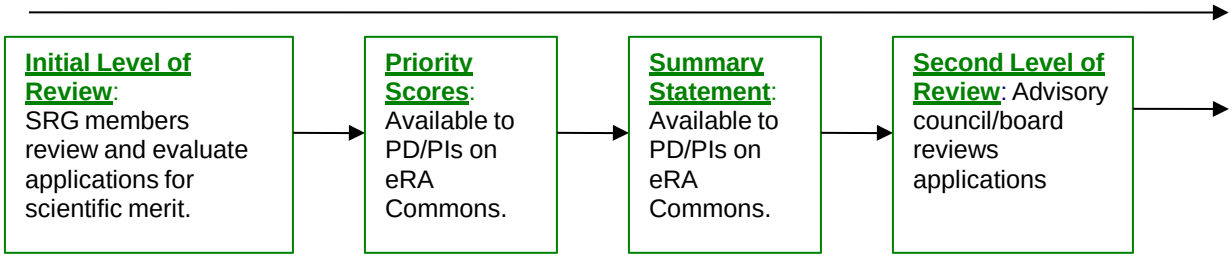
Receipt and Referral

Months 1 to 3



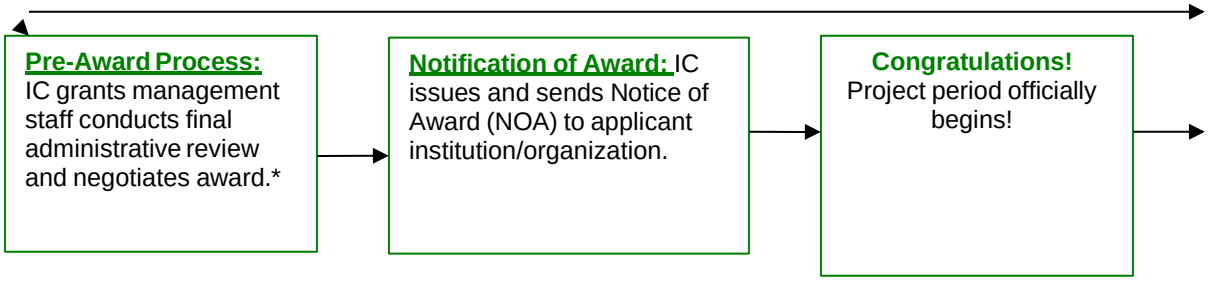
Peer Review

Months 4 to 8



Award (*Requests additional information needed just-in-time for award.)

Months 9 to 10

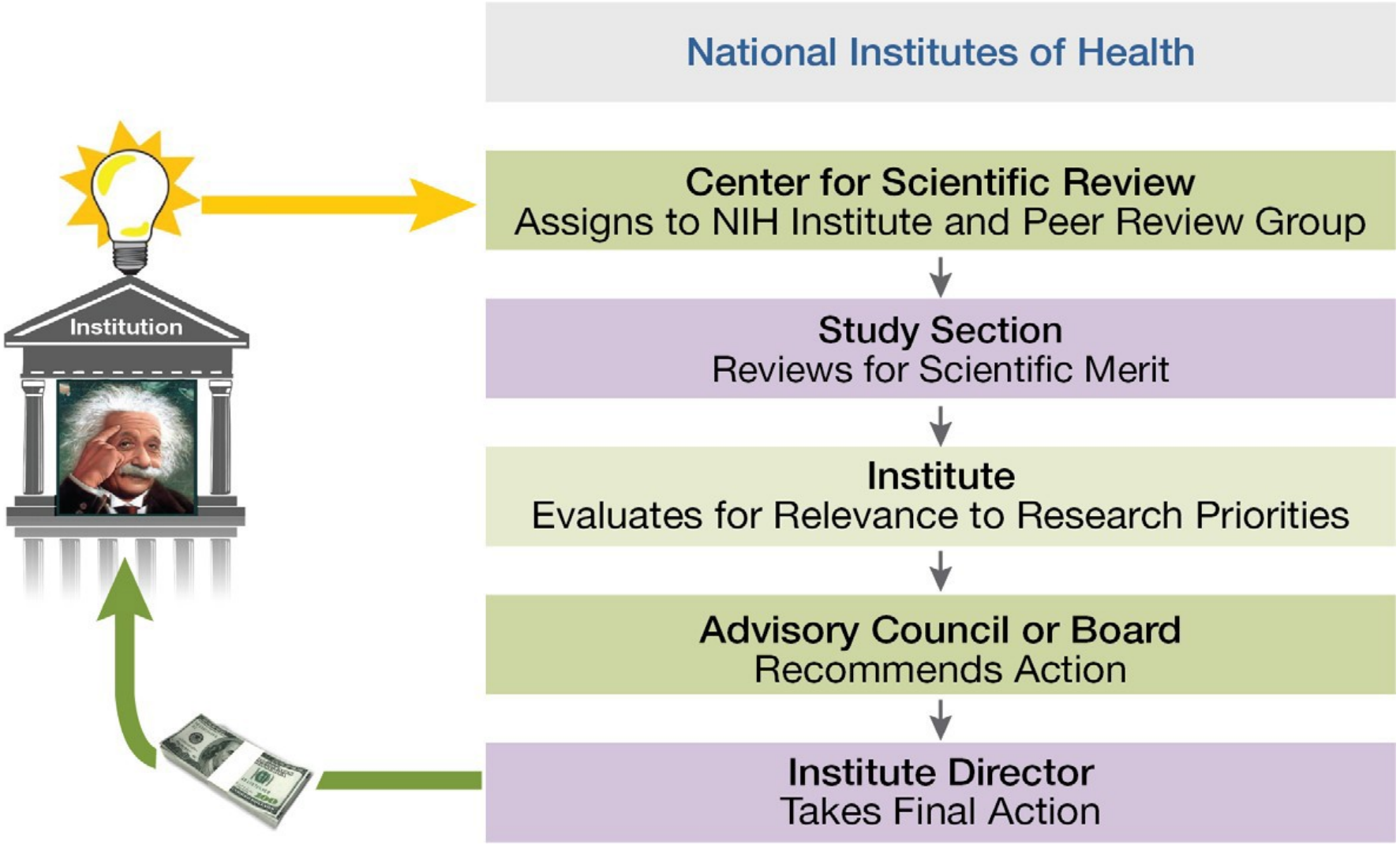


Post-Award Management

Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Peer Review and Funding of NIH Grant Applications



