FNIH
Foundation for the National Institutes of Health

RESEARCH BRINGS US
ONE STEP CLOSER TO ...

UNDERSTANDING → BREAKTHROUGHS → SOLUTIONS

2019 STATUTORY REPORT

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Tab One
FNIH Overview

The Foundation for the National Institutes of Health (FNIH) procures funding and manages alliances with public and private institutions in support of the mission of the National Institutes of Health (NIH), the premier medical research agency of the United States. The Foundation organizes and administers research programs, supports education and training of new researchers, organizes educational events and symposia, and manages a series of funds supporting a wide range of health challenges.

In almost 25 years, the Foundation has raised nearly $1.25 billion from the private sector to support the NIH and NIH-related research initiatives. Of the funds it raises, the FNIH spends an average of 90 percent on programs and 10 percent on administration. The FNIH has earned another 4-star rating from Charity Navigator for its work in 2019. This is the 6th consecutive 4-star rating. Only 9% of the charities evaluated have received at least 6 consecutive 4-star evaluations, indicating that the FNIH outperforms most other charities in America. On a related note, the FNIH President and Executive Director, Maria C. Freire, Ph.D., was named "Executive of the Year" by Non-Profit PRO for her leadership of the FNIH over the past seven years, which has fueled innovative approaches to biomedical research.

Highlights for 2019:

It is difficult to select only a handful of the many activities that the FNIH undertook in 2019. Some are continuation of well established programs, like the Alzheimer's Disease Neuroimaging Inititaitive (ADNI), the work in support of AIDS vaccines and the lung cancer initiative known as Lung-Map. These, as well as new initiatives and other programs, comprise the 126 projects in the FNIH 2019 portfolio for which the FNIH has raised $442 million from the private sector for their support. Please see Tab Four. Below are a few examples of initiatives in 2019.

The Accelerating Medicines Partnership (AMP) was first launched in 2014 in 3 program areas: Type 2 Diabetes, Alzheimer's Disease and Rheumatoid Arthritis and Lupus. The FNIH has since launched AMP for Parkinson's Disease (PD). In November 2019, AMP-PD launched a data portal to provide de-identified information from more than 4,000 people to researchers working to develop effective therapies for the disease. The portal enables scientists to study complex data sets and perform genome-wide analyses at a scale previously impossible.

The FNIH Biomarkers Consortium launched an initiative under its Metabolic Disorders Steering Committee that will standardize biological markers (biomarkers) that help diagnose Non-Alcoholic Steatohepatitis (NASH), a type of liver disease. The Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) project will directly compare imaging and blood-based biomarkers to biopsy results to define the best tools for diagnosing NASH. This information will help physicians identify patients who are most likely to progress to serious complications, such as liver failure or cancer. The project team includes experts from the FNIH, the US Food and Drug Administration (FDA) and academia, as well as the diagnostic, device and pharmaceutical industries.

In 2019, the FNIH obtained funding for GeneConvene, the goal of which is to advance best practices and informed decision-making for development of genetic biocontrol technologies to improve public health. The focus at this outset will be the use of gene drive technology to prevent malaria transmission.

Also as part of its public health portfolio, the FNIH laid the groundwork for the TB Vaccine project. Researchers at the National Institute of Allergy and Infectious Diseases (NIAID) and the University

of Pittsburgh are setting out to study whether the way the BCG vaccine is administered could make a difference in its long-term protective effects.

Much design work went into a new initiative on maternal and child health that will be launched in 2020 – the A PLUS study. The goal of this three-year study is to recruit a total of 34,000 women, in 7 low and middle-income countries, and assess whether a single oral dose of azithromycin administered during labor is effective in preventing sepsis and mortality in pregnant women and newborns. A PLUS will be carried out in partnership with the Eunice Kennedy Shriver National Institute on Child Health and Human Development (NICHD). Three FNIH staff members received the NICHD Partnership Award in 2019 for their work on enabling this study.

In 2019, the FNIH bestowed 3 major awards: the Lurie Prize in Biomedical Sciences (Lurie Prize), the Trailblazer Prize for Clinician-Scientists (Trailblazer Prize) and the Charles A. Sanders, M.D., Partnerhsip Award (Partnership Award).

Yasmine Belkaid, Ph.D., of the NIAID, was the winner of the 2019 Lurie Prize for blazing a trail in understanding the microbiome's significant role in immune regulation. Dr. Belkaid revolutionized the understanding of the role of these microbes in the gut and skin, demonstrating that they are essential for triggering an immune response to help fight infection but can also initiate inflammatory disease.

The 2nd annual Trailblazer Prize was awarded to James Kochenderfer, M.D., of the National Cancer Institute, for pioneering the development of immunotherapies that leverage chimeric antigen receptor (CAR) T-cells to treat blood cancers.

The FNIH named the Doris Duke Charitable Foundation and Jane Sayer, Ph.D., the recipients of the 2019 Partnership Award. This award recognizes persons and/or organizations that have made significant contributions to the FNIH's work to build, implement and nurture public-private partnerships in support of the mission of the NIH.

In support of the courageous patients that are part of the research carried out at the NIH Clinical Center, the FNIH and the Friends of Patients at the NIH launched a new collaboration called "Partnership for Patients" to leverage one another's competence and infrastructure to ensure that patients in need receive support to participate in groundbreaking and potentially life-saving treatments.

Further, through the NIH Clinical Center Drug Donation program the FNIH provides critical support for patient care. In 2019, Horizon Therapeutics made an in-kind gift of ACTIMMUNE, to be used for infectious disease research, that was valued at $5.5 million.

In summary, the FNIH is well-positioned to support the NIH mission and partner with a wide range of philanthropic organizations, government agencies, biomedical companies, academic institutions, members of the private sector and others to develop better methods to prevent and cure diseases and create a new era of precision medicine with therapies that are better tailored for patients.

Tab Two
FNIH Board of Directors

FNIH
Foundation for the
National Institutes of Health

Board of Directors

as of December 31, 2019

Steven M. Paul, M.D. (Chairman)
Chief Executive Officer & Chairman, Karuna Therapeutics

Maria C. Freire, Ph.D.
President and Executive Director, Foundation for the National Institutes of Health

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Distinguished Service Professor of Neuroscience, Pharmacology & Psychiatry
Solomon H. Snyder Department of Neuroscience at Johns Hopkins University

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Freda C. Lewis-Hall, M.D., DFAPA
Former Chief Patient Officer and Executive Vice President, Pfizer Inc.

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Executive Director, Center for Audit Quality

Edison T. Liu, M.D., Ph.D.
President & Chief Executive Officer, The Jackson Laboratory

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Executive Chairman/Founder, Alexandria Real Estate Equities, Inc.

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Chairman, Perspecta Trust

Jillian Sackler, D.B.E.
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President and Chief Operating Officer, Beacon Capital Partners

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Chairperson, Friends of Cancer Research

Russell W. Steenberg
Managing Director and Global Head of BlackRock Private Equity Partners

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Vice Chairman of the Executive Committee and Chief Scientific Officer, Johnson & Johnson

Elias Zerhouni
Professor Emeritus, Johns Hopkins University

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Cahill Professor in Biochemistry (Emeritus), Stanford University School of Medicine

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The Honorable John Edward Porter
Hogan Lovells US, LLP

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President, Lurie Holdings; President and Treasurer, Ann and Robert H. Lurie Foundation

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Professor of Medicine and Health Care Policy, Emeritus, Harvard Medical School; Massachusetts General Hospital

Patrick C. Walsh, M.D.
University Distinguished Service Professor, James Buchanan Brady Urological Institute, Johns Hopkins Medical Institutions

Tab Three

NIH-FNIH Steering Committee 2019 Submissions

	2019 NIH Proposal Review Committee Submissions				
UNDER CONSIDERATION					
ID	**Name of Project**	**IC**	**Date FNIH rec'd RFC**	**Project Description**	**Update**

WITHDRAWN BY NIH				.	
ID	**Name of Project**	**IC**	**Date FNIH rec'd RFC**	**Project Description**	**Update**
RFC-2019-2	**High Resolution Spatial, Molecular, and Functional Analysis of Cellular Interactions in the Human Thymus Across Developmental Stages**	NIAID	1/30/2019	A group of scientists from NIAID, the Wellcome Sanger Institute (UK), Ghent University (Belgium), and the Weizmann Institute (Israel) submitted a preproposal under the Chan Zuckerberg Initiative (CZI) Seed Networks program to develop a comprehensive cell atlas of the human thymus through development. Broad profiling of all cell types in the thymus is proposed, using single cell genomics and proteomics technologies and multiplex tissue imaging to look at patterns of cell surface markers, T cell receptor usage, signaling and cell-cell interactions. Particular attention will be paid to thymic epithelial cells, which play a central role in self- non-self recognition.	On April 24, 2019 the FNIH was informed that the investigators had arranged for NIAID to receive project funds through the University of California, Berkeley and that the Wellcome Sanger Institute would administer the funding awards to the international sites. Thus, the project was withdrawn from FNIH consideration by the NIH. (J. Wolf-Rodda, 4/9/20)
ACTIVE PROJECTS					
ID	**Name of Project**	**IC**	**Date FNIH rec'd RFC**	**Project Description**	**Update**
RFC-2019-1	**Collaboration to Prevent Maternal and Neonatal Death and Sepsis in Low Resource Settings**	NICHD	1/17/2019	Double-masked randomized placebo-controlled trial. The investigational regimen is 2g of oral azithromycin compared to an identical placebo. A successful prophylaxis intervention is likely to reduce infections and death and may reduce the need for prolonged antibiotic therapy and associated health care costs of treating drug resistant infections.	The grant proposal for this clinical trial has been assembled and submitted to the BMGF Program Officers on Friday, May 3, 2019. They've confirmed the receipt of it and will further discuss the submission on a phone call with Susan Wiener and Renata Hoffstetter that will take place on May 20th, 2019. Upon the grant acceptance and funding becoming available, sub awardee agreements will be developed between the FNIH and the consortium of institutions. (Renata Hoffstetter, 5/7/19)
RFC-2019-6	**Pediatric Preclinical Testing Public-Private Partnership (PPTP3)**	NCI	4/11/2019	The PPTP3 will involve government (NIH, FDA), pharmaceutical and biotechnology (biopharma) companies, academic researchers, nonprofit foundations, and patient advocate organizations. The overall purpose of the PPTP3 will be to develop preclinical data to inform prioritization decisions about new anti-cancer agents that are considered potentially relevant to the growth or progression of one or more childhood cancers and to disseminate these data to all appropriate stakeholders. Preclinical testing will be performed by academic researchers selected through a competitive process and will utilize molecularly characterized models and robust methodologies leading to reproducible findings. The preclinical testing will ascertain the activity of agents across relevant pediatric preclinical models using validated study endpoints and may identify biomarkers that can be used for selecting patient populations for clinical evaluations. Results from the PPTP3 may be used by FDA, biopharma companies, and academic researchers to inform decisions about agents to clinically evaluate for specific childhood cancers.	After due diligence and careful consideration, in May 2019 the FNIH Board approved the inclusion of this project in the FNIH project portfolio. The design phase of this project is nearing completion. (J. Wolf-Rodda, 4/9/20)
RFC-2019-4	**The National Institute of Neurological Disorders and Stroke (NINDS) Health Disparities in Tribal Communities (HDTC) Summer Internship Program (SIP).**	NINDS	5/1/2019	Fostering diversity by addressing underrepresentation in the scientific research workforce is a key component of the NIH strategy to identify, develop, support, and maintain the quality of our scientific human capital. Every facet of the United States scientific research enterprise—from basic laboratory research to clinical and translational research to policy formation—requires superior intellect, creativity, and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remain a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds, including those from underrepresented groups, who will help to further the NIH and NINDS mission. There are many benefits that flow from a diverse NIH-supported scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved or health disparity populations participate in, and benefit from health research	After due diligence and careful consideration, in June 2019 the FNIH Board approved the inclusion of this project in the FNIH portfolio, with conditions. Due to COVID-19, the NIH cancelled this and other NIH summer internship programs for 2020. (M. Mathews, 4/9/20)

	ADNI-Amyloid PET Early Frames Add-On Study (to ADNI 3)	NIA	6/26/2019	The Project is an add on study to the Alzheimer's Disease Neuroimaging Initiative (ADNI) third phase. The overall goal is to obtain a PET measure reflecting cerebral blood flow in ADNI participants by collecting amyloid PET data immediately after injection of an amyloid tracer. The Project proposes to use up to 200 ADNI subjects distributed across the diagnoses of normal, mild cognitive impairment, and Alzheimer's Disease. The observations from this Project have two potential uses in clinical studies. One is that acquisition of early frame data can be used to derive a "functional" measure of cerebral blood flow that may change differently over time and may reflect effects of treatment that differ from measures of amyloid accumulation. Second, the measures of tissue perfusion can potentially be used to "correct" the amyloid deposition images obtained at later time points, in order to remove the effects of perfusion changes over time that might particularly affect longitudinal measurements.	After due diligenceand careful consideration, in July 2019 the FNIH Board approved the inclusion of this project in the FNIH portfolio. (J. Wolf-Rodda, 4/9/20)
RFC -2019 - 08	**National Research Summit on Care, Services, & Supports for Persons with Dementia and Their Caregivers**	NIA	12/20/2019	The goal of the National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers is to bring together individuals with a variety of backgrounds to identify evidence-based programs, strategies, approaches, and other research that can be used to improve the care, services, and supports of persons with dementia and their caregivers. This summit follows the example of previous Alzheimer's Disease (AD) and Alzheimer's Disease-Related Dementias (ADRD) summits organized primarily by the National Institute on Aging (NIA) and the National Institute on Neurological Disorders and Stroke (NINDS), respectively. Each summit continues this strategic planning process, and like the previous summits, this event supports the goals of the of the National Alzheimer's Project Act (NAPA; P.L. 111-135). The primary aims of the 2020 summit are to evaluate progress made since the 2017 Summit and encourage individual input on current priorities and milestones.	The FNIH secured the necessary funding for this event. Scheduled for March 25-26, 2020, the event was cancelled by NIA due to COVID-19. The NIA is working to reformat the event and expects to present the content later in 2020. (Maria Mathews, 4/9/2020)
COMPLETED PROJECTS					
ID	**Name of Project**	**IC**	**Date FNIH rec'd RFC**	**Project Description**	**Update**
RFC-2019-7	**Event:Childhood Cancer Data Initiative Sympsium Poster Reception**	NCI	6/27/2019	The Childhood Cancer Data Initiative (CCDI) focuses on the need to collect, analyze, and share data from programs such as the PPTP3 to a wider scope of researchers to address the burden of cancer in children, adolescents, and young adults. Scientific stakeholders will gather in Washington, DC, July 2019 for the NCI CCDI Symposium—to establish a common understanding of the current issues and opportunities in childhood cancer research that can be addressed through enhanced data collection and maximum utilization of data such as that obtained through the PPTP3. The FNIH will collaborate with the NCI on poster sessions and an event encourage participatns to leverage existing resources such as the PPTP3 to expedite developing new approaches of treating childhood cancer and to highlight existing initiatives supporting childhood cancer research and opportunities for expansion of others such as the Partnership for Accelerating Cancer Therapies (PACT).	NCI collaborated with FNIH staff to promote the existing public-private partnerships to the larger childhood cancer community as they relate to the data sharing premise of the CCDI. The event was held on 7/29/2019. (Maria Mathews, 4/9/2020)
RFC-2019-5	**Geroscience Summit III**	NIA	4/9/2019	The third Geroscience Summit organized by the trans-NIH GeroScience Interest Group (GSIG) will provide a forum for sharing information about the latest advances in geroscience, as well as engaging disease-focused professional societies and foundations that have not been integrally involved in geroscience research previously with the community of researchers and practitioners of geroscience.	The FNIH secured funding and helped with logistics for this event, which took place on November 4-5, 2019 on the NIH Campus. (Maria Mathews, 4/9/2020)
DECLINED BY FNIH					
ID	**Name of Project**	**IC**	**Date FNIH rec'd RFC**	**Project Description**	**Update**

Tab Four

FNIH Project Summaries through December 31, 2019

FNIH

Foundation for the National Institutes of Health

FNIH PROJECT SUMMARIES – 4Q2019

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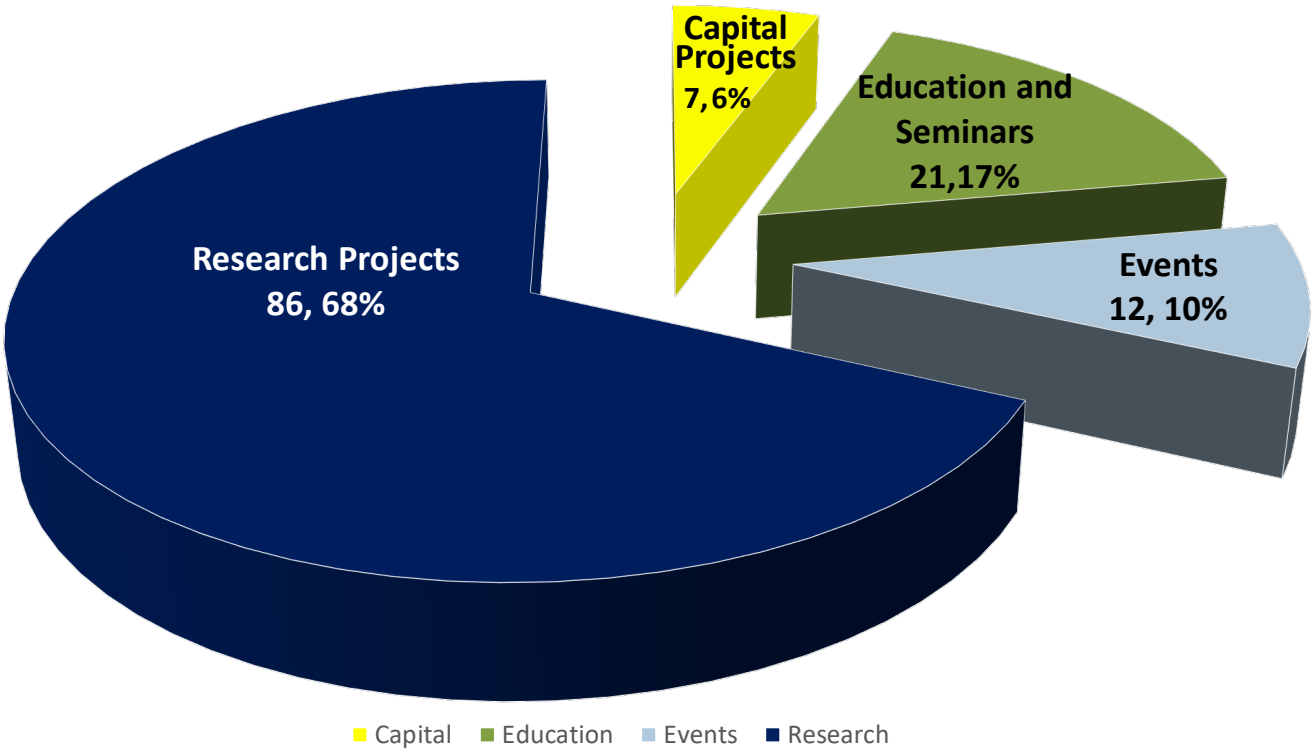
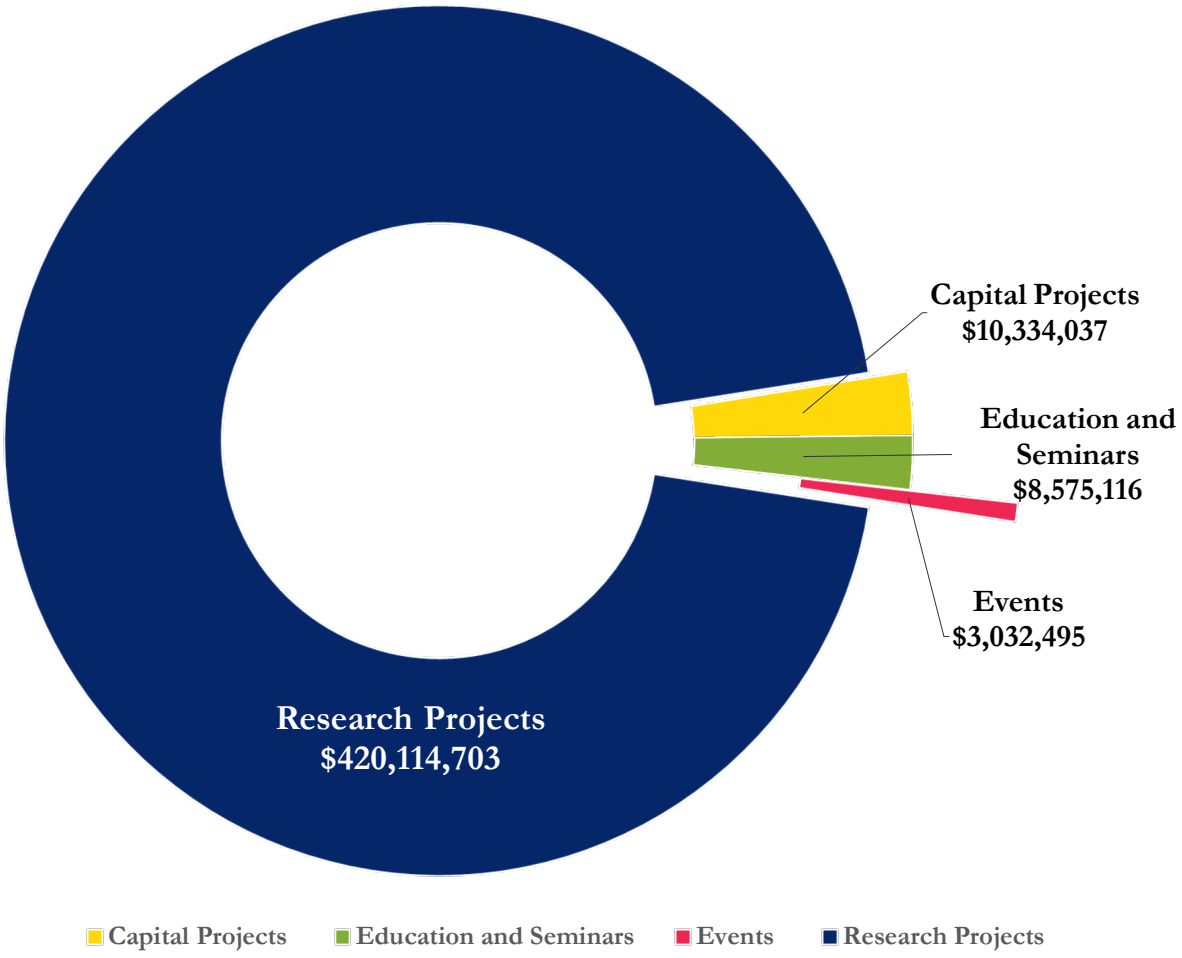
Active Projects
Current Portfolio: 126 Projects