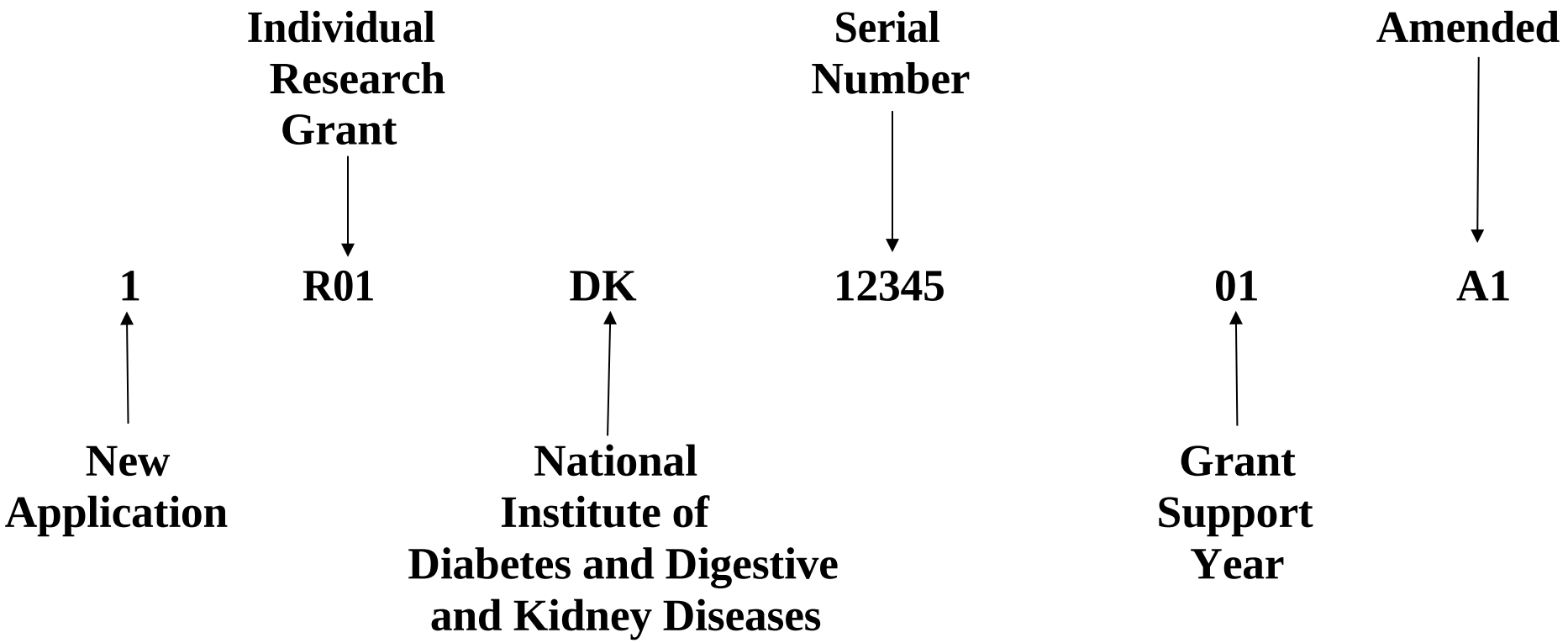
NIH Grant Receipt, Review, and Award Schedule

Jan-May **May-Sept** **Sept-Jan**	**Receipt Dates**
June-July **Oct-Nov** **Feb-Mar**	**Review Dates**
Sept-Oct **Jan-Feb** **May-June**	**National Advisory Council/Board Dates**
Dec1 **Apr 1** **July 1**	**Earliest Possible Beginning Date**

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number

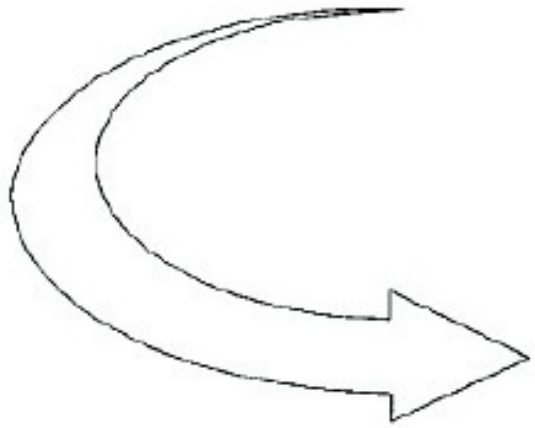


Dual Review System for Grant Applications

First Level of Review

Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award



Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications (*See Advisory Council Voting Options)*
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy

Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Initial Review Process

Overview

NIH policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.

First Level of Review

Initial peer review meetings are administered by either the Center for Scientific Review (CSR) or another NIH IC. The focus of review is specified in the Funding Opportunity Announcement. Peer review meetings are announced in the Federal Register. The meetings are closed to the public, although some meetings may have an open session; the Federal Register provides the details of each meeting.

A. Peer Review Roles and Meeting Overview

Scientific Review Officer:

Each SRG is led by a Scientific Review Officer (SRO), formerly Scientific Review Administrator (SRA)]. The SRO is an extramural staff scientist and the Designated Federal Official responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed.

SROs:

- Analyze the content of each application, and check for completeness.
- Document and manage conflicts of interest. See NOT-OD-11-120 issued on September 26, 2011, and briefly described at end of this chapter.
- Recruit qualified reviewers based on scientific and technical qualifications and other considerations, including:
    - Authority in their scientific field (42 CFR 52h.4)
    - Dedication to high quality, fair, and objective reviews
    - Ability to work collegially in a group setting
    - Experience in research grant review
    - Balanced representation
- Assign applications to reviewers for critique preparation and assignment of individual criterion scores.
- Attend and oversee administrative and regulatory aspects of peer review meetings.
- Prepare summary statements for all applications reviewed.

SRG Members

Chair:

- Serves as moderator of the discussion of scientific and technical merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest (COI) with specific applications following NIH guidance. (See COI section below.)
- Receive access to the grant applications approximately six weeks prior to the peer review meeting.
- Prepare a written critique (using Review Critique Fill-able Templates) for each application assigned per the SRO, based on review criteria and judgment of merit.
- Assign a numerical score to each review criterion
- Make recommendations concerning the scientific and technical merit of applications under review, in the form of final written comments and numerical scores.
- Make recommendations concerning protections for human subjects; inclusion of women, minorities, and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application. See Review Guidelines for:
  - Protections for Human Subjects
  - Inclusion on the Basis of Sex/Gender, Race, Ethnicity, and Age in Clinical Research
  - Applications Proposing Use of Human Embryonic Stem Cells
  - Vertebrate Animals
- Make recommendations concerning appropriateness of budget requests (see Budget Information for Reviewers).

Other NIH Staff:

- Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the SRO's discretion.

Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see below).
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact/priority scores is conducted by private ballot.

B. Peer Review Criteria and Considerations

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Review Criteria for Research Grants and Cooperative Agreements

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasib3ility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subject? If the project involves human subjects and/or NIH-defined clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sexes/gender, race, and ethnicity, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items.

Protections for Human Subjects
Inclusion of Women, Minorities, and Children
Vertebrate Animals
Biohazards

Resubmission
Renewal
Revision

Additional Review Considerations. As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

Applications from Foreign Organizations
Select Agent Research
Resource Sharing Plans
Authentication of Key Biological and/or Chemical Resources
Budget and Period of Support

C. Scoring

The scoring system described below was implemented for applications submitted for funding consideration for FY2010 and thereafter (NOT-OD-09-024)

Before the SRG meeting, each reviewer and discussant assigned to an application will give a separate score for each of five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment for research grants and cooperative agreements; see above). For all applications, even those not discussed by the full committee, the individual scores of the assigned reviewers and discussant(s) for these criteria are reported to the applicant.

In addition, each reviewer and discussant assigned to an application gives a preliminary overall impact/priority score for that application. The preliminary scores are used to determine which applications will be discussed in full. For each application that is discussed at the meeting, a final impact/priority score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers. Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact). Numerical impact/priority scores are not reported for applications that are not discussed (ND), which may be reported as *.* on the face page of the summary statement and typically rank in the bottom half of the applications.

Applicants should contact the Program Officer for the application to seek additional feedback on the score and summary statement.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

The following guidance has been given to reviewers to determine individual review criterion and overall impact/priority scores:

High Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
Medium Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact Table		
Score	*Descriptor*	*Additional Guidance on Strengths/Weaknesses*
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact
Moderate Weakness: A weakness that lessens impact
Major Weakness: A weakness that severely limits impact

D. Summary Statement

Applications that are not discussed at the meeting will be given the designation “ND” as an overall impact/priority score, but the applicant, as well as NIH staff, will see the scores from the assigned reviewers and discussants for each of the review criteria as additional feedback on their summary statement.

Understanding the Percentile

- A percentile is the approximate percentage of applications that received a better overall impact/priority score from the study section during the past year.
- All percentiles are reported as whole numbers
- Only a subset of all applications receive percentiles. Which types of applications are percentiled varies across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

E. Appeals

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system (see NIH Guide Notice NOT-OD-11-064) to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was flawed as outlined below. The appeals policy applies to appeal letters received with respect to the initial peer review of all competing applications submitted to the NIH for support for the January 25, 2011 due date and thereafter, including: 1) reviews conducted by the NIH Center for Scientific Review (CSR) and reviews conducted by the NIH Institutes and other NIH Centers; and 2) applications such as fellowship application that typically do not require Council review. This policy does not apply to appeals of the technical evaluation of R&D contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT award.

An appeal is a written communication from a Project Director/Principal Investigator (PD/PI) and/or official of the applicant institution [not necessarily the Authorized Organization Representative (AOR)] that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence of the AOR. An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers
- Conflict of interest, as specified in regulation at 42 CFR 52h "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-federal peer reviewers
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, but the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose. The Council may concur:

- with the appeal and recommend that the application be re-reviewed.
- with the SRG's recommendation and deny the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

Information from http://grants.nih.gov/grants/peer_review_process.htm.

F. Revised Conflict of Interest Policy for Initial Review

The NIH initial peer review process involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to the National Institutes of Health (NIH). The process, defined in regulation at 42 CFR Part 52h, is extended by policy to other types of applications submitted to the agency.

On September 26, 2011, the NIH issued a revised policy on managing conflict of interest (COI) in the initial peer review of NIH grant and cooperative agreement applications: see NOT-OD-11-120. This announcement provides revised policy for managing COI, the appearance of COI, prejudice, bias, or predisposition in the NIH initial peer review process.

The announcement addresses multi-disciplinary and collaborative research and clarifies the role of non-Federal and Federal employees serving as reviewers. Unlike members of NIH Advisory Councils or Boards, reviewers in the initial level of NIH peer review are not appointed as Special Government Employees and do not submit financial disclosure forms. Therefore, SROs are not in a position to collect financial information from reviewers but can ask about professional relationships and roles as defined in the revised NIH policy and make determinations about potential bias in the initial peer review process.