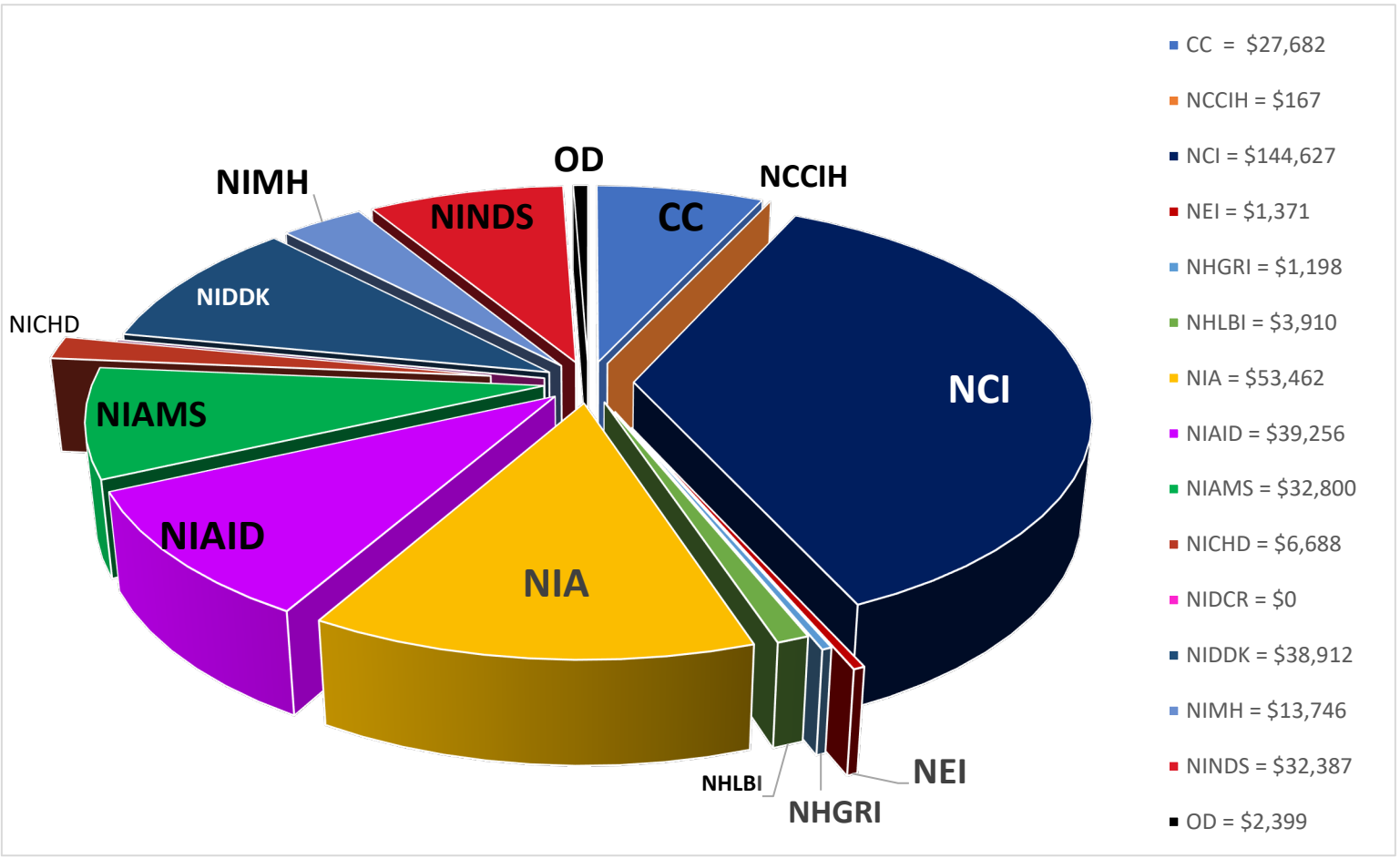


Funds Raised for Active Projects:
$442 million

Since Inception



Funds Raised for NIH ICs
Total: $398.6 million
Since Program Inception



Figures in 000s

National Cancer Institute

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
A Novel Total Lesional Automated Computerized Imaging Platform, Biomarker, and Predictive Model for Metastatic Prostate Cancer	NIP- Metastatic Prostate Cancer	Metastatic castration-resistant prostate cancer (mCRPC) is the second leading cause of cancer death of American men. Over 80% of these patients have metastases to the bone; for those with non-osseous spread, over 80% of soft tissue metastases are nodal. In a bone-dominant disease such as mCRPC, the lack of a surrogate endpoint for overall survival (OS) based on fully quantitative bone imaging has significantly impeded drug development and clinical care. To develop new biomarkers that can deliver a readout of a drug's activity earlier than OS, a whole-body imaging project is proposed that is non-invasive and addresses the challenges of tumor heterogeneity by capturing a patients' entire tumor burden. A multivariable response parameter will be created from the Cou302 trial database using imaging, serum biomarkers, clinical events, and progression and survival outcomes. A unique, fully quantitative response biomarker will be developed that is ready for validation in accordance with FDA guidelines for biomarker validation.	Janssen provided $300K funding commitment over 3 years and a Letter of Agreement for funding has been returned for signature. A Data Sharing Agreement has also been returned for execution, and two Research Collaboration Agreements are with the research sites, Columbia and Memorial Sloan Kettering under review. Project launch is expected for Q1 2020.	Fundraising efforts are underway	Aug-19
Biomarkers Consortium - Chemotherapeutic Impact on the Immune MicroEnvironment	Biomarkers Consortium - ChIIME	The clinical impact of tumor immunity in patients with cancer is variable and many patients fail to respond to immunotherapy (IO). One hypothesis for nonresponse is differential regulation of factors in the immune microenviroment (ME). Therefore, there is a need to study the ME before, during, and following therapy, to inform how to sequence and combine IO and chemotherapy and to discover new biomarkers and effective interventions. This project will use single nucleus RNA-seq (sNuc-Seq), pioneered by the Klarman Cell Observatory (KCO) at the Broad Institute, to define the heterogenous state of malignant and non-malignant cells in the tumor ME (TME) from patients undergoing clinical care. Tumor samples will be collected from the Dana Farber Cancer Institute and the Howard Hughes Medical Institute. Results could lead to therapeutic hypotheses for IO, identification of novel biomarkers, improvements in drug development, and better patient stratification.	A Project Concept was presented to the CSC at the annual in-person meeting December 2016 and sent out for review and approval. The CSC approved the concept and the Project Team developed a Project Plan and funding scan data, which were reviewed and approved for launch by the EC 6/23/17. After a lengthy funding search and negotiations the initial project scope was reduced to the pilot and phase 1 to accommodate funding offered by interested partners, and the FNIH team executed LoAs with two funders. A research agreement, including a subcontract for sample procurement with Dana-Farber, was executed 10/8/19 with the Broad and a project Launch meeting is scheduled for 1/31/20. A 6 month go/no-go will be assessed in July 2020, and phase 1 completion is expected July 2021.	$1,950,000.00	Apr-18
Biomarkers Consortium - Developing an Analytically and Clinically Validated Reference Material for ctDNA Testing	Biomarkers Consortium - ctDNA Reference Standards	Liquid biopsies are widely recognized as a key component to fully realizing precision medicine. The most widely used circulating biomarker today is circulating tumor DNA (ctDNA). There are no universally recognized reference materials however that allow laboratorians, physicians, regulators, or payers to determine if all the processing steps worked correctly, and the results are accurate. The ctDNA Quality Control Material project seeks to develop processes to enable the production of QC materials in partnership with commercial reference material manufacturers for widespread use in liquid biopsy testing. Successful development and dissemination of QC material that can be used to establish the analytical validation and accurate interpretation of clinical assays will provide the scientific and healthcare community confidence in interpretation of ctDNA biomarker assay results in clinical research, therapeutic decision-making, regulatory evaluation, and reimbursement.	The ctDNA Quality Control Materials Project Plan was presented to the CSC on 6/26/18 and received approval from the EC on 8/16. The final budget of $1,238,575 reflects in-kind contributions of $1million and $500K estimated for a phase III clinical validation study. FNIH executed 3 agreements with reference material manufacturers to transfer QC materials with 14 variants identified and refined through in-person meetings 3/20/18 and 4/16/18, and in discussions with the FDA 3/26 and 7/5. Additional discussions are being scheduled with FDA to assure a feasible Functional Characterization study and Clinical pilot design in Q1 2020. Funding is complete with 5 LoAs executed. 2 RCAs, 1 CRADA with the central lab and 1 MOU with NIST are executed and the project officially luanched 9/18/19. Initial performance evaluation data was reviewed with the manufacturing companies. 10 donated services agreements are in development for external labs to perform phase 2 clinical testing, set to begin Q3 2020.	$1,548,225.00	Apr-18

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - High Definition Single Cell Analysis of Blood and Tissue Biopsies in Patients with Colorectal Cancer undergoing Hepatic Metastasectomy (HD-SCA in CRC)	Biomarkers Consortium - HD-SCA in CRC	Colorectal cancer (CRC) is the second leading cause of cancer deaths in western countries. The five-year survival rate in early-stage CRC patients falls from 90% to 60% with lymph node involvement and to 10% with metastases. Early detection and treatment of metastatic colorectal cancer (mCRC) would benefit from an easily obtainable biomarker signature (bio-signature) to characterize patient subpopulations. The core hypothesis for this project is that a liquid biopsy can serve as a source of rare circulating tumor cells (CTCs) to represent or complement the traditional solid biopsy. The project was an observational clinical study in two stages, with a third stage proposed, to sample CTCs and solid tissue from patients with mCRC undergoing liver resection. Cell-free DNA was also collected as part of the liquid biopsies for subsequent analysis.	HD-SCA was approved by the FNIH BC EC on 2/26/15 and LoAs were completed with 4 funders. The PI reduced the scope to match funds raised to accelerate project launch with project team approval. The PI developed a second phase of the project including the originally planned correlation analysis and an additional proteomics element which was approved by the CSC but did not receive funder interest and was not presented to the EC. Project launched 4/01/16. Clinical trial sites for sample acquisition were set up and work began on assay parameters prior to kick-off on 8/3/16. 63 patients were accrued, exceeding the goal of 45, and the team demonstrated performance of an initial 3-color assay adding a 4th color marker in 2017. The first bio-signature with data from biopsies accrued over the first 18 months of the project was delivered 4/14/18. The PI requested a no-cost extension to 11/30/19, which was unanimously approved by the team, and published a manuscript on the bio-signature and assay development as a final deliverable. The project closed 11/18/19.	$1,800,000.00	Apr-16
Biomarkers Consortium - Minimal Residual Disease Detection in Adult Acute Lymphoblastic Leukemia	Biomarkers Consortium - MRD Project	Leukemia is a life-threatening but treatable type of cancer of the blood or bone marrow in which numbers of immature white blood cells increase abnormally. In 2013, there were over 48,000 new cases and 23,000 deaths in the United States; there are multiple types of leukemia in children and adults. Minimal residual disease (MRD) is the number of leukemic cells detected by molecular or cellular means in blood or bone marrow when the patient is in a clinical and pathological state of remission after treatment. MRD has been investigated extensively in pediatric acute lymphoblastic leukemia (ALL), and its detection is associated with subsequent relapse, event-free or relapse-free survival (EFS or RFS, respectively). Indeed, national pediatric studies now perform risk stratification based on MRD level after induction therapy. Data concerning the association of MRD and outcome in adult ALL have not been as well investigated, and MRD does not yet have the same application in the disease.	Goal 1 is to establish MRD as an indicator of clinical outcomes in adult ALL. Meta-analysis of data from existing trials was conducted to assess correlation between EFS in pediatric and adult ALL via MRD. Study results suggested high correlation between EFS and MRD and that MRD has potential as a surrogate endpoint for ALL. Meta-analysis data was published in JAMA Oncology 01/2017. 12 data agreements were signed for a patient level analysis completed by FDA with results presented at the ASH conference 10/6/19. Goal 2 is standardizing MRD analyses. The team standardized flow cytometric methods for MRD analysis and completed dry/wet lab analyses, findings published in Cytometry 05/2017. 3-tube, 8-color flow cytometric assays for ALL MRD classification were finalized by both BD and Beckman Coulter. FDA discussions ongoing about pathway to kit qualification and will continue with clinical studies beyond the duration of the project. A final summary meeting held 7/9/19 to recap successes and next steps and final data presented to the BC EC on 10/25/19. Project close out Q2 2020.	$2,172,500.00	Nov-14
Biomarkers Consortium - Single Cell Mass Accumulation Rate as a Biomarker for Drug Efficacy in Multiple Myeloma and Leukemia	Biomarkers Consortium - MAR	A clinical need exists to improve the efficacy of existing treatment and minimize the side effects caused by inappropriate therapy in Multiple myeloma (MM). The MAR project proposes to address this gap by establishing the clinical efficacy and utility of single-cell mass accumulation rate (MAR) to assess tumor cell drug response in MM, leukemia and other cancers. MAR, which measures change in cell growth (not proliferation), is determined by repeatedly calculating the mass of an individual cell over a 20-minute interval with a microfluidic device called a suspended microchannel resonator (SMR). The MAR assay can analyze a broad variety of drugs applicable to several tumor types. The project will provide a clinically feasible predictive response biomarker that directly measures drug effects on single living tumor cells allowing patients to be retested and their therapy adapted as they become resistant to treatment and could assist drug assessment and improve clinical trial efficacy.	The project received approval by the CSC and was presented to the EC 10/26/2018. The team responded to questions from the EC regarding consortium participation, company interest and statistical power and received approval to proceed with fundraising 11/28. 2 research agreements were executed and 1 neared completion. Amgen and Celgene expressed interest to fund the project in 2018 and Amgen exectued a LoA. Celgene organized a merger in 2019 delaying funding for 9 months. The company determined they would not fund and the team agreed to close the project due to inadequate funding and submit a new plan at a later date.	$408,000.00	May-19

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Vol-PACT: Advanced metrics and modeling with Volumetric CT for Precision Analysis of Clinical Trial results	Biomarkers Consortium - Vol-PACT	Volumetric CT for Precision Analysis of Clinical Trial Results (Vol-PACT) is a collaborative research partnership collecting imaging data and associated clinical data from large, completed Phase II/III RCTs in several measurable solid tumors. The aim is to comprehensively study metrics in the context of unidimensional, bidimensional, and volumetric tumor measurements in their ability to predict clinical outcomes. Preliminary simulation results were produced in a Pilot study using data from Sanofi's VELOUR and GSK / Novartis COMPARZ trials. Data from ten total trials has been secured, with three additional trials promised, including renal cell carcinoma, colorectal cancer (CRC), lung cancer, and melanoma. Trial data sets include both targeted and immunotherapy treatments, and the team will be synergizing efforts with the EORTC and RECIST committees.	Vol-PACT is the Phase 2 extension of the Vol-PACT Pilot project, retained the same core team and launched January 2017. Two additional companies contributed in 2017 making 7 committed funding partners for 3 years. A Project Plan Addendum provides for deeper analysis of IO response metrics, including standardization of iRECIST. At the request of the sponsors, the project team developed a radiomics and modelling pilot for an additional $800,000 in funding and contract amendments were executed. The Project Plan reflects the updated number of clinical trials targeted for analysis (12) and corresponding budget ($3.6M). 5 lead metrics were identified in the first annual report and a go/no-go decision at 1.5 years was passed unanimously. A second annual report described the split of training and validation data sets for analysis of time-dependent, kinetic and radiomic modelling metrics. A CRC methods case study and iRECIST comparison paper are being prepared for publication in Q1 2020. The team requested a NCE to produce a third and final publication and close out meeting before 6/30/20.	$3,601,000.00	Jan-17
Bradley Charitable Gift Annuity	PG - Annuity - Bradley	The Bradley family has made a $250,000 charitable gift annuity to the FNIH in support of Dr. Staudt's lab or his successors to support lymphoma and leukemia research at the NCI. In accordance with the gift annuity rates set forth by the American Council on Gift Annuities (used by most charities in their issuance of gift annuities), the FNIH is obligated to pay the family 4.6% annually, or $11,500, every year until the survivor of them dies, at which time the remaining amount reverts to the FNIH to fund the project. The FNIH will then retain 5% of the remaining amount of the annuity and transfer 95% of the remaining amount to Dr. Staudt's laboratory or his successors.	FNIH Advancement staff to provide update on annuity health and thank donor for support; meeting to be scheduled.	$250,000.00	May-12
BRCA Challenge Fund	BRCA Challenge Fund	The BRCA Challenge is based on shared data from clinicians, clinical laboratories and researchers across the world, all with the intention of improving the precision of interpreting variants identified in clinical testing of BRCA1 and BRCA2. API for all to use on smartphones to query clinically determined variants. Inherited variation in the BRCA1 and BRCA2 genes can indicate genetic predisposition to breast, ovarian and other cancers. Since the large majority of BRCA1 and BRCA2 variants are not pathogenic, there is great need to develop a comprehensive data resource for collecting, annotating and interpreting variation across both genes. The Division of Cancer Epidemiology and Genetics is co-leading the effort to develop a resource that will be a comprehensive repository of BRCA variation, linking current structure and resources while encouraging deposition of new data.	A stewardship report was submitted to Andrew Steinhaus by Dr. Chanock noting the progress made in the BRCA Exchange.	$32,450.00	Jan-18
Cancer Research Fund	Cancer Research Fund (General)	As a part of its outreach efforts to individuals who may be interested in supporting NIH and, more specifically, the work of NCI, this fund was established to hold contributions received to support cancer research. Contributions may be designated simply for "cancer research" or, if desired by the donor, for more targeted initiatives underway at NIH. The Foundation will work with NCI to determine how this growing pool of general funds might best be applied whether through fellowships, as project seed funding, or through another mechanisms.	FNIH Staff continues to receive support for this fund. A recent bequest to the FNIH, in support of cancer research, was realized.	$2,498,507.83	Feb-00

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Efficacy of heterodimeric IL-15 treatment regimens in reducing SIV reservoir	het IL-15 SIV reactivation NHP Trial	This project evaluates the ability of a heterodimeric form of the cytokine IL-15 and the IL-15 receptor (hetIL-15) to flush-out and kill HIV/SIV-infected cells that serve as virus reservoirs in in infected rhesus macaques (RM) on long-term antiretroviral therapy (ART). The program pulls together the expertise of collaborators from the University of Louisiana Laffite, Case Western Reserve University, the Vaccine Research Center at NIAID/NIH and the National Cancer Institute. RMs will vaccinated with a DNA-based vaccine followed by DNA/protein boost and either treated with hetIL-15 as single agent or in combination with a PD-1/PD-L1 check-point inhibitor. A passive immunization strategy with an SIV neutralizing antibody will be considered depending on reagent availability. The work will help elucidate mechanisms for establishing and disrupting viral reservoirs established during HIV infections while also exploring treatments with the potential of clearing the virus or controlling virus rebound to eliminate the need for antiretroviral regimens and/or eliminating the risk of further transmission of the virus	Research efforts in the Efficacy of Heterodimeric IL-15 Treatment Regimens in Reducing SIV Reservoir project began with the infection of Rhesus macaques in January of 2019. 57 monkeys are currently infected and enrolled in the study (two monkeys resisted five challenges with the SIV and a third animal had to be euthanized due to reaching IACUC clinical endpoints). Animals in the treatment arms of the study have been vaccinated (two primes and two boosters) and remain on ART. Immunotreatments with hetIL-15 or hetIL-15 + PD1a are pending. The funder has proposed a 2-year extension amendment that is under consideration at the FNIH.	$2,874,832.00	Dec-16
Follicular Lymphoma Research Fund	Follicular Lymphoma Research Fund	Mr. Andrew Feinberg has made a $100,000 pledge of support for five yearly installments of $20,000 to the laboratory of Dr. Wyndham Wilson and NCI colleagues, who are developing a research project to further understand the biology of follicular lymphoma. The project titled, "Use of functional genomics to define new therapeutic strategies in transformed follicular lymphoma" has two specific aims: 1.) Identify essential genes in cell line models of tFL using CRISPR-based genetic screens. 2.) Specific Aim 2: Identify genes that confer sensitization or resistance to BCL2 inhibitors in tFL.	FNIH requested a stewardship report for the final year of the agreement, and are developing a strategy for continued support.	$112,000.00	Nov-15
Gramlich Melanoma Research Fund	Gramlich Foundation - Melanoma Research	The Gramlich Melanoma Research Fund supports melanoma research at NIH through an annual gift provided by the estate of Jack Gramlich.	FNIH Staff continue to steward this fund.	$450,075.00	Jun-08
Jerry D. Jennings Memorial Fund	Jerry D. Jennings Memorial Fund	The fund honors the father of Catherine Jennings Davis who died of renal cell cancer in July 2006. The Jennings Family funds go to support renal cell cancer research at NIH.	The donors have expressed interest in supporting the purchase of a device to help in renal cancer research needed by the laboratory of Richard Childs of the NHLBI. FNIH met with Dr. Childs to discuss the donors' interest and to identify additional areas of renal cell cancer research that could be supported through these funds. FNIH to follow up with the Jennings Family.	$3,980.00	Sep-06
Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.	Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.	Dr. Linehan's laboratory personnel are working to develop novel approaches targeting kidney cancer gene pathways, and evaluating these agents in patients treated at the NIH Clinical Center. Their studies of the different types of kidney cancer have demonstrated that it is fundamentally a metabolic disease. Both in the laboratory and in the clinic, they are evaluating new agents targeting the metabolic pathways in kidney cancer—for patients with clear cell kidney cancer, von Hippel Lindau disease, sporadic (non-hereditary) papillary kidney cancer, papillary kidney cancer, Hereditary Papillary Renal Cell Carcinoma, Renal Cell Carcinoma, and Hereditary Leiomyomatosis— and are very encouraged about the results of these studies, which promise to build on Dr. Linehan's great legacy of finding new therapeutic approaches for patients with kidney cancer.	Driven to Cure presented FNIH with a check for Kidney Cancer Research in a ceremony at the FNIH Offices which was streamed live on social media. Remarks were made by Maria Freire, Bruce Lee, Marston Linehan and Jim Gilman.	$732,525.36	Nov-13

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer	Lung-MAP	Lung-MAP (launched in 2014) is a groundbreaking clinical trial model that uses a multi-drug, targeted screening approach to match patients with sub-studies testing investigational new treatments based on their unique tumor profiles. Patients who enroll in Lung-MAP get a state-of-the-art genomic profile to determine the genomic alterations, or mutations, which may drive the growth of their cancer. Based on those results, patients are matched to a treatment being tested on Lung-MAP. If there isn't a genomic "match" patients have an option of receiving immunotherapy treatments used in the trials. The trial has also been redesigned to include a non-match study that treats patients with a randomized immunotherapy regime. In 2018, the trial was significantly expanded to include patients with all advanced non-small cell lung cancers (NSCLC), meaning it's now opened to even more patients with lung cancer who will have access to investigational treatments to fight their disease. This new expansion now falls under the new screening protocol, LUNGMAP, (previously called S1400).	The Lung-MAP trial was activated on 6/16/14. A major revision took place on 12/18/16, after FDA approval of Opdivo (BMS). As of 1/29/2020, 924 patients have been registered/screened under the new LUNGMAP screening protocol (1864 patients were registered under S1400 (from June, 2014 to January, 2019), prior to LUNGMAP being activated). Current active sub-studies are: S1900A (1/28/19), S1800A (5/17/19) and S1900C (1/16/2020). S1400F interim analysis was finalized 10/04/19, which resulted in the closure of the primary resistance cohort, but a reopening of the acquired resistance cohort on 10/15/19. S1400A and E were closed at company request. S1400B, C, D, I, G, and K were completed after interim analysis due to lack of patient response on 12/5/16, 9/1/16, 11/1/16, 4/23/18, 7/23/18, and 11/15/18 respectively. S1400GEN was completed in 06/2019, and the findings were presented at WCLC 2019. CTEP provided an approval (7/16/18) for a new LUNGMAP screening protocol which activated on 1/28/19, expanding the trial to all NSCLC histologies, IO combinations for anti-PDL-1 refractory patients, and inclusion of a ctDNA liquid biopsy screening. Lung-MAP is negotiating with 5 companies for new sub-studies. One new study to open in February 2020 (LOXO) and one in Q1 2020 (Takeda) with concept designs for two (Tesaro and Syndax) are under development. The fifth (Amgen) was approved by the Drug Selection Committee in December 2019. FNIH continues to support meetings for the Policy, Trial Oversight, Accrual Enhancement, and Drug Selection committees. A governance committee restructure was established to be more inclusive of all NCI cooperative groups, update the appropriate committees, assign committee chairs, revise membership, and set meeting cadence for each.	$61,343,465.70	Jun-14
NCI Neuro Oncology Branch Fund	NOB Fund	The Neuro-Oncology Branch (NOB) is a trans-institutional initiative in neuro-oncology sponsored by both NCI and NINDS that launched in 2000. NOB's mission is to develop novel diagnostic and therapeutic agents for patients with primary central nervous system tumors. They are building a biology-driven, individualized, patient-centric, rational therapeutics program. The NOB receives donations from patients, their families and friends, and others to support their research and would like to establish a fund at FNIH to hold such donations.	FNIH sent the Schatzkin Lecture speaker honorarium to Dr. Michael Leitzmann and forwarded it to NCI.	$30,055.58	Mar-11
NCTN Data Archive De-Identification Project	NCTN Data Archive De-Identification Project	The NCTN Data Archive is an NCI database of individual-level data from clinical trials conducted by the National Clinical Trials Network that is broadly available for access by the entire scientific community on a controlled basis. To enable such broad sharing, the data must be de-identified, formatted and accompanied by data dictionaries. The seeks funding from the private sector support the de-identification and data preparation process to allow these datasets to become available to the public and scientific researchers more quickly than would otherwise be possible.	Currently 23 Phase 3 Clinical Trial datasets have been selected by the NCI for de-identification, including data from approximately 34,000 patients. The FNIH transferred $230,000 to NCI in April 2019 to cover de-identification costs for the 23 datasets; de-identification is currently underway and data are being uploaded. Through Q4 2019, 9 of the 23 datasets with data from approximately 16,000 patients are now available to the public and scientific researchers that previously were not. The estimated total project budget is $683,953, of which $420,000 has been raised to date. The FNIH is actively exploring additional support for the project and sending updates on the project to the current funding partners.	$420,000.00	Sep-16