The overall goal of the revised policy is to increase transparency and to inform the scientific community. With the dramatic increase in internet capability, reviewers may be looking up financial information about investigators on the websites of the investigators' institutions. Although this COI information is available publicly, SROs should instruct reviewers not to consider COI information about applicants in their reviews, discussions, or evaluations.

Similarly, applicants may be looking up financial information about reviewers on their institutions' websites and submitting appeals of initial peer review on the basis of that information. Therefore, it is important that SROs clearly explain the conflict rules for initial peer review to their reviewers.

Modified Application Submission, Referral and Review for Appointed NIH Advisory Group Members

To recognize their outstanding commitment to service to the NIH, regular members of NIH Boards of Scientific Counselors, NIH Advisory Boards or Councils, and the NIH Peer Review Advisory Committee are extended the option of modified application submission, referral and CSR review.

This alternate process is limited to R01, R21, and R34 applications that would normally be received on standard submission dates (but not special receipt dates) and will be reviewed at CSR. Depending on the timing of the submission and the number of other similar applications received during the pre-meeting time window, NIH staff will decide if the application will be reviewed in a standing Study Section or in a Special Emphasis Panel (SEP). These applications will be processed and assigned to NIH Institute Review Offices or CSR Integrated Review Groups (IRGs) using the standard referral guidelines (https://public.csr.nih.gov/StudySections).

This continuous submission process will enable appointed members of chartered NIH advisory groups to submit their applications as soon as they are fully developed. The applications will be reviewed no later than 120 days after receipt. Because of the need to assign an Advisory Council date, the following schedule will be followed. However, applications may be moved to earlier councils following review as timing permits

Standard Review and Award Cycles

	Cycle I	Cycle II	Cycle III
Application Due Dates	January 25 - May 7	May 25 - September 7	September 25 - January 7
Scientific Merit Review	June - July	October - November	February - March
Advisory Council Round	August or October *	January	May
Earliest Project Start Date	September or December *	April	July

Standard and Continuous Submission Due Dates

Excerpt from NOT-OD-20-060. See full notice for applicability and eligibility details.

For the Advisory Council Round:	Non-AIDS Standard Application Due Dates		Continuous Submission Non-AIDS Application Receipt Period Ends
	R01	*R21, R34*	*R01, R21, R34*
May	October 5 November 5	October 16 November 16	December 10
October	February 5 March 5	February 16 March 16	April 10
January	June 5 July 5	June 16 July 16	August 10

For the Advisory Council Round:	AIDS Application Due Dates	Continuous Submission AIDS Application Receipt Period Ends
	R01, R21, R34	*R01, R21, R34*
May	January 7	February 1
October	May 7	June 1
January	September 7	October 1

Further Information and Inquiries

How to check your Continuous Submission eligibility

- Instructions on how to check your Continuous Submission eligibility through your Commons account.

Frequently Asked Questions regarding Continuous Submission
(see https://grants.nih.gov/faqs#/continuous-submission.htm)

Updated Continuous Submission policy Notice
(see: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-060.html).

Any remaining issues/appeals may be directed to a NIH Continuous Submission Committee by emailing CSR.cont.sub.comm@csr.nih.gov.

Second-Level Review Procedures

The Advisory Council/Board of the potential awarding Institute or Center (IC) performs the second level of review. Advisory Councils/Boards are composed of scientists from the extramural research community and public representatives (NIH Federal Advisory Committee Information). Members are chosen by the respective IC and are approved by the Department of Health and Human Services. For certain committees, members are appointed by the President of the United States.

On June 18, 2010, President Obama issued "Lobbyists on Agency Boards and Commissions," a memorandum directing agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. On October 5, 2011, the Office of Management and Budget (OMB) issued final guidance to Executive Departments and agencies concerning the appointment of federally registered lobbyists to boards and commissions. This guidance applies not only to advisory committees subject to FACA, but to all other groups as well-even to members of working groups not appointed as SGEs. See *Federal Register* / Vol. 76, No. 193 / Wednesday, October 5, 2011/Notices under OFFICE OF MANAGEMENT AND BUDGET, Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions, AGENCY: Office of Management and Budget. ACTION: Notice of Final Guidance.

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications or applications requiring Special Council Review (SCR) where the principal investigator has more than $1 M in NIH direct cost support.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Applications Requiring Individual Consideration

- Applications from Foreign Institutions

  In reviewing and making recommendations on foreign grant applications, the Council members should be aware that ALL of the following criteria must be met in order to be supported by the NIH:

  a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
  b. The project has specific relevance to the mission and objectives of NIDDK and has the potential for significantly advancing the health sciences in the United States.
  c. The application must be approved for funding by the Council.
  d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.

- Applications With Concerns about Human or Animal Subjects and/or Gender and Minority Representation

The Council will be asked to comment on any application(s) recommended for possible funding with unresolved concerns regarding the involvement of human subjects, the use of animals, and/or gender and minority representation. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern(s).

- Applications That May Not Provide for Appropriate Biosafety, Biocontainment, and Security of Select Agents

  The Council will be asked to comment on any applications recommended for possible funding with unresolved concerns regarding biosafety, biocontainment, and security of select agents. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern.

- Letters of Appeal

  The Council reviews appeal letters that were submitted by investigators subsequent to the peer review of their application and were not resolved by program and review staff. It is the responsibility of NIDDK staff to determine whether a letter is an appeal.

  An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered an appeal. Procedural issues fall under four categories and the applicant must claim one or more of the following:

  a. The initial review was biased.
  b. A conflict of interest existed.
  c. The review group lacked appropriate scientific expertise.
  d. Factual errors entered into the review.

  Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

  The Council has two options when reviewing an appeal letter:

  a. To concur with the outcome of the initial peer review as reflected in the summary statement.
  b. To concur with the claims discussed in the applicant's appeal letter and recommend deferral for re-review either by the same or a different review group.