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Partnership for Accelerating Cancer Therapies - Implementation Phase	PACT Implementation	Recent cancer treatment success is driven by new immuno-oncology (IO) agents, leading large investment in the field. However, improvements in outcomes generated by the single agents are possible only for a minority of patients, and emerging data demonstrate the greatest impact on cancer treatment will be through combinations of agents both IO and non-IO. Successful pursuit of combination therapies is complicated by the sheer number of possible combinations, high biologic complexity, and the need for new translational biomarkers to guide patient treatment. To solve these challenges, a systematic cross-sector effort is required develop robust, standardized biomarkers to support selection and testing of combinations. The Partnership for Accelerating Cancer Therapies (PACT) is a 5-year collaboration totaling $220 million launched by the NIH/NCI, the FNIH, and 12 leading pharmaceutical companies (AbbVie, Amgen, Boehringer-Ingelheim, BMS, Celgene, Genentech, Gilead, GSK, Janssen, Novartis, Pfizer, and Sanofi) as part of the Cancer Moonshot. PACT will focus on efforts to identify, develop, and validate robust biomarkers "standardized biological markers of disease and treatment response"to advance new IO treatments. The partnership will be managed by the FNIH. The FDA and patient advocate(s) will serve in an advisory role.	The 2nd annual SITC Joint PACT-CIMAC-CIDC F2F Meeting was held 11/6-11/7/19 and was very successful. The second biospecimen tracking request was approved by the JSC on 11/7/19, the funds will be transferred after the start of the new year. Two new trials were presented to the JSC on 11/7/19 and have been partially approved for funding by the PACT JSC. SOWs for the first trial (S1400I) were written and executed by both MD Anderson and Mt Sinai. The first transfers of funds for these SOWs are in process. In preparation for the upcoming Go/No-Go Decision, calls were scheduled with all representatives from all 12 partner companies to hear their feedback and thoughts on the first 2 years of the project. As of the end of Q419, feedback had been received from 7/12 companies. The rest are scheduled for Jan 2020 prior to the end of Year 2. The CIMAC-CIDC Network began the development on a report on all their activities for the first two years of the project. A parallel report is being undertaken by the FNIH staff to report on the PACT JSC/WG/EC activities. Both reports will be delivered to all PACT members by 1/17/2020. The Go/No-Go Decision is scheduled for 1/24/2020.	$60,538,321.00	Feb-18
Predevelopment Pediatric Oncology	Pediatric Oncology	The overall purpose of this design phase will be to develop a viable PPP that will generate preclinical data to inform prioritization decisions about new anti-cancer agents considered potentially relevant to the growth or progression of one or more childhood cancers and to disseminate these data to all appropriate stakeholders. Results from the PPP may be used by regulatory agencies, biopharma companies, and academic researchers to inform decisions about which agents to clinically evaluate for specific childhood cancers to address the provisions in the FDA Reauthorization Act (FDARA) of 2017. Title V of FDARA amended the Pediatric Research Equity Act (PREA) to require "molecularly targeted pediatric cancer investigations", defined as clinical studies designed to yield clinically meaningful pediatric study data regarding dosing, safety and preliminary efficacy to inform potential pediatric labeling. The design and development of the PPP will be a collaboration with National Institute of Health, multiple biopharmaceutical companies, FDA, research foundations, philanthropies, and the FNIH.	An RFC was received from NIH to ask for FNIH's assistance with the design effort for this project on 04/12/19. The FNIH Board PPP committee reviewed and approved this proposal on 04/23/19. PhRMA provided $200,000 in support for this design phase with offer to further assist if needed. To begin the Design Phase, FNIH conducted 40+ introductory and working group calls with members of pharmaceutical companies, NCI, FCA, nonprofits, and other preclinical pediatric organizations. Information from these calls was parlayed into a 2-day in-person facilitated design session meeting on 09/05/19-09/06/19, which built consensus and helped to finalize the design of the potential public-private partnership. The FNIH then assembled writing teams after the in-person meeting and generated a first draft of a white paper that was circulated to all stakeholders on 10/18/19. Edits were gathered from all stakeholders and additional concensus calls were held and a second white paper draft was circulated on 12/07/19. The final white paper is targeted for completion by 02/02/20 and will be released to the stakeholders to determine support for implementing the full partnership as designed.	$200,000.00	Jun-19

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Rheumatology Adverse Events Due to Immunotherapy Observational Biomarker Study (RADIOS)	RADIOS	Rheumatic immune-related adverse events (rIRAEs) occur in patients after exposure to immune checkpoint inhibitors (ICIs) in the treatment of cancer. The pathobiologic, molecular and clinical features of these emerging rIRAEs are poorly understood, limiting rheumatologists' ability to select the most appropriate treatments for patients. Further research is required to understand mechanisms, determine risk factors and develop management algorithms for rIRAEs and their impact on patient burden and antitumor immunity. The goal of this project is to identify and validate: prognostic biomarkers for the development of inflammatory arthritis (IA); diagnostic biomarkers that assist with classification of rIRAEs; or susceptibility/risk biomarkers that could guide selection of appropriate immunotherapy treatment options to limit rIRAEs. These datasets would be generated through a multicenter consortium of academic rheumatology and oncology investigators who would clinically and biologically phenotype patients developing rIRAEs from cancer immunotherapy.	Although most prospective partners and donors, including rheumatology and immuno-oncology leaders at ten large pharmaceutical companies, expressed the need to better understand and identify biomarkers for the development of rheumatologic immune-related adverse events (rIRAEs) following immune checkpoint inhibition, all of these companies were doubtful in garnering funding support for the necessary multi-site infrastructure required to achieve the project's primary aims. Furthermore, several companies indicated that they were independently engaged in similar projects assessing immune-related outcomes from immune-oncology treatments. Through the Consortium's Cancer Steering Committee and Inflammation and Immunity Steering Committee leadership, FNIH engaged institute directors at both the National Cancer Institute (NCI) and the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), and reviewed the project aims with programmatic leads at the National Institute of Allergy and Infectious Diseases (NIAID). None of the ICs expressed interest in allocating existing NIH resources to support the infrastructure design and costs beyond submission for traditional NIH grant processes. Although there remains interest in the scientific aims of RADIOS, the financial support required to successfully launch the project does not appear to be a key funding priority for the organizations noted above. Per IISC leadership guidance, FNIH ceased further fundraising efforts on 10/29/19 and informed the PIs that the RADIOS project will not move forward under the Consortium. This change in status was also communicated to the Biomarkers Consortium Executive Committee, the IISC, the plan development team, and all other affected parties.	Fundraising efforts are underway	TBD
Stephen J. Solarz Memorial Fund	Solarz Memorial Fund	The Solarz Fund supports research in the laboratory of Dr. David Schrump at the National Cancer Institute. The Solarz Fund has raised over $304,000 since it was established in 2010. Funds have supported costs associated with Dr. Schrump's research using molecular biological techniques to manipulate DNA in cells taken from a patient's tumor to produce molecules that will stimulate the patient's immune system to kill cancer cells. Funds to also be used in support of International funding opportunities of post-doctorate scientists/researchers in the field of cancer.	FNIH transferred funds to NCI to establish the Solarz lab and fund an international fellow.	$657,862.44	Nov-10
The Lowy Cancer Research Support Fund	The Lowy Cancer Research Support Fund	Funds are for the discretionary purpose of Dr. Douglas Lowy, Acting Director of the National Cancer Institute to provide support to cancer program activities. These activities could include events, meetings, etc. which might include refreshments, travel or other support.	The FNIH supported the Rabson Memorial reception with these funds in partnership with the NCI.	$22,500.00	May-15
TLR Ligand Augmented, Tissue Homing AIDS Virus-Specific Adoptive Cell Therapy to Target Viral Reservoirs	CAR-T Targeting SIV Reservoirs	The study will evaluate an approach to target and reduce or eliminate persistent virus-infected T follicular helper cells (Tfh) in lymphoid tissue. Persistent virus infection of this cell type is thought to be an important component of the overall viral reservoir in HIV-infected individuals. The essential properties of this reservoir are recapitulated in rhesus macaques infected with a simian equivalent of HIV, designated Simian Immunodeficiency Virus (SIV). This study will characterize the role of persistent-infected Tfh cells in maintaining the viral reservoir in the most authentic animal model available. Furthermore, the study will provide a proof of concept for a promising immunotherapy approach to target this reservoir to achieve a more definitive treatment of HIV infection, and will have clear clinical translation possibilities.	After an extensive negotiation period (> 1yr) involving Gilead, Leidos, and the FNIH, an agreement was executed between the FNIH and Gilead on August 2, 2019. We have now turned our efforts toward finalizing the sub-award agreement (cCRADA) with Leidos. The cCRADA is under review for governmental approval at NCI/Leidos. The three-year project begins with the execution of the cCRADA.	$1,979,348.00	Jan-18

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Cancer Steering Committee Scientific Symposium	Biomarkers Consortium - 2019 CSC Scientific Symposium	The Biomarkers Consortium Cancer Steering Committee (BC-CSC) Annual Scientific Symposium brings together experts from academia, pharmaceutical companies, biotechnology companies, not-for-profit organizations, the National Cancer Institute (NCI), the US Food and Drug Administration (FDA), and other federal agencies. Together, they review advances in the field of biomarker and regulatory science relevant to the development of new public-private partnerships for biomarkers.	Following successful Symposia in 2017 and 2018, the CSC held the 2019 meeting November 4 and 5 in Bethesda, MD. A Save the Date was sent to 180 attendees including CSC members. Approval for the meeting, a draft agenda and a budget of $178,000 were approved by the EC on May 24. The Development team provided a draft agenda and high level overview to companies to initiate funding in Q2 2019 and obtained $134,000 in commitments over the summer. The Bethesda Marriott was contracted, prep calls arranged with speakers and the agenda finalized in October before the meeting. Almost 150 participants were in attendance in-person and by WebEx, with our highest WebEx attendance to date. A meeting survey, slides, and executive summary were shared with attendees after the event and a full summary will be circulated in Q1 2020 and posted to the BC website. Developmetn will provide follow up reports to donors and the events team is currently evaluating dates and venues for the 2020 meeting in November.	$130,400.00	May-19
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Adam Berry Memorial Fund	Adam J. Berry Memorial Fund	The Adam J. Berry Memorial Fund was established by Michael and Sue Berry in memory of their beloved son, Adam. Adam came from Australia to work as a research scientist at the National Cancer Institute at NIH. The fund commemorates his life and his enthusiasm for work by making it possible for promising young Australian scientists to travel to the United States and work at NIH.	2020 applications for the next Adam Berry fellow were submitted for consideration.	$22,522.00	Jan-03
Anita Roberts Memorial Fund	Anita Roberts Memorial Fund	Dr. Roberts was one of the first woman laboratory chiefs at NIH and ranked in the top 50 most-cited biological scientists in the world. She was widely recognized as an outstanding mentor, encouraging and inspiring young scientists. In recognition of her commitment to mentoring, Dr. Roberts' family and lab colleagues established scholarships to allow graduate students and post-doctoral fellows to present their work at a national meeting. Two travel scholarships are awarded to the TGF-beta Keystone Symposium held every other year. These scholarships are a fitting tribute to Dr. Roberts' passion for encouraging the career development of young scientists.	Four travel awards were given to attend the FASEB conference on TGF-Beta. Two were graduate students and two were post docs.	$60,628.10	Jun-06
Sallie Rosen Kaplan Fund for Women Scientists in Cancer Research	Kaplan Fellowship	The Kaplan Fund provides annual support for the Sallie Rosen Kaplan Fellowships for Women Scientists in Cancer Research. These post-doctoral fellowship awards are given annually to 10 outstanding woman scientists at the National Cancer Institute.	FNIH Staff submitted an end of year report on the Sallie Rosen Kaplan Postdoctoral Fellowships for Women Scientists in Cancer Research program.	$788,079.77	Jan-99

National Center for Complementary and Integrative Health

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Stephen E. Straus Distinguished Lecture in CAM	Straus Lecture	Established by Bernard and Barbro Osher in 2006, this fund honors the late Dr. Stephen E. Straus, the founding director of NIH's National Center for Complementary and Integrative Health (NCCIH). It supports the Stephen E. Straus Distinguished Lecture in the Science of Complementary and Alternative Medicine, an annual lecture that brings leading figures in science and medicine to NIH to speak about their perspective on the field of complementary and alternative medicine. Open to the public, the lecture is videocast and archived on the NCCIH website.	The 2019 Stephen E. Straus Distinguished Lecture in the Science of Complementary Therapies took place on September 23, 2019 as part of the NCCIH 20th anniversary symposium. This year's speaker was Dr. Lorimer Moseley, Professor of Clinical Neuroscience and Chair of Physiotherapy at the University of South Australia. Remarks were given by Dr. Mary Bitterman, president of the Bernard Osher Foundation.	$167,000.00	Jan-07

National Eye Institute

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Age-Related Eye Disease Study 2 (AREDS2) Ancillary Study	AREDS2 ancillary	The Age-Related Eye Disease Study (AREDS) was a major clinical trial designed to learn more about age-related macular degeneration (AMD) and cataract and to evaluate the effect of certain vitamins and zinc on the progression of AMD and cataract. Results showed that high levels of antioxidants and zinc significantly reduce the risk of advanced AMD and its associated vision loss. These same nutrients had no significant effect on the development or progression of cataract. In May 2013, the NEI completed AREDS2, which tested several changes to the formulation and found that while omega-3 fatty acids had no effect on the formulation, lutein and zeaxanthin together appeared to be a safe and effective alternative to beta-carotene. Funds raised by FNIH support development of a follow-on genetic study and analysis.	For the genetic study, funds raised by FNIH enabled NEI to collect DNA on 2,025 participants in AREDS2. A funding balance remained at the close of the study. In 2017 NEI indicated that further genetic testing and work was planned. A 10-year follow-on study was designed to examine the long-term effects of oral supplements of lutein and zeaxanthin and omega-3 long chain polyunsaturated fatty acids (LCPUFAs) on the incidence of lung cancer, development of late age-related macular degeneration (AMD), cataract surgery, cognitive function scores, and incident cardiovascular events. To support the study, the FNIH transferred the final balance of $381,764 to the NEI in November 2017. Data collection was completed in late 2018 and a publication is expected in early 2020.	$990,005.00	Apr-10
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Dr. Jane M. Sayer Vision Research Lecture & Award	Sayer Vision Research Lecture & Award	The Sayer Vision Research Fund supports the annual Sayer Lecture delivered by an investigator in the area of vision research. The fund also supports the Sayer Vision Research Award, a grant-in-aid to support the research of a promising independent investigator in the early stage of his or her research career in the Division of Intramural Research at the National Eye Institute.	FNIH staff reached out to NEI to inquire on the next Sayer Vision Lecture Award.	$381,368.43	May-20
Endowments					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Joram Piatigorsky Basic Science Lecture and Award	Piatigorsky Basic Science Lecture and Award	The aim of the Lecture and Award is to bring attention to notable basic science contributions by vision and eye scientists to a diverse general scientific audience, like molecular biology, genetics, developmental biology and computer science. This differs from the more common research themes in eye biology, vision and ophthalmology, which emphasize discoveries in the general sciences that have led to advances in eye biology and medical treatments.	This is a new fund.	Fundraising efforts are underway	Sep-20

New Projects

National Human Genome Research Institute

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Genome Research Fund	Genome Research Fund	As a part of its outreach efforts to individuals who may be interested in supporting NIH and, more specifically, the work of NHGRI, this Fund was established in January 2013 to hold contributions received to support genetics/genomics research. Contributions may be designated simply for "genetics or genomics research" or, if desired by the donor, for more targeted initiatives underway at NIH. The Foundation will work with NHGRI to determine how this growing pool of general funds might best be applied whether through fellowships, as project seed funding, or through another mechanism.	No recent activity.	$2,735.00	Oct-11
The NIH Undiagnosed Diseases Program	UDP	The UDP diagnoses patients who have long been unable to find any diagnosis, to discover new disorders that will provide insight into biochemical and cell biological pathways, and to bring genomics to modern medicine, especially in the area of rare diseases. It fosters personalized medicine. The FNIH would serve as a conduit for donations of funds and services; i.e., in-kind such as software packages and expertise.	FNIH continues to include the Undiagnosed Disease Program (UDP) among the programs it discusses with potential donors who may find it to be of interest.	$5,583.00	Sep-11
Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Human Genome Exhibition	Human Genome Exhibition	In June 2013, the National Human Genome Research Institute (NHGRI) and the National Institutes of Health (NIH), in partnership with the Smithsonian Institution, celebrated the 10th anniversary of the sequencing of the human genome and the 60th anniversary of the Watson-Crick discovery of DNA's structure with a major exhibition initiative, Genome: Unlocking Life's Code, at the National Museum of Natural History. Through high-tech, hands-on interactive activities and educational programming, Genome celebrates the advances related to the sequencing of the human genome, and helps make genomics accessible, understandable, and exciting to the general public. More than just an exhibition within the walls of the Museum, the project includes a large-scale, multi-platform educational effort that is communicating how genomic science, and the era of personalized medicine is playing, and will continue to play, a critical role in our everyday lives and health care.	GENOME: UNLOCKING LIFE'S CODE September 21, 2019 - January 2, 2020 Turtle Bay Exploration Park 844 Sundial Bridge Drive Redding, California 96003 https://www.turtlebay.org	$1,155,000.00	Oct-11

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
2019 International Summit in Human Genetics and Genomics	2019 International Summit in Human Genetics and Genomics	The International Summit in Human Genetics and Genomics is a five-year initiative (2016-2020) designed to help developing nations build and expand their knowledge base, infrastructure, systems and technologies in genetics and genomics. Each fall, researchers from abroad travel to the National Institutes of Health in Bethesda, Maryland for one month of in-person training at the National Human Genome Research Institute (NHGRI). The Summit helps them to understand the prevalence and basis of genetic diseases in their nations and to address these public health challenges. The 2019 Summit will be held on August 28 - September 28, 2018. Genetic disorders contribute significantly to the world's burden of disease. Many countries do not have genetically trained researchers and healthcare professionals available to address this burden, or the training to correct this deficit. As a consequence, opportunities to reduce the burden of disease are frequently missed. Acquiring and applying knowledge about genetics and genomic research through training programs like the International Summit makes it possible to anticipate, prevent, diagnose and treat many genetic and congenital birth defects, alleviating the burden these diseases have on individuals, their families and their nations. Outcomes from the 2016, 2017 and 2018 Summits have been remarkable. Participants have established over 50 collaborations with investigators at NIH, at other US-based academic institutions and among themselves. Over 140 articles have been published and over 25 have received grants from NIH or other funding institutions. Based on Summit survey feedback and the annual outcomes on the Summits, the Summit has trained 71 professionals from 37 countries and is making great strides in achieving its goals.	The 2019 Summit took place from August 28 - September 28, 2019. 37 candidates from over 20 countries participated. Sponsors included: American College of Medical Genetics and Genomics, American Society of Gene & Cell Therapy, American Society of Human Genetics. Mayo Clinic, Sanford Health, and Sarepta Therapeutics.	$ 35,000.00	Dec-19
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
2020 International Summit in Human Genetics and Genomics	2020 International Summit in Human Genetics and Genomics	The International Summit in Human Genetics and Genomics is a 5-year initiative (2016-2020) designed to help developing nations build and expand their knowledge base, infrastructure, systems, research efforts and technologies in human genetics and genomics. Increasing their access to these resources will help them build capacity in these areas and will help resource-poor countries address their public health challenges in genetic diseases. This will ultimately help build healthier nations worldwide. The 2020 Summit will occur on August 31 - October 1, 2020.	The FNIH is developing a Collaboration Agreement with NHGRI to lead fundraising efforts and provide assistance with hosting the 2020 International Summit. Efforts to secure sponsorship support with begin once the agreement is finalized, likely in Q1.	Fundraising efforts are underway	TBD

New Projects

National Heart, Lung, and Blood Institute

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Atherosclerosis In Silico Modeling (Metabolic Disorders)	Biomarkers Consortium - Atherosclerosis In Silico Modeling	This project seeks to integrate multiple biomarkers for atherosclerosis outcomes into a computer-based mechanistic model to predict residual cardiovascular risk following statin treatment, that allows selection of high risk patients in clinical trials. The project's goal is to identify a time-dependent, dynamically-responsive panel of extant markers that change in response to Phase II intervention and predict Phase III clinical cardiovascular outcomes to build the model. This model would support cardiovascular drug development decision-making and assessment of atherosclerotic risk in the development of drugs for other indications. In addition, the project would provide a basis for future development of consortium-based mathematical models of disease. The Atherosclerosis in Silico Modeling Project is a $2.7M project. It was launched in 2012, and was interrupted due to vendor issues and resumed activity with a new vendor, Evidera in 2015.	The Core Team has completed the methodology and modeling process using published data sets and individual level data from MESA/FHS cohorts (NHLBI, NIH) and TNT (Pfizer) to identify a time dependent group of biomarkers that predict change in clinical outcomes in atherosclerosis due to statins and residual risk after statin treatment. Resulting Project Report describes the central applications of the model in clinical trial design. The project is closed and the team is in the process of financial reconciliation.	$1,754,000.00	Jul-12
Biomarkers Consortium - Novel Cardiac Biomarkers in the General US Population	Biomarkers Consortium - Cardiac Troponin Biomarkers	The main goals of the Cardiac Troponin Biomarker Project are: 1) to define the reference ranges for novel cardiac biomarkers (BM) in a young healthy subgroup of adults and to describe the normal BM variation; 2) to characterize the cross-sectional associations of these novel BMs with other novel diabetes, kidney disease and cardiovascular disease risk BMs and 3) to characterize their associations with total mortality while comparing them head to head in their effectiveness for mortality risk prediction. The project will conduct a comprehensive national study, utilizing existing stored blood and urine specimens and data from NHANES (NCHS,CDC), providing key reference data and informing recommendations and clinical guidelines regarding the use of these BMs. The Cardiac Troponin project plan was approved by the Metabolic Disorders Steering Committee in late 2013 and by the Executive Committee in June 2014.The project was launched in January 2016 and is scheduled to complete by January 202	The investigators have collaborated with statisticians at the CDC/NCHS to finalize the pull-list and to identify the specimens from The National Health and Nutrition Examination Survey (NHANES) repository that will be retrieved for the project. The UMD laboratory has received all testing reagents. Due to unforeseen challenges (laboratory fire followed by some sample shipment discrepancies), the testing has been delayed. UMD Labs have received all samples and analyzed ~4500 of the ~25000 samples.Data sharing agreement was signed with NCHS and merging of de-identified NCHS data files is completed. A QC analysis in pooled samples demonstrated the high reliability and validity of all laboratory test analytes with concentrations falling within expected range. Transfer of final laboratory test result files to JHU and the successful linkage of final data files to mortality follow up data from the National Death Index, is currently in process. The team has received presently a total of 2,500 samples. Given this increased sample load and delay in start up, the Project Team has granted a NCE until April 2021. A F2F Project Team meeting was held in November 2019 in Philadelphia as a side bar conversation to the AHA. The team discussed next steps for the last 15 months of the project including publications.	$1,325,000.00	May-13
Dean R O'Neill Renal Cell Cancer Research Fund	O'Neill Memorial Fellowship	This memorial is in honor of Mr. Dean O'Neill, who, before he passed away, was treated for renal cancer by Richard Childs at NHLBI. FNIH is working with the O'Neill family to raise additional funds to support a post doctoral fellow to work in Dr. Richard Childs' lab, focusing on renal cell cancer research. The goal of this program is to provide critical person-power to accelerate the search for new breakthroughs in the treatment of kidney cancer. With significant contributions from individual donors and the BOO! Run For Life 10K, these funds sponsor a dedicated fellowship program to support the exploration of new and existing treatments, such as allogeneic stem cell transplantation, chemotherapy, radiation therapy, immunotherapy, vaccine therapy, and drug treatments. This program is managed by NHLBI with the support of FNIH.	The 14th annual BOO! Run for Life and Tidal Basin Walk took place October 6, 2019. Among the particpants were Dr. Childs and the O'Neill/Rancic fellow, Stefan Barisic.	$674,273.26	Dec-03
Dr. Edward T Rancic Memorial Fund for Cancer Research	Rancic Memorial Fellowship for Cancer Research	The Dr. Edward T. Rancic Memorial Fund supports a post-doctoral fellowship in Dr. Richard Childs' lab that focuses on renal cell cancer research. The fellowship was established by the family in memory of Dr. Edward Rancic.	FNIH has reached out to Bill Rancic to update on FNIH programming. Working with Brian O'Neill and Dr. Childs to engage.	$156,475.20	Jul-04