  Other letters, termed Council communications, may also be made available to the Council at the discretion of NIDDK staff.

Special Council Review of Research Applications from Program Directors/Principal Investigators (PDs/PIs) with more than $1.0 Million Direct Costs in NIH Support

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html. Pending grants going to Council from PDs/PIs who have more than $1 million in direct costs from active NIH Research Project Grants (RPGs) grants will be subjected to additional consideration. It is important to recognize that this is

a threshold only; investigators who have more research support may still receive additional awards as warranted. When making funding recommendations, staff will take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award impacts other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

- Criteria Considered by NIDDK Staff for Determining Applications Subject to SCR

    a. P01s and other Multi-Component RPGs: Only funds acquired[1] through RPGs[2] should be included when calculating a given PD/PI's support.
    b. Only competing RPGs (New and Renewals) to be considered for award to investigators with $1.0M or more of direct cost NIH support are subject to SCR via this policy.
    c. P01s and other Multi-Component RPGs:
        i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have $1.0M or more of NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
        ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the $1.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.

- Multiple PD/PI Projects:
    a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the $1.0M threshold.
    b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.

- Requests for Applications (RFAs):
    a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the IC to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
    b. Funds provided through these grants will contribute to the $1.0M threshold for the investigators' future applications.

- Competing revisions and administrative supplements:
    a. These types of grants are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the $1.0M threshold. In order

[1] Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Yr: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)

[2] Defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

to prevent Re-entry and Diversity Supplements from being an impediment to an investigator, to the extent possible, these supplements should be excluded from the threshold count.

- Guidelines for Council Consideration (Council role):

  a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
  b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
  c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the $1.0M direct cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

NIDDK Implementation of the Special Council Review Policy

Each Council round, the NIDDK Council members will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under the NIH policy as outlined above. During the closed session, for each application on the list that might actually be funded, NIDDK staff will provide information about the other NIH funding for the PI that brings his/her direct cost total to the $1 million threshold and a justification for possibly funding the application under consideration. Council members will review these cases and decide whether they have concerns.

Recommendation Process

- NIDDK program staff members examine applications, their overall impact/priority scores, percentile rankings, and their summary statements and consider these against NIDDK's needs.
- The Advisory Council also considers NIDDK's goals and needs and advises the NIDDK Director.
- The NIDDK director makes the final funding decisions based on staff and Advisory Council advice.

Post-Review

- **Not Funded – What Next?**
  The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available for limited circumstances to help applicants prepare a possible resubmission. Applications in response to a specific initiative with set-aside money typically cannot be resubmitted, but the Program Official should be consulted about next steps.

- **Fundable Score – What Next?**
  If an application results in an award, the applicant will be working closely with the NIDDK Program Official on scientific and programmatic matters and a Grants Management Officer on budgetary or administrative issues.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SROs now assign inclusion codes informed by the reviewer critiques and discussion at the review meeting to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections (OHRP) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL: https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. A subset of research involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation for the purpose of investigating the efficacy of the biomedical or behavioral intervention in large groups of human subjects (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions as well as to monitor adverse effects, and to collect information that will allow the intervention to be used safely.

A ***valid analysis*** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 18 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws

define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children ***DOES*** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- ***Risks to the subjects***
- ***Adequacy of protection against risks***
- ***Potential benefit of the proposed research to the subjects and others***
- ***Importance of the Knowledge to be gained***
- ***Data and Safety Monitoring Plan/Board***

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects

It is NIH policy that individuals of all ages, including children (i.e., individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-116.html). The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

Applications or proposals for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the recipient/offeror must provide an acceptable justification for the exclusion. Acceptable reasons for excluding individuals based on age may include:

- The disease or condition does not occur in the excluded age group, or the research topic is not relevant to the excluded age group.
    - *Example: A study of Alzheimer's disease proposes to exclude children.*

- The knowledge being sought in the research is already available for the excluded age group or will be obtained from another ongoing study, and an additional study will be redundant.
    - *Example: A drug studied and approved for use in children will now be studied only in adults.*

- A separate, age-specific study in the excluded age group is warranted and preferable. While this situation may represent a justification for excluding individuals based on age, consideration should be given to taking age differences into account in the study design, whenever feasible.
    - *Example: A clinical trial designed to promote self-monitoring of blood glucose levels in adolescents with Type 1 diabetes proposes to include only adolescents.*

- The study will collect or analyze data on pre-enrolled study participants (e.g., longitudinal follow-up studies that did not include data on children, or analysis of an existing dataset) and data inclusive of individuals across the lifespan are not available to address the scientific question.
    - *Example: A study which began prior to implementation of the NIH Policy and Guidelines on the Inclusion of Children proposes follow-up to examine long-term outcomes of individuals with the condition. The original study excluded children, and similar data are not available from a cohort that includes children.*

- There are laws or regulations barring the inclusion of individuals in a specific age group in research.
    - *Example: Regulations for protection of human subjects allow consenting adults to accept a higher level of risk than are permitted for children.*

- The study poses an unacceptable risk to the excluded group, such that their participation would not be considered ethical by the local IRB, peer review and/or NIH staff.

- *Example: Children are excluded from a Phase I study for a treatment that includes significant risk, including death. Evidence suggests the potential benefits to children do not outweigh the risks.*

Scientific review groups at the NIH will assess each application/proposal as being "acceptable" or "unacceptable" with regard to the age-appropriate inclusion or exclusion of individuals in the research project, in addition to evaluating the plans for conducting the research in accord with these provisions. NIH staff will monitor implementation of this policy during the development, review, award and conduct of research; and manage the NIH research portfolio to comply with the policy.

Age Data Collection

NIH recipients/offerors must submit data on participant age at enrollment in progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided to NIH in progress reports. Age at enrollment may be reported to NIH in units ranging from hours to years. Recipients/offerors are responsible for ensuring informed consent documents allow submission of de-identified individual-level data on participant sex/gender, race, ethnicity, and age at enrollment to NIH.

Use of Human Embryonic Stem Cells In NIH-Supported Research

The National Institutes of Health (NIH) has published final "National Institutes of Health Guidelines for Human Stem Cell Research" (Guidelines).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells.* The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research.

EFFECTIVE DATE: These Guidelines are effective on July 7, 2009.

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On April 23, 2009 the NIH published draft Guidelines for research involving hESCs in the Federal Register for public comment, 74 Fed. Reg. 18578 (April 23, 2009). The comment period ended on May 26, 2009.

The NIH received approximately 49,000 comments from patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, and private citizens. The NIH also received comments from members of Congress. Read the NIH response to the public comments that addressed provisions of the Guidelines at https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research.

NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR RESEARCH USING HUMAN STEM CELLS

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent stem cells (See Section IV). The Guidelines implement Executive Order 13505.

Long-standing HHS regulations for Protection of Human Subjects, 45 C.F.R. 46, Subpart A establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. *When research* involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A.

It is also important to note that the HHS regulation, *Protection of Human Subjects*, 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidance at http://www.hhs.gov/ohrp/policy/index.html#topics

To ensure that the greatest number of responsibly derived hESCs are eligible for research using NIH funding, these Guidelines are divided into several sections, which apply specifically to embryos donated in the U.S. and foreign countries, both before and on or after the effective date of these Guidelines. Section II (A) and (B) describe the conditions and review processes for determining hESC eligibility for NIH funds. Further information on these review processes may be found at www.NIH.gov. Sections IV and V describe research that is not eligible for NIH funding.

These guidelines are based on the following principles:

1. Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
2. Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

II. Eligibility of Human Embryonic Stem Cells for Research with NIH Funding

For the purpose of these Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing

without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. All of the processes and procedures for review of the eligibility of hESCs will be centralized at the NIH according to the guidelines available at Guidelines.

Use of NIH Funds

Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.

III. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

IV. Other Research Not Eligible for NIH Funding

A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

   See also: NIH research Involving Introduction of Human Pluripotent Cells in to Non-Human Vertebrate Animal Pre-Gastrulation Embryos: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-158.html

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;
- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the “Description” in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement.

In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant’s compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return or destroy the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition or destroyed.

There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.

As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not receive copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

Emoluments Clause of the U.S. Constitution

The Emoluments Clause of the United States Constitution applies to all U.S. Government employees, including most Special Government Employees (SGE's). The Clause places Constitutional limitations on a SGE advisory committee member's employment by a foreign government, including political subdivisions of a foreign government. This provision has particular relevance to positions with foreign universities that are government-operated rather than private institutions. United States Constitution, art. I 9, cl. 8.

The Emoluments Clause **applies at all times during an SGE's appointment**, and not just the periods of time during their actual duty on behalf of NIH. During an SGE's advisory committee appointment, they cannot be an employee of a foreign government entity. Without the consent of Congress, they cannot receive any present, emolument, office, or title of any kind whatsoever from a foreign state. They cannot accept concurrent outside employment with a foreign government or a political subdivision of a foreign government, including a public university or commercial enterprise* owned or operated by a foreign government. The constitutional ban does not apply to employment with, or presents or emoluments received from, a foreign privately owned corporation or an international organization. An emolument includes salary, honoraria, transportation, per diem allowances, household goods shipment costs, and housing allowances.

Under the Foreign Gifts and Decorations Act, 5 U.S.C. 7342, Congress has authorized employees, including advisory committee members, to accept items from a foreign government that do not exceed minimal value (currently $350). The Act authorizes acceptance of items over minimal value

when such items consist of an educational scholarship, medical treatment, or expenses for travel taking place entirely outside the United States, thus permitting hotel and meal reimbursements in the foreign country, but not airfare for flights originating or terminating in the United States. The statutory restriction on gifts over minimal value extends to the spouse and dependents of the employee.

The restrictions of the Emoluments Clause are constitutional and are not matters of policy that can be waived or reconsidered. Questions regarding possible conflicts relating to the Emoluments Clause may be referred to the Deputy Ethics Counselor for the institute the SGE committee member advises, or to the Committee's Executive Secretary.

* A list of foreign entities that are considered independent of their foreign government may be found at: https://ethics.od.nih.gov/foreign

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	**PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)**
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records	Applies to all Federal agencies, including executive and military departments and independent regulatory agencies. Pertains to: • any system of records from which information is retrieved by an individual's name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the "operation by or on behalf of the agency to accomplish an agency function."
REQUIREMENTS	Requires Federal agencies to: • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice.	Requires Federal agencies to: • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual's rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records.
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Procedures for NIDDK Advisory Council Members 2022

When you travel to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meeting, **you are considered a Government employee** of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and therefore traveling on official Government business. Your expenses are reimbursed according to Federal travel regulations.

In order for you to be reimbursed in a timely manner and to ensure that you will be reimbursed for your travel expenses, please be sure to read the information below.

Note: If you will **not be attending** the meeting, please call or email Dr. Karl Malik at (301) 594-8843 or malikk@niddk.nih.gov to inform him of your absence.

Overview of Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are as follows:
Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is $0.56 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently $79.00 per day for the Washington, D.C., metropolitan area. You will receive ¾ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. You will receive a $200.00 honorarium for each day or fraction of a day that you attend the Advisory Council meeting. For virtual-only Council meetings, you will still receive a $200.00 honorarium for each day or fraction of a day that you attend the Council meeting. These checks are processed separately using Electronic Funds Transfer.

Travel Instructions

Per Federal travel regulations, all Government employees are required to use their agency's travel management center. Therefore, **you are required to book your air or train fare through Omega World Travel (OWT) and you must book coach class.** Please mention you are attending the "NIDDK Advisory Council Meeting in Bethesda, Maryland".