National Institute on Aging

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Alzheimer's Disease	AMP - AD	In early 2014 a final research plan for AD was completed through AMP-AD Steering Committees, including representatives from AbbVie, Sanofi, Biogen Idec, GlaxoSmithKline, and Lilly as well as members from government and advocacy sectors. The AMP AD effort comprises two projects: Project A will supplement the biomarker panels already included in three NIH-funded Phase II/III registration trials in presymptomatic AD through the addition of tau PET imaging and novel fluid biomarkers. Project B will apply integrated network analysis (both RNA and proteomic studies) in human AD brain samples to identify biologic nodes and and networks linked to the development or progression of AD and create standardized open-source data structures and formats for easy analysis of biological data.	Overall, there has been continued progress in both Project A and Project B of AMP-AD over the past 5 years – milestones have been met and some have been expanded thanks to additional NIA funding. For Project A: For A4, trial enrollment is complete, and a milestone has been achieved: quantitative pre-randomization data is now available (LONI). Process to de-identify and share raw imaging and GWAS data and distribute biosamples is in progress. The academic and private partners teams continue to interact within the consortium-wide working groups, at the in-person meetings and informally. The key deliverable of the present funding period for the Project B has been the development of a data-driven process for selection and prioritization of candidate targets along with a web-based tool (Agora) that will make the candidate targets with associated annotation and consortium-wide analytical outputs broadly available. Unparalleled resource for research and drug development on AD and other neurodegenerative disorders. New NIA funding for round 2 of AMP AD with new awards announced September 2018. The FNIH is working on the development of AMP AD "2.0" with coordinated activities with NIA and interested private partners. A face to face was held in Bethesda, MD on November 7th finalizing the prioritization and details on budget, timelines and quantifiable success criteria for the research plan. The technical working group has been working on the finalization of the research plan. A final plan is expected for February 2020.	$24,263,000.00	Oct-12
Alzheimer's Disease Neuroimaging Initiative - Amyloid PET Early Frames Add on Study	ADNI - Amyloid PET Early Frames Add on Study	The project is an add on study to the Alzheimer's Disease Neuroimaging Initiative (ADNI) third phase.The overall goal is to obtain a PET measure reflecting cerebral blood flow in ADNI participants by collecting amyloid PET data immediately after injection of an amyloid tracer.The project proposes to use up to 200 ADNI subjects distributed across the diagnoses of normal, mild cognitive impairment, and Alzheimer's Disease.The observations from this Project have two potential uses in clinical studies. One is that acquisition of early frame data can be used to derive a "functional" measure of cerebral blood flow that may change differently over time and may reflect effects of treatment that differ from measures of amyloid accumulation.Second, the measures of tissue perfusion can potentially be used to "correct" the amyloid deposition images obtained at later time points, in order to remove the effects of perfusion changes over time that might particularly affect longitudinal measurements.	The NIA approved the supplement application for the study in August, and 2 sites have been approved by the IRB to begin enrolling for this add-on study. It's expected that the first 25 subjects will be enrolled by Q1 2020.	$825,000.00	Jan-19
Alzheimer's Disease Neuroimaging Initiative 3	ADNI 3	ADNI 3 is the extension of the ADNI study for an additional five years (August 1, 2016 - July 31, 2021). ADNI tracks volunteers at 60 clinical sites in the United States and Canada with normal cognition, mild cognitive impairment and Alzheimer's disease to create a widely-available database of imaging, biochemical and genetic data. Additions to ADNI 3 include recruiting 1,200 volunteers to join about 800 current participants to enrich the existing dataset, tau PET imaging, and cutting edge systems biology analyses. ADNI 3 also will assess cognitive function through computer tests at home and in the doctor's office and measure changes in subjects ability to handle money, which can be a warning sign of the disease.	Program activities for ADNI3 have continued, including monthly ADNI PPSB Teleconferences. ADNI 3 continues to focus on patient recruitment – particularly for MCI, AD, and minority enrollment with the goal of finalizing enrollment in Q1 2020 to allow more than the originally targeted 968 subjects. The Spring Face to Face meeting is scheduled for May in Washington D.C.	$15,108,181.75	Aug-15

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Inflammatory Markers for Early Detection and Subtyping of Neurodegenerative Disorders	Biomarkers Consortium - Inflammatory Markers for Neurodegenerative and Mood Disorders	There is an acute need for biomarkers for diagnosing and subtyping patients with neurodegenerative disease and psychiatric disorders. CSF and plasma measurements of inflammatory markers represent an easily accessible biomarker opportunity with great potential, but require a harmonized, well-designed approach for sample collection, handling, and evaluation. While aberrant levels of inflammatory markers have been observed in patients, meta analyses of published studies show small effect sizes and large confidence intervals due to small sample size and the absence of a uniform analyte panel. Using technically well-validated, highly sensitive assays that operate in the linear range for biomarker quantification, and appropriately powered and harmonized sample collection and handling procedures, this 4-year Biomarkers Consortium project is expected to identify and validate plasma- and/or CSF-based multi-marker inflammatory biosignatures in Alzheimer's Disease and Major Depressive Disorder.	For Aim 1, all the assay validation work has been completed. The additional transferrin based interference testing was completed, allowing for a quantitative measure of whole blood contamination for both Aim 1 and Aim 2 sample testing. The University of Gothenburg has provided CSF samples from Control, MS and AD populations for Aim 1. As Janssen could not relinquish the samples to the FNIH, we are in active negotiations with other sources of samples (CAN-BIND, Emory, and NYU). Aim 1 is expected to be completed by March 2020. The project team has begun preparations for Aim 2 testing. The Wellcome Trust and a UK CRO have been identified forthe analysis of MDD plasma samples for Aim 2 and the contract negotiations have begun. For the Aim 2 AD samples, the team is currently drafting the application for the samples. Aim 2 is expected to begin in Q2 2020 and finalize in Q3 2020.	$1,182,205.00	Dec-16
Biomarkers Consortium - Plasma Aβ as a predictor of amyloid positivity in Alzheimer's disease	Biomarkers Consortium - Plasma Abeta project	The objective of the current proposal is to apply the next generation of plasma amyloid beta assays to determine whether low plasma Abeta42/Abeta40 ratios increase the probability of identifying patients with amyloid positivity. Such a test could significantly improve clinical trial screening efficiency and reduce clinical trial costs for early Alzheimer's Disease. Additionally, this would decrease patient burden by limiting the number of lumbar punctures and PET scans needed for trial enrollment. This study aims to independently validate recently published findings by performing a head-to-head comparison of the most promising Abeta plasma measurement techniques in well characterized sample sets with comprehensive clinical data along with Amyloid PET and/or CSF data available for confirmation and analysis.	The Plasma Abeta project was approved by the Biomarkers Consortium Executive Committee on December 3rd, 2018. The project has a final budget of $2,010,467. To date, LOAs are finalized with five funders (AbbVie, Takeda, Janssen, Alzheimer's Association, and Biogen) and we are fully funded. There is, however, one additional prospective funder (ADDF) with which we are currently negotiating the LOA. Additionally, agreements have been finalized for four of the vendors and two are out for signature. Agreements are underway for the donated pooled plasma samples from AbbVie and Takeda. The application for samples in Study 1 was approved by the ADNI RARC Committee. The Working Group is in communications has had identified TRC-PAD (ATRI @ USC) as the sample source for Study 2 and we have met a verbal agreement to collaborate and agreements are being drafted. The project is poised to launch in early February.	$2,001,433.00	Apr-19
Mechanisms of Cognitive Remediation in Older Adults	Mechanisms of Cognitive Remediation in Older Adults	The vast majority of older adults experience some deterioration in cognitive function as they age. This initiative supports an intervention trial to remediate or prevent age-related cognitive decline. A key goal is to encourage therapeutic approaches that aim to drive beneficial plasticity of the aging brain and require investigators to monitor plastic changes through behavioral and biological markers. The McKnight Brain Research Foundation (MBRF) is the private funder/partner and committed $5 million to this effort. NIA's investment brings the total project funding to $15M.	FNIH entered into a Memorandum of Understanding (MOU) with NIA for this project in August 2013 and finalized its Letter of Agreement with the McKnight Brain Research Foundation (MBRF) in October 2013. NIA made a five-year grant award of $15M in late 2014 to fund a multicenter clinical research trial in cognitive aging: "Remediating Age Related Cognitive Decline: Mindfulness-Based Stress Reduction and Exercise." The Principal Investigator is Eric J. Lenze, MD, of the Washington University School of Medicine. NIA awarded a no-cost extension to the investigators through 2019. A final report is expected in 2020.	$5,000,000	Jan-08
Research Partnership in Cognitive Aging 3	Research Partnership in Cognitive Aging 3	With joint support from the McKnight Brain Research Foundation and the National Institute on Aging, this initiative will funds a new 5-year program in cognitive aging research, overseen by the NIA. It is expected that an RFA will be released in 2019.	The FNIH and MBRF entered into a 5-year, $5M commitment to support this program in 2018. NIA's timelines for an RFA have been delayed, and the program timeline has been adjusted. The RFA's release is expected in 2020.	$5,000,000.00	Nov-20

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
2019 Geroscience Summit	2019 Geroscience Summit	The 2019 Geroscience Summit will be hosted by the National Institute on Aging (NIA) in collaboration with the National Institute on Aging (NIA) and held November 4-6, 2019 at the Natcher Auditorium on the NIH Campus. The third in a series organized by the trans-NIH Geroscience Interest Group (GSIG), the Summit will build on the 2017 Geroscience Roundtable, which the FNIH helped to organize. The event will provide a forum for sharing information about the latest advances in geroscience, as well as engaging disease-focused professional societies and foundations that have not been integrally involved in geroscience research.	The NIH Geroscience Summit took place on November 4-6, 2019 on the NIH campus in Bethesda, MD. Sponsors included: the Alliance for Aging Research, Alkahest, the American Federation for Aging Research, the American Society of Clinical Oncology, Glenn Foundation for Medical Research, Regeneron Pharmaceuticals and The Shiley Foundation.	$82,500.00	Apr-19
National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers	National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers	The National Institute on Aging is hosting its second National Research Summit on Dementia Care: Building Evidence for Services and Supports, to be held on March 24-25, 2020 in Bethesda, Maryland. The Summit will build on the foundation laid by the 2017 National Research Summit on Dementia Care. Through the Summit, the National Institute on Aging seeks to accelerate the development, evaluation, translation, implementation and scaling up of evidence-based and evidence-informed services for individuals with dementia, their family and caregivers. The Summit will bring together experts in research on care, services and supports in order to develop recommendations for research that will inform annual updates to the National Plan to Address Alzheimer's Disease and advance both public sector and private sector delivery of services.	The FNIH is finalizing the Collaboration Agreement with NIA to lead fundraising efforts and provide assistance in planning the event. The Office of Development will engage in efforts to secure sponsorships in Q1 of 2020.	Fundraising efforts are underway	TBD

New Projects

National Institute of Allergy and Infectious Diseases

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Developing Endpoints for Clinical Trials in CABP and Skin Infections	Biomarkers Consortium - CABP - Skin Infections	The goal of this project is to develop approaches that will help the FDA develop efficacy outcome measures (endpoints) for modern-day clinical trials of investigational agents for community-acquired bacterial pneumonia (CABP) and acute bacterial skin and skin structure infections (ABSSSI) that can be tied to historical data in each indication, thereby providing the basis for sound non-inferiority (NI) trial design and NI margin justification. A key deliverable includes the development and content validity of a Patient-Reported Outcome (PRO) instrument for CABP and ABSSSI to use as a tool to assess how a patient feels, functions and survives in anti-infective clinical trials and studies. The project launched in January 2012.	Both the CABP (Pneumo-PRO) and ABSSSI (SKINFECT-PRO) patient reported outcome (PRO) instruments are complete, copyrighted, and FNIH has established a licensing agreement with the MAPI Research Trust to distribute and manage the use of these clinical tools to the field. In collaboration with FNIH, MAPI Research Trust is planning a live webinar in Q2 2020 to highlight the availability of the instruments and their utility in clinical trials. ICON received a FDA BAA award to support the psychometric validation of the PROs, however with challenges in patient enrollment and inclusion criteria, the FDA has ended its contract with ICON due to slow recruitment. Currently, ICON and the FNIH Project Team are beginning to close out the contracts for the project.	$820,000.00	Jan-11
Biomarkers Consortium - HABP/VABP Working Group	Biomarkers Consortium - HABP/VAPB	The goal of this project is to 1) develop reliable, well-defined, clinically relevant endpoints for Hospital-Acquired Bacterial Pneumonia (HABP) and Ventilator-Associated Bacterial Pneumonia (VABP) and 2) develop at patient reported outcome that measure tangible benefits for patients in terms of how they feel, function and survive. Currently, there are limitations in the information to quantitatively assess the effect of antibacterial drug treatments vs. no treatment or placebo and in comparisons between active agents. These undefined clinical endpoints impede the field of drug development for these indications and limit the ability to perform clinical trials in this area. The lack of outcome measures impedes patient care since clinicians and patients cannot understand similarities and differences between therapeutic agents that are not measured in a well-defined, reproducible and clinically relevant manner.	The HABP-VABP Project had completed its primary aim with the FDA docket submission to provision strategies for HABP and VABP clinical trial design and provide an update to the symptomatic endpoints for these disease indications. The submission occurred on June 5, 2017 and the results of the project were presented at ECCMID in April of 2018 and now published in January 2019 in the Journal of Infectious Disease (JID). The manuscript was in the top 10 downloaded articles in the last two years for JID. The FNIH Project Team also had developed a draft HABP PRO instrument and completed content validity in partnership with ICON plc. The HABP PRO content validity established that patient responses of how they feel, function, and survive were very strongly aligned with CABP and therefore the Pnemuo-PRO tool would also support HABP populations. The team is working on a publication and guidance documentation to support the use of Pneumo-PRO in HABP clinical trials.	$361,500.00	May-13
Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine	Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine	The proposal objectives are to identify epitopes for broadly effective antiodies against influenza A and B that are most suitable for vaccine elicitation. Employ antigenically-assessed structural mimics (created in multivalent formats) to elicit antibodies capable of neutralizing diverse influenza viruses. And lastly, optimize iteratively target antibody responses to achieve titers in animals that protect from diverse influenza virus challenge.	The Flu Project Grant Agreement was officially executed in August 2019. Thereafter we diligently worked to execute a sub-award agreement with Columbia University in December 2019 and an MOU agreement with NIAID in January 2020. The research has started, and we have realigned the two-year timeframe accordingly.	$1,750,000.00	Aug-19
Comprehensive Cellular Vaccine Immune Monitoring Consortium	CCVIMC	The goal of this program is to provide high-quality cellular immune monitoring to the Collaboration for AIDS Vaccine Development (CAVD), a consortium of consortia funded by the BMGF to discover, test and develop candidate vaccine strategies to prevent the transmission of HIV. The Comprehensive Cellular Immune Monitoring Consortium (CCVIMC) provides a coordinated effort for assessing vaccine-elicited T and B cell responses in humans and nonhuman primates that facilitates the sharing of standardized data sets and allows for data mining capabilities. In the current iteration of the program (third 5-year grant), both T and B cellular immune monitoring assays are being improved and new tools are being developed through the application of cutting-edge technologies. In addition to taking the lead role in administrative oversight of the entire operation, the Foundation for the NIH provides scientific project management support to lead scientific director and consortium PI, Richard Koup (VRC/NIAID).	Work at the VRC is investigating a purported synergistic host immune response to passive immunizations, referred to as vaccinal effects. This important work will help to clarify some early reports which hadn't been substantiated. Many clinical trials are currently investigating passive immunization with broadly neutralizing antibodies (bNAbs) or bNAb combinations for protecting people from acquiring HIV. The B cell Analysis Core at the VRC has completed the analysis of samples from the first arm of a dose-escalating clinical trial designed to stimulate and clonally expand B cell lineages that could eventually give rise to VRC01-class of bNAbs. The early data will help researchers to assess the ability of vaccine to elicit the desired responses and, through the molecular identification of antigen-specific B cells, will play a critical role in informing the design of the follow-on antigens used to guide the cellular immune response to selectively expand those B cells capable of producing the desired bNAbs. This novel vaccine strategy has become a priority at the BMGF and the B cell Analysis Core has been asked to take a lead role in the design and analysis plan for a second clinical trial funded by the BMGF. The FNIH has applied for ~$6MM supplement to support these efforts at the VRC.	$10,716,282.00	Jul-16

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Developing leads to shorten duration of TB chemotherapy: SHORTEN-TB	SHORTEN-TB	SHORTEN-TB will build upon the lessons learned from HIT-TB and from other recent advances in our understanding of the rate-determining lesions in determining the treatment shortening potential of individual TB drug series as early as possible. We will progress advanced series from the HIT-TB program that are predicted to be associated with those characteristics that define agents with potential to shorten the duration of chemotherapy based on clinical evidence (oxazolidinones) or mechanistic novelty where the engaged targets are predicted to be essential in the context of human pathogenesis.	In November 2016, FNIH was awarded a grant from the Bill & Melinda Gates Foundation to manage the SHORTEN-TB project. In addition to the NIAID, the sub-awardee partners are based in the UK, Germany, and South Africa. The group ratified a Research Collaboration Agreement in May 2017. The project held annual team meetings of the collaborating partners in Cape Town, South Africa and in Saarbrücken Germany. The year 2 annual progress report was submitted in February 2019 to the Gates Foundation. The grant was approved for a no-cost extension to July 31, 2020.	$7,575,351.00	Nov-16
Global Health Fund	Global Health Fund	FNIH has many programs at work in dozens of countries around the world as well as across the United States. The programs aim to alleviate wide spread suffering and death from diseases such as malaria, enteric infections and HIV, as well as train researchers and medical personnel in the developing world. The Global Health Fund was established by FNIH in January 2013. Contributions directed to this fund will be used within the global health field as directed by FNIH.	No recent activity.	$4,495.00	Jan-13
Onchocerca volvulus-specific biomarkers for macrofilaricidal activity	Ov Biomarkers	This project aims to develop detection systems for parasite-specific biomarker(s) present in human subjects with viable adult females of Onchocerca volvulus (Ov) and to demonstrate their disappearance/diminution after drug administration targeted against these adult parasites. This would be a final and necessary tool in the progress towards elimination of onchocerciasis, an important neglected tropical disease.	The FNIH was awarded a grant from the Bill & Melinda Gates Foundation in August 2018. The project supports two partner institutions through sub-award agreements with the NIAID and New York Blood Center. The first year interim report was submitted in February 2019 to the Gates Foundation. The grant was awarded a no-cost extension through June 2020.	$340,616.00	Aug-18
Structure-based Vaccine Design Against HIV-1	Structure-based HIV Vaccine Design	This project evaluates structure characteristics of the trimeric envelope proteins from newly transmitted HIV-1 (transmitted-founder [T/F] HIV-1) that are susceptible to broadly neutralizing antibodies (bNAb) and bind to the B cell receptors of naïve B cells in corresponding lineages. Using this information, proteins will be engineered and evaluated for immunogenicity. Promising candidates will be engineered into a vector-based delivery system and evaluated for induction of protective immunity in small animal and non-human primate models. The project takes advantage of a longitudinal study that has been monitoring a high-risk population in China and aims to develop candidate vaccine immunogens that will elicit bNAbs to the locally circulating HIV strains.	A structure-based HIV vaccine design strategy is a more sophisticated approach to development of broadly protective vaccines against HIV-1 than the traditional approach which can proceed with a limited understanding of the molecular mechanisms involved in protection. The project has successfully identified stable trimeric HIV-1 Env from clades AE, BC, and B as diverse primer/boost reagents, explored the effects of the transmembrane domain on the immunogenicity of genetically delivered HIV-1 trimers and performed studies that enables the presentation of identified immunogens on nanoparticle platforms for enhanced immunogenicity. Antigen testing in animal models is expected to be completed before the end of the new year.	$602,859.00	Mar-17
Understanding NHP protection against TB induced by intravenous BCG	TB Vaccine	Two billion people worldwide are infected with Mycobacterium tuberculosis (Mtb) resulting in 10 million cases of clinical disease and 1.5 million deaths each year. The hurdles for developing a highly protective and durable vaccine against Mtb require addressing four central tenets of T cell immunology – magnitude, quality, breadth, and location of the response. These specific elements of the problem will be addressed by focusing on how changing the dose and route of administration from intradermal (ID) to intravenous (IV) greatly increases the vaccine's ability to protect rhesus macaques from infection following exposure to Mycobacterium tuberculosis (Mtb), the bacterium that causes	The FNIH received an award in August 2018 from the Bill & Melinda Gates Foundation for the TB Vaccine project. The FNIH has negotiated sub-award agreements with NIAID and the University of Pittsburgh for the project. In March 2019, the FNIH posted a web announcement (https://fnih.org/news/announcements/tb-vaccine) to highlight the official launch of the TB Vaccine project. A meeting on Animal Models for Tuberculosis Vaccine Development was held in September 2019. In January 2020, a Nature publication, "Prevention of tuberculosis in macaques after intravenous BCG immunization" highlighted data and results from the previous study with our collaborators at NIAID and the University of Pittsburgh. Those findings led directly to the the current TB Vaccine project.	$3,331,037.88	Jul-18

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Using Biomarkers to Predict TB Treatment Duration	PredictTB	This is a prospective, randomized, noninferiority phase 2b clinical trial of pulmonary drug sensitive TB subjects in South Africa and in China. PredictTB makes use of state-of-the-art tools (specifically, PET/CT imaging and GeneXpert) to identify participants with a lower burden of disease , and will test whether treatment can be shortened to 16 weeks in this lower risk cohort. The study hypothesizes that a combination of microbiological and radiographic biomarkers will identify patients with tuberculosis who are cured with 4 months (16 weeks) of standard treatment.	The PredictTB trial officially commenced on June 19, 2017, with patient enrollment starting at the South African sites. Patient enrollment in China began on October 18, 2017. The Data and Safety Monitoring Board met on October 10, 1018 to assess the performance of overall study operations. The annual team meeting of the PredictTB trial consortium was held in Shanghai, China on May 23-25, 2019. The Data and Safety Monitoring Board met in November 2019. The board will meet again in March 2020 to appraise safetly before patient recruitment is complete. The next meeting of the PredictTB trial consortium is scheduled for April 2020 in South Africa. Current news and updates are posted on the project's public website (predict-tb.com).	$12,932,525.00	Nov-16
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
African Centers of Excellence - Uganda	ACE - Uganda	The National Institute of Allergy and Infectious Diseases will establish a bioinformatic center, the African Centers for Excellence, in Kampala, Uganda. The program will create a tele-learning center at Makerere University that provides high-performance scientific computing infrastructure, a "Collaboratory" space for consultations and a virtual reality-based laboratory, for students studying to receive a graduate degree in bioinformatics.	Letter of Agreements are being negotiated with the following partners: BioTeam, the Infectious Diseases Institute, Makerere University, Research Education and Network for Uganda, and the Texas Advanced Computing Center. The following LOA has been finalized: Enduvo. The FNIH has drafted the NIAID-FNIH ACE-Uganda Memorandum of Understanding.	Fundraising efforts are underway	Feb-19
Pew Latin American Fellows in the Biomedical Sciences Program	Pew Latin American Fellows	The Pew Latin American Fellows in the Biomedical Sciences program has awarded a Pew Latin American Fellows award to support the research of several post-doctoral fellows within a laboratory at an NIH institute. The Pew Charitable Trusts asked to use the FNIH as a conduit to provide awards to the Fellows.	FNIH currently manages three Pew Latin American Fellow awards: 1) Dr. de Andrade-Oliveria, who is currently conducting his fellowship at NIAID. 2) Dr. Djalma de Souza Lima Junior, NIAID, 3) and Dr. Diego Fernandez, NIMH. Pew has issued a one-year no-cost Amendment for Dr. Diego Fernandez's research grant (through 2020).	$572,250.00	Aug-09
Roth Fellowship for CAEBV-HV Research	Roth Fellowship for CAEBV-HV	Richard and Susan Roth are donating to fund a 2 year Fellowship in the lab of Dr. Jeffrey Cohen of NIAID. The Fellow will conduct research to accelerate efforts to find new drugs to treat Chronic Active Epstein Barr Virus (CAEBV) and Chronic Active Epstein Barr Virus-Hydroa Vacciniforme (HV) as well as find and understand genetic causes of the diseases to lead to new treatments. Richard and Susan Roth's grandson, Aiden Aronoff, suffers from CAEBV-HV.	FNIH Staff met with Mr. Roth to discuss a program update.	$105,200.00	Feb-14
Swanson Family Fellowship in Genetic Thyroid Benign Chorea & IgA Deficiency (TTF-1)	Swanson Family Fellowship	The Swanson Family Fellowship supports research in TTF-1 Mutation Causing Benign Chorea in the laboratory of infectious diseases under the direction of Steven M. Holland, M.D., Chief of the Laboratory of Clinical Infectious Diseases at the National Institute of Allergy and Infectious Diseases at NIH.	Dr. Steven Holland of NIAID provided an update of needs in his laboratory that might be supported by the Fund. FNIH sent the donors a proposal for use of the funds. FNIH Advancement staff continue periodic outreach efforts to the Swanson Family regarding their gift.	$92,500.00	Oct-06
The Dr. Franklin A. Neva Memorial Fund	Neva Fund	This Fund supports two ongoing programs to honor the memory and further the legacy of Dr. Franklin A. Neva, a former director of NIAID's Laboratory of Parasitic Diseases (LPD). The first is an annual lecture on a topic related to clinical tropical medicine and associated pathophysiology as part of the LPD's ongoing weekly lecture series. The second is an annual session devoted to parasitic and/or tropical medicine that features discussions of individual cases held by the LPD and the Greater Washington Infectious Disease Society.	Planning began for the next Neva Lecture to take place 4/2/2020.	$51,059.08	May-12

National Institute of Arthritis and Musculoskeletal and Skin Diseases

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Rheumatoid Arthritis, Systematic Lupus Erythematosus & Related Autoimmune Disorders	AMP - RA/SLE	The Accelerating Medicines Partnership (AMP), is a pre-competitive effort among government, academia and industry to harness collective capabilities, scale and resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases – Type 2 Diabetes, Alzheimer's Disease, and Rheumatoid Arthritis, Lupus and Related Autoimmune Disorders. In Dec 2013 a final research plan for RA-Lupus was completed through the RA-Lupus Steering Committees, including representatives from AbbVie, BMS, Janssen, Merck, Pfizer, Sanofi, Takeda, multiple key disease-focused not-for-profits and government. The plan focuses on the molecular analyses of gene expression and signaling in specific subsets of leukocytes and resident cells in control and RA synovium and blood and Lupus kidney biopsy, skin and blood. This may lead to biomarkers which predict pathological processes that lead to end-organ damage and identify potential new pathways or target for drug development and intervention.	The AMP RA/Lupus Program has focused the resources on analyzing single-cell RNA-seq expression profiles in kidney and synovial samples to identify and validate novel drug targets and cell pathways from RA and lupus cell populations. A sixth year of the program was added and supported to expand next generation analytics and include blood (RA and Lupus), skin and urine (Lupus) patient samples and analysis. Phase 2 sample accrual is now complete and sample processing and analysis is ongoing. NIH grants continue to support the program infrastructure and core RNA-seq pipeline. FNIH Research Collaborative Agreements are supporting urine proteomics and CyTOF analytics. Additional ancillary studies for ATACseq and immune cell subset analyses are being incorporated into the pipeline cell prococessing. In late 2019, the Program secured the committment of a 7th Industry partner, GSK. The Steering Committee approved them joining as full members at a consistent level to other new partners (Janssen) at $1.38M. The AMP RA/SLE Program has recently formed a working group to explore development of a new plan for a 2.0 AMP Program in rheumatic disease and autimmunity. The group has representation of all stakeholders and an equal number of NIH Network investigators and are currently development a concept for full review at the end of 2Q 2020.	$26,455,505.00	Mar-14
Biomarkers Consortium - Biomarkers of Diagnosis and Disease Activity in Axial Spondyloarthritis	Biomarkers Consortium - axSpA	Axial spondyloarthritis (axSpA) is a highly morbid chronic debilitating condition presenting with chronic inflammatory low back pain and stiffness caused by inflammation of the sacroiliac joints and lumbar spine. No serologic tests are available to aid in the diagnosis, existing biomarkers are neither sensitive nor specific, and plain radiographs are often negative early in disease. This has resulted in delays in diagnosis of up to 10 years for patients and have caused the FDA to reject multiple applications for new therapies based on concerns about reliable diagnosis or accuracy in monitoring disease activity and treatment response. The project plans to utilize proteomics and whole-blood RNA expression profiling to both validate and expand on existing biomarkers and pathologic pathways for axSpA diagnosis and disease monitoring. The study will utilize on the infrastructure, established data and patient samples from two ongoing patient studies: Prospective Study of Outcomes in Ankylosing Spondylitis (PSOAS) and Classification of axSpA Inception Cohort (CLASSIC)/SPARTAN registry.	The Biomarkers Consortium Executive Committee approved the project concept on February 4, 2019. The project objectives and aims were presented to the Spondyloarthritis Research and Treatment Network (SPARTAN) Executive Committee on April 2, 2019 to determine if the FNIH Biomarkers Consortium axSpA Project could be granted access to the prospectively acquired biospecimens from the (CLASSIC)/SPARTAN registry. FNIH has engaged and assembled potential project partners into a plan development team. The team is scheduled to begin developing the project concept into a finalized project plan, starting with a kick-off discussion on January 30, 2020. The group expects to receive a final determination on which samples are available, along with an updated budget from the project Principle Investigators.	Fundraising efforts are underway	Sep-19

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Bone Quality Project	Biomarkers Consortium - Bone Quality	The Bone Quality Project aims to evaluate and to identify biomarkers of bone strength and quality changes by analyzing pooled imaging and biochemical data from multiple clinical studies to allow definition of better clinical endpoints. The goal is for these biomarkers to be utilized in future clinical studies and practice in osteoporosis, and ultimately be formally qualified by the U.S. Food and Drug Administration (FDA). A major outcome of this project, once completed, will be to make recommendations to the FDA to qualify the identified biomarker(s) for such purposes. This is a $2.4M, 5-year project, with two subprojects to critically evaluate: 1) bone marker density and imaging-derived bone strength measurements to estimate bone strength and fracture risk; and 2) bone turnover markers (BTMs) to use as markers of anti-fracture efficacy in osteoporosis drug development and for patient management in clinical practice. The project launched in late 2013.	The research team at UCSF, led by Dennis Black, has built a database from ~ 170,000 individual level data sets from 9 companies, ~ 160,000 of which are from PBO trials including ~110,000 DXA BMD, ~900 QCT/FEA imaging markers and ~45,000 biochemical BTMs, with hip, vertebral and non-vertebral fracture endpoints. UCSF has published 2 manuscripts on the study level DXA scan and study level BTM analysis from published data. Two DXA BMD analysis papers from BQ data (study and subject level), a subject-level BTM and a combination DXA /BTM are underway. The team's LOI to FDA to qualify a proportional change in total hip bone mineral density (BMD) as measured by DXA as a surrogate endpoint for hip fracture was approved per the new BQP process (CDER/OND). The project team had a F2F meeting in Montreal where it agreed on a NCE till december 2019 to complete development of Qualification Plan, per FDA's guidance. The project received a project extension to complete all work until end of 2019. Several manuscripts have been submitted and are awaiting review. The project team produced a Statistical Analysis Plan (SAP) to the FDA as a follow up to the response to the LOI submitted in February 2019 to FDA. Following review of hte SAP by FDA, the team has now submitted the Qualification Plan. As the bone quality project has now ended, but UCSF is continuing work on the full qualitication plan with funding outside of FNIH, FNIH has agreed to extend the data use agreement to allow access to the clinical trial data for the purpose of the full qualification plan until end 2021. The BQ team received an FDA grant for work on the full qualification, with input from FNIH once the project ends. The project is now closed and is undergoing financial reconciliation.	$2,560,000.00	Jan-13
Biomarkers Consortium - PROGRESS OA - Osteoarthritis (OA) Biomarkers Qualification	Biomarkers Consortium - PROGRESS OA	PROGRESS OA - Clinical Evaluation and Qualification of Osteoarthritis Biomarkers Project is the second phase of a two-stage strategy to address the most fundamental obstacles to the development of new treatments for Osteoarthritis (OA). This project will validate the highest performing radiographic measures, MRI measures and biochemical markers from the Phase I OA Biomarkers Consortium Project, which was completed in 2015. This project will combine data sets from six previously conducted clinical trials and will analyze whether the imaging and fluid biomarkers can predict OA disease progression. The ultimate goal is to qualify the biomarkers with the FDA and EMA to be used as a prognostic markers of OA disease progression for use in OA drug development. The results of PROGRESS OA Project will provide a set of qualified biomarker tools that will impact clinical trial design by decreasing the number of patients needed, and decreasing the time and costs needed for OA drug development.	The PROGRESS OA - Osteoarthritis Biomarkers Qualification Project has raised $2.48M and launched in Auguust 2018. The Project Team met face to face in May 2019 at the Osteoarthritis Research Society International (OARSI) annual meeting in Toronto. A sub team of industry and academic statisticians has finalized the statistical analysis plan and power analysis for the OA Biomarker Qualification Project. Contracts with data providers are exectued in order to gain access to knee MRI images, knee x-rays, and biospecimens from previously conducted clinical trials. FNIH submitted the Legacy Biomarker Qualification Status Update form for the MRI biomarkers to FDA on November 20, 2018, and received approval in May 2019 from FDA Biomarker Qualification Team to move forward with the qualification plan, which was submitted to the FDA on January 22, 2020. On September 4, 2019 FNIH submitted 2 Letters of Intent to the FDA to qualify 1) radiographic measure of bone texture a a predictor of OA progression and 2) biochemical markers from the serum and urine to predict OA progression. As of July 2, 2019 FNIH leadership has put a hold on using any funds or data from the company Kolon TissueGene and its parent company in Korea, Kolon Life Sciences, due to a potential false ingredient or mislabeling of cells that were being used in the cell therapy. FDA has paused the phase III trial in the US and is currently investigating. Once more information is available FNIH executive leadership will determine the best course of action.	$2,482,000.00	Mar-16

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - TARGET Biomarkers Study	Biomarkers Consortium - TARGET BMx Study	Cardiovascular disease (CVD) is the leading cause of deaths in the general population, however Rhuematoid Arthritis (RA) is associated with an increased risk of developing CVD by almost two fold. Therapies that reduce joint inflammation in RA patients may also reduce CVD disease. This project seeks to utilize validated proteomic biomarkers of RA disease activity and inflammation to categorize baseline and DMARD-associated changes in vascular inflammation - measured by FDG PET-CT - in RA patients. Leveraging a NIH randomized controlled clinical trial (The TARGET Trial), this companion BMx project will compare and correlate the changes in these proteomic biomarkers with vascular FDG PET-CT between two treatment regimens in methotrexate inadequate responders that represent a critical and common decision point for rheumatologists and patients: addition of a TNF inhibitor vs. addition of sulfasalazine plus hydroxychloroquine (triple therapy) to background MTX.	The FNIH executed agreements of $1.125M with 3 pharmaceutical companies and a key arthritis-focused not-for-profit organization. The in-kind services agreements with Crescendo Biosciences and Myriad RBM are executed, and provide all of the biomarker testing needed for the project. The grant with Brigham and Woman's Hospital has met the year 2 milestones and over one hundred twenty five patients out of the total goal of two hundred patients have been accrued. The Project Team has drafted the statistical analysis plan for the biomarker testing.	$1,275,000.00	Sep-14

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
11th Annual International Forum for Rheumatoid Arthritis	IFRA Meeting	The 11th International Forum on Rheumatoid Arthritis (IFRA) is scheduled for September 25-27, 2019 and will be held in Washington, D.C. at the Washington Marriott Metro Center. This Forum is designed to bring together leading rheumatologists from Europe, the United States and Asian countries working to better understand the pathogenesis and emerging therapeutic strategies in rheumatoid arthritis (RA). The field of rheumatology has made great advances in recent years through consortia-based efforts, including the Accelerating Medicines Partnership (AMP RA/SLE) and the Rheuma Tolerance for Cure (RTCure), as well as disease-focused groups such as the International Forum on Rheumatoid Arthritis (IFRA). Providing a joint congress for international leaders from each of these impactful partnerships to interact and collaborate is essential to harmonize strategic priorities, discuss prominent research datasets, and advance novel technologies at the RA frontier to move the field forward. Challenges in RA that remain unsolved include disease heterogeneity as well as uneven responsiveness to existing and novel treatment regimens. For promoting next-generation rheumatology, we must convene and construct global networks to best treat and serve our patients worldwide.	The 11th International Forum on Rheumatoid Arthritis was held on September 25th - 27th in Washington DC. This joint AMP, RTCure (IMI) and IFRA (internation Forum for RA) meeting of nearly 200 academicians, governement, industry and patient representatives provided a global forum on progress in RA pathophysiology and emerging therapeutics. In addition, strong representation from the AMP Network of investigators enabled the sharing of these paradigm-shifting, single-cell technologies and findings with other larger consortia efforts. The Forum was roundly successful and brought together large contingents of gloabl RA leaders for the first time. Multiple sessions focused on international collaboration and partnership for next generation projects related AMP RA/SLE 2.0 or other initiatives utilizing AMP RA/SLE data, samples and learned expertise. A webpage is also posted on the FNIH site including the program agenda. The joint organizers aim to continue working together to find ways to utilize data and results from each of the consortia to cross-validate individual findings and create a strategy for future international collaboration and support. A manuscript that highlgihts the seminal presentations, data and outcomes from the meeting has been submitted to the Annals of Rheumatic Diseases and under review for publication in 2Q 2020.	$27,100.00	Sep-19

National Institute of Biomedical Imaging and Bioengineering

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Remote Monitoring for Medical Product Development Workshop	Biomarkers Consortium - Workshop	As mobile monitoring health technologies (e.g. smartphone apps, wearables, and mobile-device-based tools) – hardware and software – become increasingly available to consumers, providers, and researchers, there are new opportunities to better connect patients and health care providers. Real-world data and measurements from these digital technologies could improve the patient experience and incorporate this patient input in support of novel biomarkers for use in drug research and development (R&D). This workshop will provide a venue to discuss challenges, and opportunities in mobile monitoring health technologies for improving the probability of success in drug development and enabling precision medicine and considerations for an evidence-based framework for applying mobile monitoring health technologies towards drug research and development.	The FNIH Biomarkers Consortium (BC) is hosting a public meeting entitled Remote Digital Monitoring for Medical Product Development Workshop on February 18th and 19th, 2020 at The Bethesdan in Bethesda, Maryland. Digital health technologies have garnered tremendous interest from consumers, providers, and researchers as a new way to improve therapeutic research and development (R&D). However, many challenges and opportunities in the use of remote sensing technologies for improving the probability of success of therapeutic clinical trials still need to be addressed, especially for regulatory decision-making in drug development. This 2-day workshop will provide a forum for open discussion on multiparametric mobile monitoring approaches and a framework for analytical and clinical validation needs for device developers, drug developers and regulators.	Fundraising efforts are underway	Aug-19

New Projects

National Institute of Child Health and Human Development

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
A plus Trial (NICHD / Global Network)	Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	This study proposes to conduct a clinical trial to assess the value of a single oral dose of azithromycin to prevent maternal death or peripartum sepsis and intrapartum/neonatal death or sepsis in laboring women. The trial will be conducted through NICHD's Global Network for Women's and Children's Health Research, which supports and conducts clinical trials in resource-limited countries by pairing foreign and U.S. investigators, with the goal of evaluating low-cost, sustainable interventions to improve maternal and child health and build local research capacity and infrastructure. The project would evaluate the value of a single oral dose of azithromycin (plus usual care) in a population of approximately 34,000 women in labor across south Asia, sub-Saharan Africa, and Central America. This will involve a collaboration between NICHD and the Bill & Melinda Gates Foundation (BMGF). The FNIH would serve as the recipient of the BMGF award and would manage sub-awards to the Data Coordinating Center at RTI and US affiliates of the eight partner sites. The study will include a subset of 5,500 high risk women, at the highest risk for infection because they have prolonged labor (≥18 hours) and/or prolonged membrane rupture (≥8 hours), and 28,500 low-risk women. In addition, BMGF wishes to add biospecimen and antibiotic resistance measurements for the full sample. The low-risk cohort increases the generalizability of the study findings significantly, which increases the utility of the study in helping to inform sounder health care policy for women and children.	The FNIH was awarded a grant from the Bill & Melinda Gates Foundation in August 2019 to support the study. The project will support eight U.S. partner institutions and one Data Coordinating Center through sub-award agreements. A pilot study will be conducted during Q4 2019, and the full study is anticipated to begin in Q1 of 2020.	$6,687,509.00	Oct-19

National Institute of Dental and Craniofacial Research

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Diagnostic Biomarkers of Sjögren's Syndrome	Sjögren's Syndrome	The Sjögren's Syndrome (SS) project will be managed by the Foundation for the National Institutes of Health (FNIH) Biomarkers Consortium, through the Inflammation & Immunity Steering Committee. The primary objective of this project is to develop and validate diagnostic biomarkers in SS patient subgroups by better defining and understanding disease heterogeneity and identifying diagnostic biomarkers for patient stratification. Multi-dimensional molecular characterization of disease spectrum in diverse SS and sicca populations will be performed, followed by tests for associations with clinical sub-phenotypes in salivary gland tissue. The project also aims to identify blood-based molecular signatures that correlate with salivary gland signatures and clinical sub-phenotypes for development of minimally invasive biomarkers.	The Biomarkers Consortium Executive Committee approved the project concept on December 4, 2019. FNIH continues to seek input and expertise from BC member organiations and potential project partners in the Sjogren's Working Group to assist in the development of a detailed project plan. The plan development team is scheduling to meet monthly, beginning in December 2019.	Fundraising efforts are underway	TBD

New Projects

National Institute of Diabetes and Digestive and Kidney Diseases

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Type 2 Diabetes	AMP - T2D	The Accelerating Medicines Partnership (AMP) is a multiple-sector, pre-competitive partnership whose goal is to harness collective capabilities, scale and resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases. In late 2013, the AMP Type 2 Diabetes (T2D) research plan was finalized by Steering Committee (SC), currently comprised of the following partners: NIDDK/NIH, Eli Lilly and Company, Janssen Research and Development, LLC, Merck Sharp & Dohme Corp., Pfizer Inc., Sanofi US Services. AMP T2D aims to build a public, searchable AMP T2D Knowledge Portal for analysis of relationships between potential therapeutic target gene sequence variations and T2D risk or protection, quantitative traits, complications, and molecular phenotypes to inform the drug development process.	Significant progress has been made to enhance our Knowledge Portal (KP). The KP now features 71 publicly available T2D related genetic datasets from around the world, and 182 traits associated with T2D. We have a new heuristic to predict effector genes, along with additional new tools that allow multiple query-based analyses on these datasets. AMP T2D KP provides seamless open access to data housed at the US node and the European federated node. Additional opportunities have been identified for potential new collaborations outside of AMP T2D consortium to promote KP network formation across cardio-metabolic disease area, as well as adding capabilities to query non-coding regions. The portal now features sophisticated tools like an interactive manhattan plot, a genetic variance finder, and genetic risk scores in addition to PheWeb, a sophisticated tool to compare risk loci with associated traits. Currently, the KP houses sequencing and traits data from >1.3M samples from across 5 ancestries and geographies, and many cardiometabolic, hepatic and renal traits. The project has been extended to April 2020. In Feb and Mar 2019, the team issued 10 RFPs and has selected 12 proposal to build and grow the portal and add functional validation in selected tissues. FNIH has finalized contracts with 10 of the 12 parties and successfully met all the new collaborators at the annual Parliament meeting from October 2-3, 2019. The AMP SC ran successful webinars for outreach into the extension of this program after April 2020 which embarks on an complications focused intiative titled 'AMP Metabolic Disorders'. The team had its kickoff meeting on December 10, 2019 and is currenlty meeting weekly to define the project scope and develop the project plan. The AMP T2D/MD team are currently planning for a F2F meeting in May 2020.	$21,775,000.00	Mar-14
BC - Mucosal Healing in UC: Definition, Treatment Target and Clinical Endpoints	BC - Mucosal Healing in UC	Ulcerative colitis (UC) is a chronic, relapsing and remitting inflammatory bowel disease (IBD) that affects 249 per 100,000 persons in the United States, and the incidence and prevalence of UC is increasing worldwide. UC is associated with mucosal inflammation in the rectum that may extend proximally to involve part or all of the mucosal lining of the colon. There is currently no community consensus on a method for assessing mucosal healing. The objective of this project is to establish a common methodology for a histologic measurement of a mucosal healing endpoint for treatment of ulcerative colitis (UC) that demonstrates clear prognostic value for long-term outcomes for patients. The project aims to 1) establish the number, location, size, and density of biopsies required to capture variability across the colon and standardize protocols for biopsy collection 2) establish a histolopathologic measurement of mucosal healing that correlates with long-term patient important outcomes 3) establish a machine learning methodology as a validated objective method for scoring of mucosal healing for use in clinical trials, regulatory approvals, and clinical practice.	The Biomarkers Consortium Executive Committee approved the project plan on December 4, 2019. The project budget is $3.45M and is officially in fundraising as of the project plan approval date of December 4, 2019. We expect two not-for-profits organizations and six pharma partners to fund the project. As of 1/21/2020 there are two letters of agreement exectued to fund the project.	$620,000.00	Jun-19