It is the Council member's responsibility to contact Omega Travel at 855-326-5407 (M-F 7am-10pm; for after-hours emergencies please contact 855-326-5407) to confirm/change the travel reservation. All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

What do I need to do to make a change on my airfare so I can be reimbursed for additional expenses due to changes?

If you need to make a change on your airfare, you are required to contact OWT (see phone numbers above). **We recommend that you carry their after-hours number with you in case you need to make a change to your airfare or train ticket.**

What if I don't contact OWT? How will this affect my reimbursement?

Please note that if you book either business class for airfare and/or a train ticket, you will not be reimbursed. In addition**, you cannot pay the difference for a change in your airfare or train ticket by paying the additional money in cash.** Again, you must contact OWT; they will charge additional travel expenses to our government account. *Travelers who choose to not use Omega World Travel to make their travel reservations will not be reimbursed by NIH/NIDDK.*

Will I receive a confirmation from OWT of my airfare or train ticket reservations?

Yes. OWT will process your reservation with an electronic ticket and send you a confirmation notice via email. Retain this confirmation number.

Can I be reimbursed for rental car expenses?

Rental car expenses are rarely approved and must be pre-approved on the travel order. Under no circumstances will rental care expenses be reimbursed without prior authorization.

Can I be reimbursed for the expense of using a sedan instead of a taxi

You can always be reimbursed for taxis but not for use of a sedan.

What documents should I carry with me when I travel?

- OWT's phone numbers in case you need to make a change in your itinerary

OMEGA WORLD TRAVEL Business Hours: (855) 326-5407 (M-F: 7am-10pm EST) After-hours Emergency: (855) 326-5407

- A **government-issued photo ID** (license, passport, etc.)
- A **copy of your electronic ticket** with confirmation number.
- The **NIH travel order** to verify that you are traveling on official Government business. NIDDK will fax the travel order to you prior to your travel.

Hotel Information

NIH/NIDDK books and pays for hotel rooms for all Council members. Hotel room confirmation numbers will be submitted to you prior to your departure. Also please confirm your check-in and check-out dates, especially if arriving late. You will typically be lodging at the Hyatt Regency Bethesda.

Hyatt Regency Bethesda
7400 Wisconsin Avenue
Bethesda, MD 20814
T: (301) 657-1234
F: (301) 657-6453
http://bethesda.hyatt.com/en/hotel/home.html?src=agn_mls_hr_lclb_blocal_bethe

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include:

- Travel stubs or the travel itinerary showing the price of the ticket
- Other travel related receipts over $75.00 (e.g., receipts for taxi fares, tolls, parking fees)
- Original hotel bill
- Rental car receipt (reimbursement must be pre-approved).

Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days. No receipts are needed. (See M&IE above.)

Travel Expense forms and receipts should be sent or emailed within 5 days of your complete travel to:

Bratati Chowdhury, Program Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 7100 ex.10
6707 Democracy Boulevard
Bethesda, MD 20892-5452
Email: bratati.chowdhury@nih.gov

Once your completed Travel Expense Form with all receipts attached is received, you will be sent a travel voucher for your signature. The travel voucher is a document prepared at the conclusion of your trip itemizing all claims for reimbursement.

After the travel voucher is received at NIH, the payment will be deposited into your banking account within 14 business days in the amount indicated on the travel voucher as "NET TO TRAVELER."

Note: Your honorarium will be processed separately as noted above.

If you have any questions, please do not hesitate to contact Bratati at 301-594-8843 or email her at bratati.chowdhury@nih.gov.

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

(NIDDK Advisory Council Meeting)

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket $_____
- **Original Hotel** itemized receipt:
  - Room Rate $_____
  - Hotel Taxes $_____
  - Phone Calls ($5.00 per day are reimbursable) $_____
- Other travel-related receipts **over $75.00** $_____
- Rental car (reimbursement must be pre-approved) $_____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x $0.56 cents) $_____
- Parking Fees $_____
- Taxis:
  - From Residence to Terminal $_____
  - From Terminal to Hotel $_____
  - From NIH Campus to Terminal $_____
  - From Terminal to Residence $_____
  - Other $_____
- Tolls $_____
- Other miscellaneous expenses $_____

  (Please describe:_____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of $79.00 per day while you are on official government business. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBERS

(A Cheat Sheet for New NIDDK Council Members)

I. Before the meeting

Early Concurrence

- All grant applications (excluding those from foreign organizations) which have no concerns noted that would represent a bar to award (e.g., for human subjects, animal welfare, biohazards, etc.) or need Special Council Review, will follow an expedited concurrence process.
- A few weeks prior to the meeting NIDDK will alert the early concurrence committee members that these applications are available in the Electronic Council Book (ECB).
- As a new member it is unlikely that you will be asked to be a member of the early concurrence committee, but during this process all Council members are provided the list of all applications eligible for early concurrence for review and any member may bring any of these applications to full Council consideration.

Bottom line: *You may wish to spend a little time looking over the early concurrence list to see if you have any concerns--and if you do let Karl Malik know A.S.A.P.*

Council Materials

- About ten days before the Council meeting Council Members are notified that materials for the meetings are available for their review.
- These materials are available via the ECB using the same access information that was earlier given for access to the early concurrence list.
- Scientific members are frequently asked in advance to review particular applications or proposed actions in the closed portion of the subcommittee meeting, and they are often provided additional materials.

Bottom line: *Please thoroughly review these materials prior to the meeting & contact the appropriate NIDDK Division Director if you have any concerns or if you would like additional information.*

Additional Requests

- Occasionally a Division Director, or other NIDDK staff member, will contact a Council member to request that they participate as a discussant of a presentation at an open portion of the meeting.
- If available, the slide set or additional materials will usually be provided to the Council member.