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Clinical Evaluation and Qualification of Kidney Safety Biomarkers	Biomarkers Consortium - Kidney Safety	The Kidney Safety Project, managed by the Executive Committee of the Biomarkers Consortium, aims to qualify novel biomarkers of drug-induced acute kidney injury. The project is designed to include a learn-and-confirm phase. The learn phase consists of retrospective analyses of mesothelioma patient and healthy volunteer data in order to establish a prioritization for the novel biomarkers that seem most promising for the prospective analyses. The prospective analyses are based on data collected from two observational clinical trials conducted at 4 different sites - 2 with aminoglycosides and 2 with cisplatin - aiming to validate some important biomarkers of acute kidney injury (AKI) that perform better than serum creatinine and BUN (the currently used biomarkers of AKI). This project is funded by 6 pharma companies.	The Kidney Safety Project received the first ever qualification of a clinical safety biomarker awarded by the FDA – a major milestone that will improve the detection of drug-induced kidney injury in early phase drug development. The newly qualified biomarker can now be used in Phase I clinical trials to aid in the detection of acute kidney tubular injury in healthy volunteers and guide selection of appropriate single and multiple ascending dose to be tested in the trial cohort populations. The team has drafted a User's Guide to help drug developers apply this composite biomarker. A post and link to this User's Guide is on the FNIH website. Blinded data adjudication and analyses have been delayed awaiting submission of the FDA Qualification Plan and related necessary feedback and guidance from FDA on inclusion of certainly biomarker data. The program has intiiated the final closeout of the IBM project database and data transfer, in CDISC format, to the Critical Path Institute (CPI). Data adjudication will be completed using data and clincial data in the CPI final database to support the next qualification package.	$3,570,830.00	Jul-11
Biomarkers Consortium - Non-Invasive Biomarkers of Metabolic Liver Disease	Biomarkers Consortium - NIMBLE	The MDSC formed a working group to look at areas of interest for NASH biomarkers. Broad areas include exploration of soluble factors, dynamic tests for liver function, and imaging modalities. The group is looking at a project towards developing credible technologies, other than biopsy, to allow staging and quantification of diffuse liver disease, for which there are currently neither surrogates nor agreed upon outcomes.	The NIMBLE Project Plan was approved by the MDSC in August and by the EC in October 2017. This project carries a substantial budget obligation (originial budget $9.7m). As of October 2018, we have signed 12 contracts pharmaceutical partners who have committed to financially support the project (adding up to ~$13M). Additionally, 13 companies have agreed to donate assays, biomarkers, data, samples and technology to support the NIMBLE project. Many academic leaders are donating their time and expertise. The project team has finalized CROs and consultants to complete stage 1 statistical analyses. Contracts with academic insitutions are completed and contracts with vendors and biomarker developers are underway. The full project team (academic and industry leaders) met for a project team meeting in April 2019 at the EASL meeting and shared the NIMBLE project with the larger audience there. The team submitted their first LOI to the FDA to qualify circulating biomarkers and is in the process of revising the LOI. An official announcement was made on the FNIH website in June 2019. The team held a project team meeting in November 2019 as AASLD at which it reviewed the progress of the project for stage 1 and mapped out next steps with the plan to submit to the BC EC the go / no go milestones review by year end 2020.	$12,945,888.00	Nov-18

National Institutes of Health Clinical Center

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Clinical Center Drug Donations	Clinical Center Drug Donations	An initiative to secure donated medical products/therapeutic agents from pharmaceutical companies for use by the NIH Clinical Center. Receiving these products free of charge enables funds from the Clinical Center's budget to support other clinical research activities.	NIH Clinical Center executed an MOU for receipt of in-kind drug donations on December 20, 2018. FNIH has executed a letter of agrement with Horizon Pharma for an in-kind donation of ACTIMMUNE to the NIH Clinical Center and the second of two shipments of the product was received in November 2019. The FNIH is now in discussion with Eli Lilly and with the NIH Clinical Center regarding a possible in-kind donation of a drug for use by NIMH and NIAMS.	$16,108,628.73	Jun-08
Dr. John L. Barr Memorial Fund for Cancer Research	Barr Memorial Fund for Cancer Research	The Dr. John L. Barr Memorial Fund helps to support the Intramural Research Training Award Fellowship Program at the NIH Clinical Center's Pain and Palliative Care Service. The objective of the fellowship is to conduct research on pain and palliative care, and also to encourage young investigators to become more familiar with the importance of this field of study.	FNIH Staff met with Jill Barr to discuss the future of the Fund. Next steps from obtain an update from Dr. Berman on use of the previous funds.	$25,284.00	May-04
John and Elaine Gallin Fund	Gallin Fund	The Gallin Fund provides support for the Edmond J. Safra Family Lodge and to support clinical research needs of the intramural research program at the National Institutes of Health.	The 2nd Annual Trailblazer Prize was awarded at the FNIH Fall Board Dinner to Dr. James Kochenderfer, for pioneering the development of immunotherapies that leverage chimeric antigen receptor (CAR) T-cells to treat blood cancers.	$157,047.30	Jan-13
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
John Laws Decker Memorial Fund	Decker Memorial Lecture Lunch	During his lifetime, Dr. John Laws Decker strived to connect scientific communications around the world to exchange information and accelerate important research. His dedication to education and communication about science makes this annual lecture at NIH an especially fitting tribute to a recognized leader and teacher. The recipient of the annual Distinguished Clinical Teacher's Award given by the NIH Fellows Committee is the invited lecturer as part of the Contemporary Clinical Medicine: Great Teachers Grand Rounds Program.	Outreach to begin planning for the next Decker Lecture and luncheon.	$42,910.00	Jan-03
Medical Research Scholars Program Class of 2019-2020	MRSP 2019-2020	The National Institutes of Health (NIH) Medical Research Scholars Program (MRSP) is a comprehensive, year-long research enrichment program designed to attract the most creative, research-oriented medical, dental, and veterinary students to the intramural campus of the NIH in Bethesda, MD. Student scholars engage in a mentored basic, clinical, or translational research project that matches their professional interests and career goals. The MRSP combines and replaces two successful NIH training programs, the NIH-Howard Hughes Medical Institute Scholars and the Clinical Research Training Program.	The MRSP class of 2019-2020 is comprised of 50 medical, dental and veterinary students from over 30 unique institutions. Current sponsors include: the American Association for Dental Research, Colgate-Palmolive, Doris Duke Charitable Foundation and Genentech.	$675,025.00	Jul-19
Medical Research Scholars Program Class of 2020-2021	MRSP 2020-2021	The National Institutes of Health (NIH) Medical Research Scholars Program (MRSP) is a comprehensive, year-long research enrichment program designed to attract the most creative, research-oriented medical, dental, and veterinary students to the intramural campus of the NIH in Bethesda, MD. Student scholars engage in a mentored basic, clinical, or translational research project that matches their professional interests and career goals. The MRSP combines and replaces two successful NIH training programs, the NIH-Howard Hughes Medical Institute Scholars and the Clinical Research Training Program.	The process of selecting the Class of 2020-2021 is underway. Applications have been received and 87 candidates will come to the NIH for interviews on Monday, March 2. The Doris Duke Charitable Foundation has committed support in the amount of $337,500. Additional sponsorship requests will be made.	$337,500.00	Jan-19

Capital Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Edmond J. Safra Family Lodge (Bricks and Mortar)	Safra Family Lodge (Bricks and Mortar)	The Edmond J. Safra Family Lodge offers a home-like residence for families and loved ones of adult patients who are receiving care at the NIH Clinical Center, a comfortable environment intended to alleviate the incredible burden that accompanies serious illness. The Family Lodge features 34 guest rooms, family gathering areas including living room, dining room, kitchen, playroom, library, exercise room, and telecommuting facilities that allow families to manage their home and business lives during their time at NIH. This project was funded by the Edmond J. Safra Philanthropic Foundation and other generous individual and corporate contributors.	No active campaign.	$3,270,478.30	Jan-98
Edmond J. Safra Family Lodge GSK Endowment	Safra Family Lodge GSK Endowment	The GlaxoSmithKline Endowment supports programs and activities for families staying at the Edmond J. Safra Family Lodge, including services that help residents stay in touch with employers and loved ones.	FNIH is looking into plans on how to best use these funds; there is a proposal to utilize fund to support Lodge Breakfast program	$1,500,000.00	Jan-01
Edmond J. Safra Family Lodge Weinberg Endowment	Safra Family Lodge Weinberg Endowment	The Weinberg Endowment supports Edmond J. Safra Family Lodge operations and maintenance, ensuring that guests are provided a comfortable home away from home for years to come.	FNIH is looking into plans on how to best use these funds; there is a proposal to utilize fund to support Lodge Breakfast program	$750,000.00	Dec-00
Lifecycle Replacement Plan for the Edmond J. Safra Family Lodge	Lifecycle Replacement Plan for the Edmond J. Safra Family Lodge	This project helps the FNIH and the Family Lodge to prioritize maintenance needs, anticipate costs, align resources and plan accordingly. The Lifecycle Replacement Plan strategy for the long-term conservation of the Family Lodge will be implemented in two phases. Phase I is a comprehensive assessment of the Family Lodge, with a maximum allocation of $40,000 for the report. Phase II will be incremental disbursements of funding over a five-year period allocated to the preservation of current Family Lodge standards, with a maximum expenditure of $70,000 per year as informed by the Lifecycle Replacement Plan.	FNIH staff continue quarterly meetings and ongoing communications to discuss maintenance items and future needs of the Lodge.	$640,225.00	Jan-16
Safra Family Lodge - All Programs	Safra Family Lodge - All Programs	The Edmond J. Safra Family Lodge offers a home-like residence for families and loved ones of adult patients who are receiving care at the NIH Clinical Center, a comfortable environment intended to alleviate the incredible burden that accompanies serious illness. The Family Lodge features 34 guest rooms, family gathering areas including living room, dining room, kitchen, playroom, library, exercise room, and telecommuting facilities that allow families to manage their home and business lives during their time at NIH. This project was funded by the Edmond J. Safra Philanthropic Foundation and other generous individual and corporate contributors. Ongoing gifts from donors provide support of the Family Lodge's operations and comfort of its guests. Annual investment income generated by an endowment fund supports program expenses, while the principal remains intact to ensure future funding.	FNIH Advancement continues to receive contributions in support of the Safra Family Lodge-All Programs. Fundraising communications/appeals are being considered for 2020.	$4,049,592.25	May-05
Tracy's Toy Box Memorial Fund	Tracy's Toy Box	This fund supports the purchase of toys and activities for children staying at the Edmond J. Safra Family Lodge to help make their time there more comfortable and pleasant. Tracy's Toy Box was established in memory of Tracy Nadel.	Strategy for the future of the fund is to be determined.	$13,982.00	Jan-04

New Projects

National Institute of Mental Health

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership - Schizophrenia	AMP - SCZ	The proposed AMP SCZ Project Concept aims to establish a system to run proof-of-concept clinical trials that can test biological hypotheses in CHR individuals and in individuals with schizophrenia. In order to establish such a system, AMP SCZ is proposing to leverage NAPLS and EPINET to characterize a large cohort of CHR individuals in terms of polygenic risk scores, brain activity, physiology, behavioral processes, and life experience. Then, with all of this phenotypic data, AMP SCZ will stratify individuals from this cohort into risk pools and will conduct proof-of-concept trials in order to test hypotheses in this population, which will help investigators to determine which markers (1) might be useful in future clinical trials, (2) are useful for stratification, and (3) are treatment responsive. The AMP SCZ partnership may catalyze testing of therapeutic interventions in CHR individuals by (1) validating a set of risk stratification algorithms (e.g., using multimodal biomarkers) to predict outcomes in CHR individuals, and (2) testing whether these predictive algorithms are responsive to compounds contributed by the private sector in proof-of-concept studies. Thus, AMP SCZ will consist of two phases. During Phase 1 (months 0 to 12), AMP SCZ will conduct a meta-analysis of existing biomarkers studies and will select a risk stratification algorithm for use in clinical trials. AMP SCZ must determine whether developing this risk stratification algorithm is achievable using only existing data (e.g., from NAPLS and HARMONY) or will require the consortium to generate prospective biomarker data, perhaps by leveraging EPINET. Next, during Phase 2 (months 12 to 60), AMP SCZ will conduct proof-of-concept clinical trials, test biomarkers for their stratification utility and drug responsiveness, and incorporate biomarker algorithms into already existing and planned clinical trials. In parallel, industry may incorporate one or more of the biomarkers being assessed in CHR subjects by AMP SCZ into FEP or early psychosis trials to help validate a multivariate predictive biomarker.	The FNIH has led a 6 month design effort (April-September 2019) in the development of this new public private partnership. The outcome of this first phase has been the development of a white paper that will serve as the basis for the AMP SCZ partnership research plan. The design effort was spearheaded by 58 scientists from different stakeholder organizations including industry, government, non-profit and academia. The FNIH held a Face to Face meeting in Bethesda, M.D. on December 2019 to gather feedback as well as interest from the private partners in participating in this initiative in preparation. The private partners will prioritize and further discuss the details of the different components of the AMP SCZ research plan. The goal is to have a finalized research plan for review by partners by February 2020.	Fundraising efforts are underway	Aug-19
Baby Connectome Project	Baby Connectome Project (BCP)	The Baby Connectome Project is one of several programs that build upon the NIH Human Connectome Project (HCP), designed to map the neural pathways that underlie human brain function. The HCP's initial five-year version supported technology development and assessment followed by data collection on a cohort of 1,200 healthy young adults (ages 22-34). The goal of the Baby Connectome is to obtain structural and functional connectivity data for the healthy human brain in the 0 to 5 year age range. The Baby Connectome Project grant was awarded in September 2016 to the University of North Carolina at Chapel Hill, with a sub-award to the University of Minnesota.	Research is ongoing. A Human Connectome Project Investigators meeting, including the BCP Investigators was held in May 2019 at NIH.	$2,939,873.00	Dec-14

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Biomarkers Consortium - Longitudinal Proteomic Changes in CSF from ADNI: Towards Better Defining the Trajectory of Prodromal and Early Alzheimer's Disease	Biomarkers Consortium - Longitudinal CSF Proteomics	The lack of tools for early diagnosis and measurement of disease progression in Alzheimer's Disease (AD) continues to be a major hurdle in AD drug development; the current AD biomarkers do not work in this context. The present study addresses this need by extending the work on promising proteins identified in a previous BC project. The study will measure the rate of change of 5 protein biomarkers within MCI, AD and HC patients, utilizing a multiplexed mass spectrometry-based approach. The proposed longitudinal sample set has at least 3 CSF samples from each individual drawn over a three-year or greater period, as well as available clinical and imaging data. Success within this project could greatly improve progression and treatment monitoring in early Alzheimer's Disease patients. The study is expected to have a duration of 18 months, and results will be available to the public on the Laboratory of Neuroimaging (LONI) website as they become available.	The Longitudinal CSF Proteomics Project was approved by the Biomarkers Consortium Executive Committee on July 2016. The project launched in July 2017 with funding from Janssen, Lundbeck, and Takeda. Additionally, Merck, Genentech, and Janssen all agreed to repurpose funding that remained from other projects to help support this project. RARC approval was attained to use 750 ADNI samples (originally 645) from 198 subjects (originally 215) in this study. Extensive MRM method optimization has been performed to improve and demonstrate superior assay performance for the 5 high priority assays. The study samples have been tested and raw data QC and normalization has been finalized. The study data was submitted and uploaded to LONI to enable sample unblinding for implementation and execution of the project statistical analysis plan (SAP). The project SAP was executed on July 2019 and the team found significant differences in one of the 5 candidate analytes that correlated with cognitive decline measures. Further additional analyses are being completed as a result of the SAP findings. The project will be completing Phases 3 and 4 to analyze and measure the concentration of the candidate analyte by ELISA to provide an orthogonal assessment of marker performance as well as test the feasibility of generating the same results with a low cost assay. A publication writing group was formed with a goal to submit analyses findings by Q2 2020	$524,472.85	Aug-16
Biomarkers Consortium - The Autism Biomarkers Consortium for Clinical Trials (ABC-CT)	Biomarkers Consortium - ABC-CT	The ultimate goal of the project to qualify a set of measures that can be used as stratification biomarkers and/or sensitive and reliable objective measures of social impairment in ASD clinical trials that could serve as indicative markers of long term clinical outcome. The project will support a multi-site study to assess a well-justified set of standardized investigator-administered assessments of domains of social impairment as well as neurophysiological measures (resting state and task-based EEG and eye tracking) that show promise in school age individuals with ASD (ages 6-11) at baseline, 6- and 24-week time points. In addition, at least one task-based EEG and one eye tracking measure from the European Autism Interventions (EU-AIMS) study will be included among the set of proposed biomarker paradigms. The inclusion of these measures will foster harmonization and independent replication of a common subset of biomarker measures in the proposed projects.	All the timepoints were collected for the clinical trial and the data lock is planned for March with results expected in June 2020. The N170 LOI that was submitted, accepted into the FDA Biomarker Qualification Program has since received a DDT Grant from the FDA. The group had submitted another LOI for an eye-tracking biomarker and has since debriefed and submitted revisions to the FDA in December and January. ABC-CT and EU-AIMS groups also met recently to align on the data that would be shared across groups to support both FDA and EMA submissions.	$2,000,343.45	Sep-15
Deeda Blair Research Initiative Fund for Disorders of the Brain	Deeda Blair Research Initiative	The Research Initiative Fund will be used for the purpose of funding grants to accelerate innovative research in the field of mental health, the focus shall be to fund basic research, training and novel programs in bipolar disorder, depression, and related psychotic, anxiety and mood disorders. Emphasis should be given to support the most creative investigators as defined and identified by the award selection committee. The members of this committee will have been carefully selected for their experience, wisdom, quality and leadership. It is expected that monies will be disbursed or be fully committed as soon as possible and practical after the establishment of the Research Initiative Fund to ensure high impact and to provide momentum to the research projects selected. These monies are meant to provide highly meritorious researchers with emboldening support to carry out the most novel science. The Research Initiative Fund is not meant to be intensively structured.	Mrs. Blair has assembled her scientific steering committee. Through her outreach, additional contributions are being made in support of this Initiative.	$8,281,617.00	Apr-16

National Institute of Neurological Disorders and Stroke

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Accelerating Medicines Partnership: Parkinson's Disease	AMP - Parkinson's Disease	The Accelerating Medicines Partnership (AMP) for Parkinson's Disease (PD) is a Public-Private Partnership between the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute on Aging (NIA), the Food and Drug Administration (FDA), Celgene, GSK, Pfizer, Sanofi, Verily and the Michael J. Fox Foundation (MJFF). The AMP PD research plan encompasses a deep molecular characterization and longitudinal clinical profiling of PD patient data and biosamples with the goal of identifying and validating diagnostic, prognostic and/or disease progression biomarkers for Parkinson's disease (PD). AMP PD utilizes well-characterized cohorts with existing biosamples and clinical data that are collected under comparable protocols and using common data elements. The cohorts include MJFF and NINDS BioFIND Study, the Harvard Biomarkers Study (HBS), the NINDS Parkinson's Disease Biomarkers Program (PDBP), and MJFF Parkinson's Progression Marker Initiative (PPMI). AMP is generating broad profiling data on biospecimen from these cohorts. The proposal includes open data sharing of molecular and clinical data generated to enable dissection of new targets, disease subtypes, and the identification of predictive markers for disease progression and disease prognosis.	This program has as an ultimate goal the validation of clinical biomarkers to be used in Phase 2 POC trials. The partnership has 6 private and 3 federal government partner, and 1 nonprofit partner. We have $10M in cash and $2M in kind form Verily for the Knowledge portal. During August-September 2019 period a 1) Completed clinical, whole genome, and transcriptome data quality control; 2) Launched Data Analysis Working Group; 3)AMP PD public portal release Q4 2019; 5) Release RFA for AMP PD data use 2020; 6) H5ld Society for Neuroscience satellite meeting on Data Science 7) Hosted AMP PD webinar; 8) Funded AMP PD system architect and engineering costs. Upcoming deadlines: 1) Go-no/go vote to move from phase 1 to phase 2 for unbiased CSF proteomics using Data Independent Acquisition (DIA) Mass Spectrometry; 2) ½ day Steering Committee (SC) teleconference; 3)Decide on level of outreach needed (see summaries from SC calls for further details)	$12,034,400.00	Mar-17
CarMollNat Muscular Dystrophy Endowment	CarMollNat Muscular Dystrophy Endowment	Carol-Ann Harris will create an Endowment to fund research into one or more of the major types of Muscular Dystrophy at the Neurogenetics Branch of the NINDS.	VP of Advancement spoke with Ms. Toth about her future visit to the NIH and administering the planned gift intent once realized.	$4,064,187.07	Jul-13
Edna Williams Curl & Myron R. Curl Fund for Multiple Sclerosis Research	Curl Fund for MS Research	As specified in this bequest to FNIH, interest income from the Edna Williams Curl and Myron R. Curl Fund, established in 2007, is designated to support multiple sclerosis research at NIH.	Per the terms of the endowment agreement, once sufficient interest income has accrued, the FNIH will use the income to support NINDS research in the field of multiple sclerosis. When sufficient income is available, the FNIH will discuss possible uses for the fund with NIH.	$60,302.52	Aug-07
Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D.	Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D.	Dr. Zaghloul's research focuses on using direct human intracranial recordings in patients undergoing surgical treatment for epilepsy to understand these mechanisms, which can provide new and potent understanding of complex neurophysiologic circuitry in the human condition. Funds support a fellow in the lab of Dr. Zaghloul for 2 years and a piece of equipment for the lab.	NINDS has indicated that they have a Fellow in place and that they will likely be requesting funds be transferred soon.	$290,000.00	Nov-13
SHRP CTE Neuropathology Research	SHRP Research - RP2	This component of the Sports and Health Research Program (SHRP Research Plan #2) provided a competitive opportunity for a multicenter team to: 1) more fully characterize the neuropathology associated with chronic traumatic encephalopathy (CTE) and delayed effects of traumatic brain injury (TBI) through systematic, rigorous, and collaborative studies of post-mortem biospecimens; 2) validate the neuropathological criteria for a post-mortem diagnosis of CTE and delayed post-traumatic neurodegenerative diseases through independent and blinded analyses; 3) better understanding of the incidence and prevalence of CTE, and 4) identify neuroimaging signatures of the neuropathology as a foundation for the development of diagnostic tools in the future.	Two cooperative agreements awarded under this funding opportunity announcement [http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-13-013.html Collaborative Research on Chronic Traumatic Encephalopathy and Delayed Effects of Traumatic Brain Injury: Neuropathology and Neuroimaging Correlation (U01)] were extended under no-cost extension by NINDS. One project, awarded to Boston University School of Medicine, has been completed and a final report has been submitted to the donor shortly. The other project, awarded to Mount Sinai Hospital, was active on a no-cost extension through December 2019 and FNIH is awaiting a final report from NINDS.	Fundraising concluded	Mar-13
SHRP CTE Pilot Projects on Sports-Related Brain and Spinal Cord Injury Research	SHRP CTE Pilot Projects - RP 3	This component of the Sports and Health Research Program (SHRP Research Plan #3) funded pilot projects for sports-related traumatic brain injury (TBI) and spinal cord injury (SCI) research. The scope comprised a wide range of research topics, including mechanical and biological mechanisms of injury and recovery, development of diagnostics and biomarkers, and interventions for minimizing injury and improving outcomes. Several projects obtained no-cost extensions but all have now been completed. A final technical report will be submitted to the donor shortly.	The six grants awarded under two funding opportunity announcements [http://grants.nih.gov/ grants/guide/rfa-files/RFA-NS-13-014.html Pilot Projects on Sports-Related Brain and Spinal Cord Injury (R21), and http://grants.nih.gov/grants/guide/rfa-files/RFA-NS-13-015.html Pilot Projects on Sports-Related Brain and Spinal Cord Injury (R03)] have now ended. A final report has been provided to the donor.	Fundraising concluded	Mar-13