Bottom line: *Please review these materials & come to the meeting prepared to participate as requested. Please be sure that you understand & follow any specific guidance — especially when considering appeals. NIDDK needs advice on the merit of the appeal, not the merit of the application.*

Attendance

- Members are encouraged to attend the entire Council meeting. Staff will work with you or your assistant to arrange travel plans that will allow you plenty of time to catch your flight after the meeting.

Bottom line: *Please don't plan on leaving Council meetings early.*

II. At the meeting

Closed Sessions

- Council members are requested to come prepared to fully participate in the closed sessions.
- Members are reminded that all matters discussed or materials available for discussion in closed sessions and the discussions themselves are confidential and should not be shared with anyone outside of the meeting.

Bottom line: *What happens in closed session stays in closed session.*

Open Sessions

- Council members are requested to come prepared to participate fully in the open sessions, including the discussions that follow presentations.
- Members are encouraged to provide specific feedback to NIDDK staff about any of the matters discussed or potential matters or issues they would like to hear discussed at a future meeting.
- Remember that ***members of the public, of advocacy groups, and of the press may attend our Council meetings*** and anything that you say in the open sessions of Council meetings could be reported.

Bottom line: *Please interact & give us your perspective and advice, but be careful about seeming/being too prescriptive in open session and also please be careful in open session not to say anything that you (and we) might regret if it gets reported and appears in print.*

III. After the meeting

Special Requests

- Occasionally Council members may be requested to review certain matters (for example, an appeal that arrived too late for consideration at the meeting) after the meeting.
- Please provide the requested advice within the timeframe allowed and treat all of these matters as confidential, just as you would were they are being considered within closed session.

Bottom line: *These matters are essentially an extension of the closed session.*

What do we really want from you?

- Your scientific expertise
- Your understanding of patient and clinical issues
- Your wise council about our general portfolio
- Your thoughts about NIH/NIDDK policies, the public landscape and help in avoiding pitfalls
- Your outreach and advocacy on behalf of NIH/NIDDK both within your community and to the public to explain the processes, the considerations, the rigor, and the fairness of how we do business and the important work that we support
- Your help in keeping NIDDK at the cutting edge of science and scientific administration

What should you be careful about?

- Keeping closed session materials and discussions confidential

- Paying attention to and avoiding/disclosing any real or apparent conflicts of interest as soon as they arise

- Advocating to elected officials while on official government travel
    - You are a special government employee when you are traveling to attend Council meetings and during this time you are not allowed to advocate!
- Keeping in mind that anything you say in the open sessions of the Council meeting (both the main sessions and open sessions of the sub-councils) could wind up in print
- Not appearing to be too prescriptive in your remarks – You represent NIDDK's broad community rather than advocating for a particular segment of that community
    - Sparking disease or research area wars is not in anyone's best interest

NIDDK Advisory Council Orientation Reference Links
January 2022

General background information about Council

- **Advisory Council page on the web:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees
- **Advisory Council Charter:**
  https://www.niddk.nih.gov/-/media/Files/Advisory-Coordinating-Committees/NIDDK-Advisory-Council/Council-Charter.pdf
- **Advisory Council Operating Procedures:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/operating-procedures
- **Advisory Council Membership Roster:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/members

General background information about NIDDK and funding

- **NIDDK Mission, Vision, & Guiding Principles:**
  https://www.niddk.nih.gov/about-niddk/meet-director
- **NIDDK Organization:**
  https://www.niddk.nih.gov/about-niddk/offices-divisions
- **NIDDK Research Programs & Contacts:**

  https://www.niddk.nih.gov/research-funding/research-programs
- **NIDDK Funding Policy:**
  http://www.niddk.nih.gov/research-funding/process/award-funding-policy/Pages/award-funding-policy.aspx

Administrative matters regarding Council membership

- **Ethics Training for Special Government Employees**
  (Financial Disclosure, Conflict of Interest, Representation, Misuse of Position)**:**
  https://www.oge.gov/web/oge.nsf/0/77E34818F9A59979852585B6005A24BB/$FILE/Guide%20for%20Nominees%202020_accessible.pdf
- **Procedures for Avoiding Conflict of Interest for Special Government Employees:**
  http://oma1.od.nih.gov/manualchapters/management/1810-1/
- **Travel Reimbursement:**
  https://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-diseases-advisory-council/travel-expenses-reimbursement

The Grant Process

- **NIH Grants Process Overview, from application to award:**
  http://grants.nih.gov/grants/grants_process.htm
- **Types of NIH grants:**
  http://grants.nih.gov/grants/funding/funding_program.htm
- **About Funding Mechanisms, including information about how NIDDK utilizes certain funding mechanisms:**
  https://www.niddk.nih.gov/research-funding/process/apply/funding-mechanisms
- **Peer Review Policies & Practices:**
  http://grants.nih.gov/grants/peer/peer.htm

Grant Policies & Regulations

- **FOIA & Privacy:**
  http://www.nih.gov/icd/od/foia/5usc552.htm
- **NIH Grants Policy & Guidance:**
  http://grants.nih.gov/grants/policy/policy.htm
- **NIH Intellectual Property Policy:**
  https://grants.nih.gov/grants/intell-property.htm
- **NIH Invention Reporting (iEdison):**
  https://s-edison.info.nih.gov/iEdison/
- **NIH Public Access Policy:**
  http://publicaccess.nih.gov/
- **NIH Genomic Data Sharing Policy:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html
- **NIH Sharing Policies and Related Guidance On NIH-Funded Research Resources:**
  https://grants.nih.gov/policy/sharing.htm
- **Research Integrity/Research Misconduct:**
  https://grants.nih.gov/grants/research_integrity/index.htm
- **Information about NIH grant applications from foreign countries:**
  http://grants.nih.gov/grants/foreign/index.htm
- **Simplified NIH Policy for Late Application Submission:**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-039.html
- **Changes to the Biographical Sketch and Other Support Format Page for Due Dates on or after May 25, 2021:**
  https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-073.html