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Sports and Health Research Program	Sports & Health	The Sports and Health Research Program (SHRP) is partnership among the National Institutes of Health (NIH), the National Football League (NFL) and the FNIH. Launched in 2012, the program aims to help accelerate the pursuit of research to enhance the health of athletes at all levels, past, present and future, and to extend the impact of that research beyond the playing field to benefit others in the general population, including members of the military. Made possible by a founding commitment of $30 million from the National Football League (NFL), and with an initial focus on traumatic brain injury, the SHRP was designed to allow expansion to other areas of research on serious medical conditions prominent in athletes and to engage additional funding partners representing a breadth of relevant interests. Research supported through the SHRP will be conducted under the direction of the NIH.	The six pilot projects on sports-related traumatic brain injury and spinal cord injury (R03, R21) were completed and a final report has been submitted to the donor. The CTE Neuropathology cooperative agreements (Research Plan #2) also were delayed. One final report has been submitted, but the other project continued on a no-cost extension through December 2019. The final technical reports on all projects but the one remaining cooperative agreement and the financial report have been submitted to the donor.	$13,675,628.00	Dec-11
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
National Institute of Neurological Disorders and Stroke - Congress of Neurological Surgeons Getch Scholar	NINDS/CNS Getch Scholar	Beginning in 2016, an early career neurosurgeon will be competitively selected as the National Institute of Neurological Disorders and Stroke Congress of Neurological Surgeons Getch Scholar (NINDS/CNS Getch Scholar). The Scholar, appointed as part of a larger, ongoing NINDS national career development program, will receive two years of funding to help launch a dual, clinical-research career for neurosurgeons who possesses unique clinical and research skills that identify them as the next generation of neurosurgical leaders.	In February 2019, CNS expressed interest in providing funding for an additional scholar (K12). In September 2019, FNIH and CNS executed an amendment to the existing agreement which expands the program and provides funds for an additional scholar beginning in 2020. Funds for the third Getch Scholar were received and transferred to NINDS in December 2019. The 2020 Getch Scholar has been selected and will be anounced in Q1 2020. Collaborative discussions ae underway between NINDS, FNIH and CNS Communications teams to support the announcement. Previously in July 2017, CNS committed to supporting a new Getch Scholar in 2018-2019. The second Getch scholar, Babacar Cisse, MD, PhD, Assistant Professor of Neurological Surgery at Weill Cornell Medicine, was selected in November 2017 and began in Q1 2018. The first Getch Scholar was selected in November 2015. The awardee was Brian Dlouhy, MD, Assistant Professor of Neurosurgery at the University of Iowa Carver College of Medicine.	$800,000.00	Aug-15
Robert Whitney Newcomb Memorial Lecture and Internship	Newcomb Memorial	The Robert Whitney Newcomb Memorial Fund was established by the family to remember Dr. Newcomb, who began his scientific career at NIH as a high school summer intern in a laboratory at the National Cancer Institute. The Fund endows an annual lecture by a recognized expert in neuroscience, selected by the National Institutes of Neurological Disorders and Stroke (NINDS) at NIH. Honoring Dr. Newcomb's own experience, it also provides for internships for high school students and fellows at NINDS.	FNIH Staff met with Dr. and Mrs. Newcomb for a program update and inquired on their bequest intent. Additionally the 20th annual Newcomb Lecture took place December 2, 2019 in the Porter building.	$1,243,883.25	Jan-00
The Pew Scholars Program in the Biomedical Sciences	Pew Scholars Program	The Pew Scholars Program in the Biomedical Sciences program provides awards to young investigators who show promise for making advances in science relevant to human health. The Pew Charitable Trusts asked to use the FNIH as a conduit to provide awards to the Scholar(s).	Kevin Briggman, Ph.D., a Pew Scholar at NINDS, advised the Pew Charitable Trust in April 2018 that his lab would move to Max Planck Institute in Germany in June 2018. As a result, Dr. Briggman relinquished his Pew award and final payments of the grant were discontinued to FNIH. The remaining fund balance received by the FNIH from Pew was transferred to NINDS. The final narrative and financial report were submitted to the Pew Charitable Trust. The MOU expired in December 31, 2019.	$189,000.00	Sep-14

Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
2020 National Institute of Neurological Disorders and Stroke Healthcare Disparities in Tribal Communities Summer Internship Program	2020 NINDS SIP	The NINDS Health Disparities in Tribal Communities Summer Internship Program (NINDS SIP), an 8-to-10-week summer training opportunity, is a unique chance for a diverse group of academically talented students to conduct brain and nervous system research at NIH. The program recruits students from traditionally underrepresented populations, including Native American, African American, Mexican American and Hispanic communities. Participants receive hands-on neuroscience experience working with leaders in the Institute's Division of Intramural Research.	The Memorandum of Understanding (MOU) for the 2020 NINDS Healthcare Disparities in Tribal Communities Summer Internship Program has been finalized. Fundraising efforts will begin in Q1 2020.	$30,000.00	Aug-19

Office of the Director

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
AMP-Partnership for Gene Therapy Manufacturing Technologies	AMP-Gene Therapy	The Accelerating Medicines Partnership (AMP), is a pre-competitive effort among government, academia and industry to harness collective capabilities, scale and resources toward improving current efforts to develop new therapies for complex, heterogeneous diseases. The limited access to gene therapy, especially to populations in the ultra-rare or bespoke category, was recognized by the leadership of AMP in early 2019. Thus, we began an investigation to identify the major challenges to access and manufacturing that could be addressed in a precompetitive public-private partnership. ies. The team has identified that basic AAV life cycle biology and regulatory hurdles are areas of greatest need and largest potential impact for a partnership	Over the course of the year, a discussion has been extended to include industry, NIH, FDA and academic representatives and multiple teams of stakeholders have had many teleconferences and in person meetings. The discussions have focused on a single delivery vector, Adeno Associated Virus, as the team believed aspects of the process would be generalizable and also provide more rapid access to bespoke therapies.	Fundraising efforts are underway	TBD
Helping to End Addiction Long - Term (HEAL) Partnership	HEAL Partnership	HEAL is a $500M, 3-year trans-NIH research initiative to improve prevention and treatment strategies for opioid misuse and addiction and enhance pain management. FNIH has been retained by NIH under a government contract to support the operation of the HEAL Partnership Committee, a public-private group that is providing additional scientific perspective to NIH under HEAL.	FNIH has worked with NIH OD to set up and manage two HPC face to face meetings, which were held in March and in August 2019. The March meeting focused on how NIH can best attract potential assets (drug molecules) from industry and other applicants for development via its Early Phase Pain Investigation Clinical Network (EPPIC-Net). The second meeting reviewed discussed animal and human preclinical testing of such assets. NIH renewed its contract with FNIH for a second year (through September 2020), and FNIH is awaiting further word from NIH/OD on what additional meetings it may be required to support.	$271,940.29	TBD
NIH Director's Initiative Fund	NIH Director's Fund	This Fund was established in 2008 to honor then NIH Director, Elias Zerhouni, MD, and his vision and commitment to public-private partnerships. This Fund, established with gifts in honor of Dr. Zerhouni, allows the current NIH Director to have a pool of unrestricted funds available, managed by the FNIH, to support special initiatives not possible through other sources.	No substantive update.	$38,350.00	Nov-08

Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Amgen NIH Scholars Program	Amgen Scholars Program	Amgen will sponsor 20 undergraduate research scholars per year for four years to participate in NIH's Summer Internship Program. The program will begin in June 2015. The Program will have four core components: 1) independent research performed under the mentorship of an NIH intramural scientist; 2) Career guidance and mentorship focused on the broad array of biomedical careers; 3) roundtable discussions exploring the intersection of research and public policy; and 4) leadership training focused on the development of skills needed to successfully work in the team-oriented global research environment.	FNIH was awarded a new grant on October 3, 2018 for Phase 4 of the Amgen Scholars Program. The new grant period is 2019-2022 and will support 15 students per year. The 2019 program is complete and annual reporting requirements have been met by FNIH. 2020 grant funds have been received and will be transferred to OD upon request.	$1,578,823.00	Jun-14

Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
JKTG Foundation - Post-Bacc and Graduate Intramural Research Training Fellows	JKTG Foundation - Post-Bacc and Graduate Intramural Research Training Fellows	The Jayne Koskinas Ted Giovanis Foundation for Health Policy (JKTG Foundation) will provide scholarship support of two young investigators in the Office of Intramural Training and Education under the mentorship of Dr. Sharon Milgram. The scholarship recipients are: Jose Delgado-Jimenez for the Postbaccalaureate Intramural Research Training Award with research interest in nanotechnology and cancer therapeutics, and Ryan Phillips for the Graduate Partnerships Program with research interest in mathematical/molecular modeling, brain circuitry and pain. A total investment of $105,210 is for first year funding of both student researchers which includes: stipend, insurance,and travel/education/research allowance.	Graham Atkinson met with FNIH, Sharon Milgram and Jose Delgado to discuss Mr. Delgado's recent work.	$335,234.55	Jun-15
Oxford Cambridge Scholarship Program	Oxford Cambridge Scholarship Program	NIH developed a graduate training program in collaboration with Oxford University and Cambridge University in England. Trainees spend part of their time at NIH and part at Oxford or Cambridge. The latter is the degree granting institution. The program attracts very high caliber students and NIH would like to expand it. FNIH granted FAES permission to handle this program. FNIH has agreed to handle any in-kind donations to the program.	The FNIH paid an invoice in Q2 for the 2018-2019 Oxford Cambridge Scholar Program and has not had any subsequent requests.	$174,569.34	Jan-04

New Projects

Other

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Abrams Charitable Fund	Abrams Charitable Fund	The Abrams Charitable Trust provides financial support to the FNIH to support translational research directed at treatment and/or cure of neurodegenerative diseases with a focus on the various forms of common dementias. The research must be translational in nature and must be directed at finding treatments and/or cures for neurodegenerative diseases focused on, but not limited to, the common causes of dementia such as Alzheimer's disease, Parkinson's dementia, Lewy body dementia, Frontotemporal dementia, etc. Other neurodegenerative disease such as ALS, MS, prion disease and other degenerative motor neuron diseases are also eligible for funding.	FNIH sent the annual package, as per the agreement, including a report from Dr. Youle and FNIH Financial Statements	$25,190.00	Oct-18
Biomarkers Consortium - Contributing Membership	Biomarkers Consortium - Contributing Membership	The Biomarkers Consortium engages a broad spectrum of stakeholders and funders (which may include NIH, FDA, industry, associations and foundations) to support the infrastructure required to facilitate the development of a variety of biomarkers projects. In addition to creating and supporting an infrastructure for broad, cross-sector communication and consensus and identifying areas of promising research, the Biomarkers Consortium also facilitates joint financial investment in the identified research activities each of which emerge as a distinct scientific initiative under the Consortium administrative "umbrella."	Currently, the Biomarkers Consortium (BC) has 60 contributing members. In Quarter 4 of 2019, the following activites occured: A face-to-face meeting of the Executive Committee was held on October 25 in Bethesda, MD and a teleconference on December 4. Steering Committee teleconferences were held by the Inflammation and Immunity Steering Committee on October 29; the Neuroscience Steering Committee on November 6; and the Cancer Steering Committee on December 6. And, the Annual Symposium of the Cancer Steering Committee was held on November 4-5 in Bethesda, MD.	$22,777,135.78	Mar-05
Charles A. Sanders Legacy Fund - Project Legacy	Charles A. Sanders Legacy Fund	The creation of the Charles A. Sanders Legacy Fund will provide the flexibility for FNIH to incubate new ideas, to enable the FNIH to provide oversight and seed funding for novel, transformative scientific initiatives and launch innovative, creative initiatives that will continue to enhance biomedical research. (Excludes fellowships.) This investment will also allow FNIH to react rapidly and responsibly to new NIH requests under unique circumstances: unexpected budget reductions like sequestration, for example, or when immediate funding is critical, such as during the Ebola crisis. Lastly, the fund will enable FNIH to establish the Charles A. Sanders Partnership Award to recognize an outstanding, top-contributing partner each year. See attached full-length document	The 2019 Charles A. Sanders, M.D. Partnership Award was presented to Jane M. Sayer, Ph.D. and the Doris Duke Charitable Foundation at the FNIH Fall Board Dinner in October.	$3,112,788.47	May-15
Consensus Pathway for Gene Drive in Mosquitoes	Consensus Pathway for Gene Drive in Mosquitoes	Research is ongoing to use natural or engineered gene drive systems to create a low-cost, sustainable tools for controlling transmission of vector-borne diseases. The goal is to reduce or eliminate vector mosquitoes, or render them less competent to transmit pathogens. Either outcome should contribute to disease reduction. The CRISPR/Cas system provides a molecular tool to create driving transgenes. Not yet optimized, such mosquitoes have been developed with the intent of testing in the field. Guidance and oversight mechanisms are needed to help ensure safe use of the technology before field testing begins. This project convened a panel of prominent experts to think through resources and activities needed to ensure safe and efficient field testing of Anopheles gambiae mosquitoes modified with low threshold gene drive systems for the elimination of malaria in Sub-Saharan Africa. Recommendations are intended to inform researchers, funders, and regulators, and policy makers.	FNIH established a multidisciplinary Core Working Group (with expertise in malaria transmission, vector control, epidemiology, ecology, evolutionary biology, biosafety, bioethics, global health and clinical trial design) to develop consensus recommendations on requirements for safe, ethical and efficient field testing of mosquitoes modified with driving transgenes. The report – "Pathway to Deployment of Gene Drive Mosquitoes as a Potential Biocontrol Tool for Elimination of Malaria in Sub-Saharan Africa: Recommendations of a Scientific Working Group" – was published in 2018 (doi: https://doi.org/10.4269/ajtmh.18-0083). Importantly, in 2020, the FNIH continues collaborating with the World Health Organization (WHO) to update the WHO 2014 publication "Guidance framework for testing of genetically modified mosquitoes" with gene drive-specific guidance based on the 2018 "Pathway to deployment..." recommendations. The final WHO product will have a positive influence on research activities through the guidance provide to a number of stakeholder groups (researchers and developers, regulators and policy makers, and funders).	$1,836,845.00	Jul-16

Research Projects					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
FNIH Travel support for NIH Scientists	NIH Travel for Gates	This travel grant is used to arrange for and provide support to National Institutes of Health (NIH) personnel to participate in technical, strategic and advisory meetings as needed and requested by the Bill & Meinda Gates Foundation.	The FNIH initiated this program in August 2013 when it was awarded a grant from the Bill & Melinda Gates Foundation. Supplemental funds awarded in November 2017 provided support for NIH VRC and BMGF Discovery collaboration projects that use BMGF GH-VAP platforms. This mechanism is funding travel and meetings to conduct approved vaccine studies and discuss data with the goal of accelerating the research under an MOU that was executed between FNIH and NIAID. Annual progress reports are submitted every November.	$928,440.00	Aug-13
GeneConvene Global Collaborative	GeneConvene Global Collaborative	The GeneConvene Global Collaborative's mission is to support coordination among stakeholders that enables the development and dissemination of scientifically rigorous information, consensus best practices guidance and standards, and administrative, regulatory and technical advice and training that will advance responsible research, development and, if warranted, implementation of gene drive technologies to eliminate vector borne diseases, with a focus on malaria in Africa, and improve public health.	The GeneConvene Global Collaborative was awarded a grant in October 2019 from the Bill & Melinda Gates Foundation to support the project. The project was initiated at the beginning of 2020.	$23,058,806.00	TBD
Pamela Anne Cafritz Renal Cell Carcinoma Award Fund	Cafritz Fund	The fund is designed to support the development of highly innovative approaches and technologies aimed at addressing kidney cancer. The Award will be disseminated as a special call for proposals at the National Cancer Institute, under the leadership of the Director of the Center for Cancer Research or his/her designee. The Award seeks to provide an investigator enabling research support in hopes of reducing the proliferation of and death from this disease.	FNIH Staff sent a stewardship report for each award recipient to the Cafritz family.	$500,000.00	Jan-18
Support functions for development of new technologies for controlling transmission of mosquito-borne	Support functions for VCTR	This project covers funding for a variety of activities to support develop novel biological methods to prevent transmission of vector-borne diseases under the Eliminate Dengue (now World Mosquito Program) and Target Malaria projects, which have been managed by FNIH under other funding. The activities supported by this new grant include consulting contracts, meeting planning and support, and a jointly funded (with NIH) study conducted by the US National Academies of Science, Engineering and Medicine.	FNIH received this initial award in 2015 from the Bill & Melinda Gates Foundation, and the project obtained supplemental funding in 2016 extending the grant to January 2020. In 2019, the project has supported several workshops as well as regulatory capacity strengthening efforts to underpin responsible research on gene drive.	$3,818,907.00	Feb-15
Transitional Support for Gene Drive Research	Transitional Support for Gene Drive Research	Gene drive is a naturally occurring mechanism that can promote the preferential inheritance of a genetic trait, thereby causing specific genetic elements to spread throughout populations. Rapid advances in CRISPR gene-editing technology have provided researchers with a facile way to produce gene drive synthetically, as demonstrated by recent laboratory successes showing its potential to reduce malaria transmission by mosquitoes. Many applications of this emerging technology are being considered for public health purposes. FNIH is facilitating collaboration, coordination and/or alignment of stakeholders to advance responsible research, development and, if warranted, implementation for the public good. Acting as a neutral convener, FNIH aims to enable development and dissemination of scientifically rigorous information, support construction of consensus best practices guidance, and provide administrative, regulatory, and technical advice and training to build capacity in these areas.	The FNIH gene drive staff has conducted and has plans to conduct workshops designed for various stakeholder groups to further safe, ethical, and efficient research using gene drive technologies. In addition, the Gene Drive Research Forum - a loose federation of stakeholders from research, government, not-for-profit organizations, for-profit companies and other parties with interests in gene drive research across various proposed applications (public health, conservation, and agriculture) - continued its activities focused on data sharing, transparency, and regulatory and research/technical capacity building throughout 2019. And, FNIH gene drive team members continued to collaborate with international organizations to provide educational 'trainings' on the basics of gene drive technology and its potential benefits and risks, and to develop and make public best practices guidance documents.	$7,642,738.00	Nov-16

Events					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Gene Drive Research Forum	Gene Drive Research Forum	The Gene Drive Research Forum is a loose federation of gene drive-interested organizations and researchers that meets periodically to discuss the status and challenges of gene drive research, and identify areas of potential mutual interest where collaboration, coordination and cooperation among stakeholders will move the field forward in a positive manner. Interest areas include data sharing, transparency, regulatory capacity strengthening, and technical/research capacity strengthening.	Funds from this grant provided by the Wellcome Trust were used to travel stakeholders (mainly researchers) from low- and middle-income countries to particpate at the Gene Drive Research Forum meeting that was held October 31-November 1, 2019 in Addis Ababa, Ethiopia.	$24,495.56	Apr-19
The Lurie Prize in Biomedical Sciences	Lurie Prize	In 2013, FNIH presented the first Lurie Prize, an annual award recognizing outstanding achievement by a promising young scientist in biomedical research. The Prize amount is $100,000, to be used as the recipient chooses. It is made possible by a generous gift from FNIH Board member Ann Lurie. The winner is selected by a jury of six distinguished biomedical researchers, chaired by Solomon H. Snyder, M.D., Distinguished Service Professor of Neuroscience, Pharmacology & Psychiatry, The Solomon H. Snyder Department of Neuroscience at Johns Hopkins University and Vice Chairman for Science of the FNIH. Past Lurie Prize winners are Dr. Ruslan Medzhitov (2013), Dr. Jennifer Doudna (2014), Dr. Karl Deisseroth (2015), Dr. Jeannie Lee (2016), Dr. David Sabatini (2017), and Dr. Zhijian "James" Chen.	Jury selected winner. The winner is to be announced at end of Q1 in 2020. FNIH Advancement provided Ms. Lurie with a report on the 2019 and 2020 FNIH Award Ceremonies, at which the Lurie Prize is presented annually.	$1,000,000.00	Nov-11
2020 FNIH Award Ceremony	2020 FNIH Award Ceremony	In 2020 FNIH will hold its eighth annual award ceremony at which it will present the Lurie Prize in Biomedical Sciences.	The 2020 FNIH Award Ceremony will take place on May 20, 2020 where the eighth annual Lurie Prize in Biomedical Sciences will be presented.	Fundraising efforts are underway	TBD
Education and Seminars					
Project Name	**Display Name**	**Description**	**Latest News**	**Money Raised (as of Dec 31, 2019)**	**(Anticipated) Launch Date**
Norman P. Salzman Memorial Award and Lecture in Virology	Salzman Memorial Award & Lecture	Dr. Norman P. Salzman's family, colleagues and friends remember the legacy of this noted pioneer in molecular biology through contributions to the Salzman Memorial Fund, which supports the annual Norman P. Salzman Memorial Award and Symposium in Virology. The half-day symposium addresses key topics in virology and immunology and presents an award to a young researcher, in recognition of Dr. Salzman's mentorship of so many young scientists. In 2008, the Salzman Memorial Fund celebrated its 10th anniversary.	The 21st annual Salzman Memorial Symposium and Award took place on November 18, 2019 at the Clinical Center at NIH.	$232,062.55	Jan-99
Notkins Biomedical Research Fund	Notkins Biomedical Research Fund	Dr. Notkins' 58-year career at the NIH includes publishing approximately 430 scientific papers, serving as editor of five books, and authoring three patents. As a capstone to this service, Dr. & Mrs. Notkins wish to provide funding for small, two-day workshops with the aim of gathering participants to discuss basic science issues pertaining to the biology and pathogenesis of disease ("Workshops").	FNIH Staff reached out to Dr. and Mrs. Notkins by phone to check in for planning the first inaugural Notkins workshop.	$1,200,000.00	Jun-18

New Project

Tab Five
FNIH Donors Report

2019 Donors Report

The FNIH acknowledges and thanks each of its donors, whether they are an individual, not-for-profit, foundation or corporation. Their generosity ensures that the FNIH has the essential resources required to advance a wide variety of pace-setting and innovative research, training and education initiatives. While unrestricted gifts allow the flexibility to use donations where they are urgently needed, restricted gifts serve a specific area of research. Other donors choose to establish funds and endowments to pay tribute to their loved ones. Gifts identified with a [§] reflect multi-year pledge commitments and cash received. The lists that follow include donors of $250.00 or more.

2019 Individual Donors by Program Supported

2019 FNIH Award Ceremony

Robert Balthaser and Ricardo C. Araneda, Ph.D.	$500
Mrs. William McCormick Blair, Jr.	$500
Bobby Burchfield	$500
Buffy Cafritz	$10,000
John M. Connors	$10,000
Dr. and Mrs. Marijn Dekkers	$2,000
Drs. Maria & Ernesto Freire	$5,600
Donald Hill and Carolyn Ross	$500
Willard Hillegeist	$250
Dr. and Mrs. Thomas R. Insel	$500
Dr. and Mrs. Gary J. Kelloff	$500
Peter and Judy Kovler	$1,000
Ronald L. Krall, M.D. and Susan J. Krall	$1,000
Julie Bell Lindsay In memory of T. Douglas Lindsay	$10,000
Edison T. Liu, M.D., Ph.D. and Margaret B. Liu	$500
Jan M. Lundberg, Ph.D.	$500
Mrs. Marlene Malek	$500
Paul D. Manca, J.D.	$500
Torrey McClary	$500
Marilyn H. Paul	$500
Amy and John Porter	$1,000
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Charles A. Sanders, M.D. and Ann E. Sanders	$2,000
Mary Anne Schofield, Ph.D.	$500
Fred A. and Donna Seigel	$13,600
Solomon H. Snyder, M.D.	$7,000
Russell W. Steenberg and Patricia Colbert	$10,000
Paul Stoffels, M.D. and Katelijne Bruurs	$10,000
Samuel O. Thier, M.D. and Paula Thier	$500
Paul M. Thompson	$2,000
Marica and Jan Vilcek	$1,000
Caren, Lexi and Alyssa Weakley	$2,000
Mary Woolley	$500

2019 International Forum on Rheumatoid Arthritis

Yin Bao	$1,000
Stephen Benoit	$1,000
Robert J. Benschop, Ph.D.	$1,000
Dr. Sean Connolly	$1,000
Emanuele deRinaldis	$1,000
Minya Fan	$1,000
Dr. Sheng Gao	$1,000
Dr. Jun Hirose	$1,000
Martin Hodge, Ph.D.	$1,000
Scott Jelinsky, Ph.D.	$1,000

2019 Individual Donors by Program Supported

Ayumi Kato	$1,000
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Dr. Navit Naveh	$500
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Frank Nestle	$1,000
Souhei Ohyama	$1,000
Dr. Stephen Rapecki	$1,000
Qian Tang	$1,000
Dr. Ritu Valiyil	$1,000
Chao Wang	$1,000
Aaron Winkler	$1,000
An Yu	$1,000
Ke Zhan	$1,000

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Joseph N. and Michie Flanz	$500
Henry L. Hecht	$1,000
Lori A. Rolnick	$300
Dr. Stuart H. Yuspa and Eleanor H. Yuspa	$500

Alzheimer's Disease Neuroimaging Initiative 3

Jeffrey Chow	$500
John Madden, Jr.	$1,000
Mr. Mehdi Nafissi and Dr. Ann F. Welton	$1,000
Sunny Raspet	$2,500
Mary Anne Schofield, Ph.D.	$6,000
Joel Yesley	$400

Biomarkers Consortium – Membership

Arlene L. Feit	$450

BRCA Challenge Fund

Richard and Susan Roth	$100
Andrew and Elyse Steinhaus	$6,000

Cancer Research Fund

Marc and Debbie Breslawsky	$1,500
Jeffrey Chow	$500
Erin Williams	$1,000

CarMollNat Muscular Dystrophy Endowment

Carol-Ann Harris	$9,681

Dean R. O'Neill Renal Cell Cancer Research Fund

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Chadwick Brown	$250
Ryan Cox	$2,172

2019 Individual Donors by Program Supported

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Shauna Ensrud	$410
Faye Fager	$250
Margaret Gavin	$272
Todd and Eileen Grams	$1,500
Mr. Scott Green	$1,086
Gerald Haley	$272
Meg Halvorsen	$489
Barry and Sandy Harris	$258
Tracy Haugen	$272
Robert Heady	$250
James W. Jones	$10,000
Michael and Nancy Kelly	$272
Kathleen Mellody	$250
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Tuan Tran	$250
Anthony E. Vellek	$500
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Deeda Blair Research Initiative Fund for Disorders of the Brain

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Dr. Tun-Hou Lee	$2,500
William and Stephanie Marra	$250
Steve and Sherry Mayer	$100,000
Caroline R. Milbank	$2,500
Renvy Graves Pittman	$10,000
Susan Butler Plum	$10,000
Harold R. Werner	$10,000

Dr. Jane M. Sayer Vision Research Lecture & Award

Jane M. Sayer, Ph.D.	$20,000

Edmond J. Safra Family Lodge-All Programs

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Paula L. and William C. Bradley	$1,000
Keith F. and Alison Burrows	$400
Daniel Cunningham and Mary Hennessey	$1,000
Roland D. Eavey	$250
Gene and Esther Gorman	$1,250

2019 Individual Donors by Program Supported

Randall and Holly Griffin	$500
Chris and Laura C. Hazzard	$2,000
Stephan Kennedy	$500
Kevin and Teresa Klock	$175
Patricia S. Kohlen	$11,235
Louis W. and Judith A. Leibert	$1,300
Thomas A. and Nancy I. Lusk	$200
Philip J. Mares	$500
Gretchen Naylor	$500
Donna Nichols	$2,000
Matt and Robyn Nichols Painter	$1,000
The Relias Family	$500
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Alissa Roston	$500
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Suresh and Feroza Subramani	$300
William, Zani and Aycen Tolentino	$500
Jay A. Yarington	$250

Follicular Lymphoma Research Fund

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Futures Fund

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Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.

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William Morley and Caroline Trahan	$1,000
Leonard Morrissey	$250
Thomas and Pam Timbie	$3,500

Kovler Prize

Peter and Judy Kovler	$100,000

Lurie Prize

Ann Lurie	$100,000

Medical Research Scholars Program 2016-2017

Buffy Cafritz	$30,000

2019 Individual Donors by Program Supported

NINDS Summer Internship Program

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Norman P. Salzman Memorial Fund

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Pamela Anne Cafritz Renal Cell Carcinoma Award Fund

Buffy Cafritz	$100,000

Robert Whitney Newcomb Memorial Fund

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Solarz Memorial Fund

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Eric Hirschhorn and Leah Wortham	$1,000
The Honorable Matthew McHugh	$500

Stephen E. Straus Distinguished Lecture in CAM

James M. Felser, M.D.	$1,000

Temporarily Restricted

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John Bertschy	$10,000
Thomas J. and Marie B. Dolan	$500
Roger W. Ferguson and Annette L. Nazareth	$25,000
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Jeffrey Grundman Family	$1,000
Carolynne K. Grundman	$500
Gregory and Barbara K. Hack	$250
Ralph H. and Janette G. Moore	$1,000
Bernice Passaretti	$300
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Lorene Steinberg	$500

Unrestricted

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Ella Bronstein	$3,000
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Michael Gottlieb, Ph.D. and Joan Gottlieb	$500
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Darren Schneider	$250
Susan Segatti	$250
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Paul Stoffels, M.D. and Katelijne Bruurs	$25,000
Rainer F. Storb, M.D.	$375
Suresh and Feroza Subramani	$500

2019 Individual Donors by Program Supported

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Anthony Tassone	$250
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Marica and Jan Vilcek	$500
Nathaniel Walker and Tracy Towsley Walker	$500
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David Wholley	$1,000
Stewart K. Wilson	$1,000
Gregory Winkelman	$500
Julie and Howard Wolf-Rodda	$600
Richard G. Wyatt, M.D. and Linda S. Wyatt, Ph.D.	$3,000
Lucas and Katrina Yun-Nikolac	$2,728
Elias A. Zerhouni, M.D. and Nadia Zerhouni, M.D.	$10,000
Daniel Zhao	$900

2019 Organizational Donors by Program Supported

AbbVie Inc.	$400,000	Alzheimer's Disease Neuroimaging Initiative 3
	$201,000	BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's disease
	$200,000	BC - Mucosal Healing in Ulcerative Colitis
	$10,000	BC - CSC 2019 Scientific Symposium
Abrams Charitable Trust	$8,190	Abrams Charitable Fund
Adaptive Biotechnologies	$25,000	BC - CSC 2019 Scientific Symposium
	$10,000	BC - Membership
ADx NeuroSciences	$10,000	BC - Membership
The Air Products Foundation	$375	Unrestricted
Alector, Inc.	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
	$27,000	BC - Membership
Alexandria Real Estate Equities, Inc.	$125,000	Futures Fund
Alkahest	$5,000	2019 Geroscience Summit
Alkermes PLC	$15,000	BC - Membership
Allen Matkins Leck Gamble Mallory & Natsis LLP	$5,000	2019 FNIH Award Ceremony
Alliance for Aging Research	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
	$5,000	2019 Geroscience Summit
Alzheimer's Association ®	$200,000	Alzheimer's Disease Neuroimaging Initiative 3
	$196,717	BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's disease
	$25,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
	$13,500	BC - Membership
Alzheimer's Drug Discovery Foundation	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
	$75,000	ADNI - Amyloid PET Early Frames Add on Study
	$13,500	BC - Membership
	$527	Unrestricted
American Association for Dental Research	$75,000	MRSP 2019-2020
American College of Medical Genetics and Genomics	$5,000	2019 International Summit in Human Genetics and Genomics
American Diabetes Association	$5,000	BC - Membership
American Endowment Foundation	$15,000	Unrestricted
American Federation for Aging Research	$2,500	2019 Geroscience Summit
American Heart Association, Inc.	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
	$5,000	BC - Membership
American Society for Microbiology	$5,000	2019 FNIH Award Ceremony
American Society of Clinical Oncology	$5,000	2019 Geroscience Summit
American Society of Gene & Cell Therapy	$5,000	2019 International Summit in Human Genetics and Genomics
The American Society of Human Genetics	$5,000	2019 International Summit in Human Genetics and Genomics
America's Charities	$2,477	Unrestricted
Amgen Foundation	$167,500	Amgen Scholars Program

2019 Organizational Donors by Program Supported

Amgen, Inc.	$60,000	BC - TARGET BMx Study
	$25,000	BC - CSC 2019 Scientific Symposium
	$150,000	BC - Membership
AMRA Medical	$5,000	BC - Membership
	$10,000	BC - Membership
AMS Foundation for the Arts, Sciences and Humanities	$5,000	2019 FNIH Award Ceremony
Apple Inc.	$1,000	Unrestricted
Araclon Biotech, S.L.	$20,000	Alzheimer's Disease Neuroimaging Initiative 3
Arthritis Foundation	$13,500	BC - Membership
Association for Molecular Pathology	$5,000	BC - Membership
Association of American Cancer Institutes	$2,500	Lowy Cancer Research Support Fund
Association of American Medical Colleges	$10,000	2019 FNIH Award Ceremony
AstraZeneca Pharmaceuticals, LP	$1,111,943	Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation
	$103,215	BC - ctDNA Reference Material
Bayer AG	$60,000	NCTN Data Archive De-Identification Project
	$5,000	BC - CSC 2019 Scientific Symposium
Berger Family Foundation, Inc.	$25,000	Cancer Research Fund
Bharat Biotech	$10,000	2019 FNIH Award Ceremony
Bioclinica, Inc.	$25,000	Alzheimer's Disease Neuroimaging Initiative 3
	$10,000	BC - Membership
Biogen	$100,000	Alzheimer's Disease Neuroimaging Initiative 3
	$201,000	BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's disease
	$10,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
	$28,000	BC - Membership
	$2,000	2019 FNIH Award Ceremony
Bio-Rad Laboratories, Inc.	$30,000	BC - Membership
Biotechnology Innovation Organization	$2,000	2019 FNIH Award Ceremony
The Bluefield Project to Cure Frontotemporal Dementia	$13,500	BC - Membership
BrightFocus Foundation	$500	2019 FNIH Award Ceremony
	$5,000	BC - Membership
Bristol-Myers Squibb Company	$10,000	2019 FNIH Award Ceremony
	$5,000	BC - CSC 2019 Scientific Symposium
C2N Diagnostics	$10,000	BC - Membership
Celgene Corporation	$1,200,000	Accelerating Medicines Partnership: Parkinson's Disease
	$5,000	BC - CSC 2019 Scientific Symposium
Cerf-Dunbar Fund	$1,000	Unrestricted
Chrono Track	$21,052	Dean R. O'Neill Renal Cell Cancer Research Fund
Citigroup Inc.	$5,000	2019 FNIH Award Ceremony
City of Hope	$2,000	2019 FNIH Award Ceremony
Cleary Gottlieb Steen & Hamilton LLP	$10,000	2019 FNIH Award Ceremony
Clovis Oncology	$3,311,354	Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation

2019 Organizational Donors by Program Supported

	$0	BC - Membership
Cofactor Genomics	$10,000	BC - Membership
Cognition Therapeutics, Inc.	$10,000	BC - Membership
Cogstate Ltd	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
Colgate-Palmolive Company	$37,500	MRSP 2019-2020
Compass Group, North America	$3,243	Edmond J. Safra Lodge-All Programs
Congress of Neurological Surgeons Foundation	$100,000	2019 NINDS/CNS Getch Extension
Consumer Healthcare Products Association	$500	2019 FNIH Award Ceremony
Crohn's and Colitis Foundation, Inc.	$5,000	BC - Membership
Cushman & Wakefield	$10,000	2019 FNIH Award Ceremony
Daftuar Family Foundation	$5,000	Unrestricted
Davis Polk & Wardwell LLP	$10,000	2019 FNIH Award Ceremony
The Geaton & JoAnn DeCesaris Family Foundation, Inc.	$10,000	Accelerating Medicines Partnership: Parkinson's Disease
Denali Therapeutics Inc.	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
DiamiR	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
Driven To Cure, Inc.	$102,062	Kidney Cancer Research in the Laboratory of W. Marston Linehan, M.D.
eBay, Inc.	$625	Unrestricted
EIP Pharma Inc.	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
Eisai Inc.	$100,000	Alzheimer's Disease Neuroimaging Initiative 3
Emergent BioSolutions, Inc.	$2,000	2019 FNIH Award Ceremony
EUROIMMUN AG	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
F5 Networks	$2,667	Unrestricted
Facebook Donors	$3,643	Unrestricted
Figure 1	$4,500	Temporarily Restricted
The Michael J. Fox Foundation for Parkinson's Research and the Aligning Science Across Parkinson's Initiative	$3,200,000	Accelerating Medicines Partnership: Parkinson's Disease
Frederick National Laboratory for Cancer Research	$5,000	BC - Membership
Fremont Group	$500	Unrestricted
Friends of Cancer Research	$2,000	2019 FNIH Award Ceremony
	$5,000	Unrestricted
FUJIFILM Corporation	$25,000	Alzheimer's Disease Neuroimaging Initiative 3
Bill & Melinda Gates Foundation	$1,464,744	Developing leads to shorten duration of TB chemotherapy: SHORTEN-TB
	$2,640,522	Using Biomarkers to Predict TB Treatment Duration
	$3,188,501	Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs
Bill & Melinda Gates Foundation	$1,612,586	Combining Epitope Based Vaccine Design with Informatics-Based Evaluation to Obtain an Universal Infl
	$5,294,112	Global collaborative for coordination of gene drive research and development
	$119,258	Support functions for development of new technologies for controlling transmission of mosquito-borne
	$608,000	Consensus Pathway for Gene Drive in Mosquitoes
	$125,000	Structure-based Vaccine Design Against HIV-1

2019 Organizational Donors by Program Supported

	$2,478,743	Comprehensive Cellular Vaccine Immune Monitoring Consortium
	$2,870,166	Support functions for development of new technologies for controlling transmission of mosquito-borne
Gates Ventures	$15,000	BC - Membership
GE Healthcare	$75,000	Alzheimer's Disease Neuroimaging Initiative 3
Genentech, Inc.	$40,000	BC - Membership
	$5,400	BC - CSC 2019 Scientific Symposium
	$10,000	2019 Geroscience Summit
Genmab A/S	$5,000	BC - CSC 2019 Scientific Symposium
	$15,000	BC - Membership
GHR Foundation	$15,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
Gilead Sciences, Inc.	$660,804	Gilead Leidos (Car-T)
GlaxoSmithKline	$1,200,000	Accelerating Medicines Partnership: Parkinson's Disease
Glenn Foundation for Medical Research	$25,000	2019 Geroscience Summit
Global Impact Combined Federal Campaign	$10,685	Unrestricted
Goldman Sachs Gives	$10,000	2019 FNIH Award Ceremony
Google Matching Gifts Program	$2,018	Unrestricted
Goulston & Storrs PC	$10,000	2019 FNIH Award Ceremony
The Grass Foundation	$60,000	NINDS Summer Internship Program
Harmony Biosciences LLC	$2,000	2019 FNIH Award Ceremony
The John A. Hartford Foundation	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
Harvey Grossman Revocable Trust	$10,000	Deeda Blair Research Initiative Fund for Disorders of the Brain
Estate of Jean Lough Heagy	$762,000	Cancer Research Fund
Henry Schein, Inc.	$5,000	2019 FNIH Award Ceremony
Hewlett Packard Enterprise	$500	Alzheimer's Disease Neuroimaging Initiative 3
	$500	Cancer Research Fund
Hogan Lovells US LLP	$1,500	2019 FNIH Award Ceremony
	$50,000	Unrestricted
Home Instead Senior Care	$1,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
Horizon Therapeutics plc	$5,488,560	Clinical Center Drug Donations
Imaginostics	$10,000	BC - Membership
Institut De Recherches Internationales Servier	$100,000	Alzheimer's Disease Neuroimaging Initiative 3
Invicro	$16,667	Alzheimer's Disease Neuroimaging Initiative 3
	$10,000	BC - Membership
IQ Solutions	$1,500	Dean R. O'Neill Renal Cell Cancer Research Fund
IXICO Ltd.	$16,667	Alzheimer's Disease Neuroimaging Initiative 3
Jack Gramlich Foundation	$24,606	Gramlich Trust Melanoma Research
Johnson & Johnson	$400,000	Alzheimer's Disease Neuroimaging Initiative 3
	$201,000	BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's disease
	$690,000	Accelerating Medicines Partnership - RA/SLE
	$50,000	ADNI - Amyloid PET Early Frames Add on Study
	$22,000	BC - Longitudinal Proteomic Changes in CSF from ADNI: Towards Better Defining the Trajectory of Prod
Johnson & Johnson Family of Companies Matching Gift Program	$1,000	Alzheimer's Disease Neuroimaging Initiative 3
King & Spalding LLP	$1,000	2019 FNIH Award Ceremony

2019 Organizational Donors by Program Supported

Peter and Judy Kovler	$100,000	Kovler
Lafayette 89	$300	Edmond J. Safra Lodge-All Programs
Life Molecular Imaging	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
	$75,000	ADNI - Amyloid PET Early Frames Add on Study
Eli Lilly and Company	$200,000	Alzheimer's Disease Neuroimaging Initiative 3
	$2,630,581	Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation
Lundbeck	$100,000	Alzheimer's Disease Neuroimaging Initiative 3
Lupus Foundation of America	$25,000	Accelerating Medicines Partnership - RA/SLE
Ann and Robert H. Lurie Foundation	$10,000	2019 FNIH Award Ceremony
MagQu Co., Ltd.	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
Marriott International, Inc.	$2,000	2019 FNIH Award Ceremony
Martha B. and Michael S. Horne Charitable Fund	$10,000	Unrestricted
Mayo Clinic	$10,000	2019 International Summit in Human Genetics and Genomics
Merck Sharp & Dohme Corp.	$175,000	BC - Volumetric CT, Improving Metrics for Phase II Analysis of Clinical Trials Results
	$56,250	BC - TARGET BMx Study
	$400,000	Alzheimer's Disease Neuroimaging Initiative 3
	$1,811,574	Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation
Metcor/LSI	$2,000	2019 FNIH Award Ceremony
Microsoft Corporation	$290	Unrestricted
Milken Institute	$5,000	BC - Membership
Miller Bros.	$250	Unrestricted
Morgan Stanley & Co. Incorporated	$10,000	2019 FNIH Award Ceremony
Morgan Stanley GIFT (Global Impact Funding Trust)	$1,000	Unrestricted
National Alliance on Mental Illness	$2,000	2019 FNIH Award Ceremony
National Dairy Council	$5,000	BC - Membership
National Institutes of Health	$500,000	Government Appropriation
	$220,665	Helping to End Addiction Long-term Partnership
	$270,780	Unrestricted
The New York Community Trust/Community Funds, Inc.	$10,000	2019 FNIH Award Ceremony
Nordic Bioscience A/S	$10,000	BC - Membership
Northrop Grumman Corporation	$260	Edmond J. Safra Lodge-All Programs
Olink Proteomics	$10,000	BC - Membership
Omega World Travel Inc.	$2,000	2019 FNIH Award Ceremony
OncoImmune, Inc.	$2,000	2019 FNIH Award Ceremony
Ortho Clinical Diagnostics	$25,000	BC - Novel Cardiac Biomarkers in the General US Population
Oxford BioDynamics Plc	$27,000	BC - Membership
Paramount Group	$10,000	2019 FNIH Award Ceremony
Paul, Weiss, Rifkind, Wharton & Garrison LLP	$10,000	2019 FNIH Award Ceremony
PeopleBio, Inc.	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
The Pew Charitable Trusts	$15,750	Pew Latin American Fellows Awards
Pfizer Inc.	$1,200,000	Accelerating Medicines Partnership: Parkinson's Disease
	$773,272	Master Protocol for Treatment of Advanced Squamous Cell Lung Cancer Implementation

2019 Organizational Donors by Program Supported

Pharmaceutical Research and Manufacturers of America	$200,000	Predevelopment Pediatric Oncology
	$130,000	BC - Membership
The Pittsburgh Foundation	$525	Dean R. O'Neill Renal Cell Cancer Research Fund
Andrew & Lillian A. Posey Foundation	$20,000	Temporarily Restricted
Margot & Thomas Pritzker Family Foundation	$2,000	2019 FNIH Award Ceremony
The Procter & Gamble Company	$10,000	2019 FNIH Award Ceremony
ProMIS Neurosciences, Inc.	$10,000	BC - Membership
ProSciento, Inc.	$10,000	BC - Membership
PTA Jankowski Charitable Fund	$1,100	Accelerating Medicines Partnership: Parkinson's Disease
	$1,100	Alzheimer's Disease Neuroimaging Initiative 3
	$1,100	Temporarily Restricted
Radiological Society of North America	$5,000	BC - Membership
Radius Health, Inc.	$10,000	BC - Membership
Regeneron Pharmaceuticals, Inc.	$50,000	BC - TARGET BMx Study
	$200,000	BC - Membership
	$5,000	2019 Geroscience Summit
Reuben, Junius & Rose, LLP	$10,000	2019 FNIH Award Ceremony
Roche	$400,000	Alzheimer's Disease Neuroimaging Initiative 3
Sage Therapeutics	$15,000	BC - Membership
Saladax Biomedical, Inc.	$10,000	Alzheimer's Disease Neuroimaging Initiative 3
Samumed	$75,000	BC - PROGRESS OA - Osteoarthritis (OA) Biomarkers Qualification
The San Diego Foundation	$2,000	UNR-Foundation Gifts
Sanford Health	$5,000	2019 International Summit in Human Genetics and Genomics
Sanofi	$1,200,000	Accelerating Medicines Partnership: Parkinson's Disease
	$150,000	BC - Membership
	$2,500	BC - CSC 2019 Scientific Symposium
Sarepta Therapeutics	$5,000	2019 International Summit in Human Genetics and Genomics
Seattle Genetics, Inc.	$15,000	BC - Membership
Sengenics Corporation	$10,000	BC - Membership
The Shiley Foundation	$25,000	2019 Geroscience Summit
Sjögren's Foundation, Inc.	$5,000	BC - Membership
Skadden, Arps, Slate, Meagher & Flom LLP	$5,000	2019 FNIH Award Ceremony
Society for Immunotherapy of Cancer	$2,500	BC - CSC 2019 Scientific Symposium
The Stephen J. Solarz Living Trust	$2,000	2019 FNIH Award Ceremony
Spectrum Science	$2,000	2019 FNIH Award Ceremony
Sullivan & Cromwell LLP	$5,000	2019 FNIH Award Ceremony
SunTrust Banks, Inc.	$2,000	2019 FNIH Award Ceremony
Takeda Pharmaceutical International, Inc.	$200,000	Alzheimer's Disease Neuroimaging Initiative 3
	$201,000	BC - Plasma Aß as a predictor of amyloid positivity in Alzheimer's disease
	$5,000	BC - CSC 2019 Scientific Symposium
The Association for Frontotemporal Degeneration	$5,000	BC - Membership
Tischfield Family Charitable Gift Fund	$300	Unrestricted

2019 Organizational Donors by Program Supported

TM Capital Corp	$500	Solarz Memorial Fund
UCB, Inc.	$5,000	2019 FNIH Award Ceremony
United Way of the California Capital Region	$291	Unrestricted
UnitedHealth Group Incorporated	$10,000	2019 FNIH Award Ceremony
UsAgainstAlzheimer's	$10,000	2019 FNIH Award Ceremony
Verde Technologies	$10,000	2019 FNIH Award Ceremony
The Wellcome Trust	$24,496	Gene Drive Research Forum
Wellmed Medical Management	$5,000	2019 Alzheimer's Disease Related Dementias (ADRD) Summit
Wiley Rein LLP	$500	Unrestricted - Corporate Partner Society
Wolk Family Fund	$2,000	Unrestricted
Wyeth Nutrition	$580,644	Baby Connectome Project
	$20,000	Baby Connectome Project

Foundation for the National Institutes of Health
Donor and Funding Partner Selection Criteria

The FNIH accepts unrestricted gifts, and gifts for specific programs and purposes, provided that they are not inconsistent with its mission, purposes, and priorities.

The FNIH applies a variety of criteria to aid in determining the appropriateness of a gift or contribution to the organization or its programs, to avoid gifts that would reflect unfavorably on or compromise the integrity of the FNIH or the NIH.

The FNIH does not accept gifts that are:

- in violation of the FNIH's statutory authority or state corporate charter
- too restricted in purpose, or too difficult or burdensome to administer
- intended for purposes outside the mission of the FNIH
- from the tobacco industry, unless given as the result of a court settlement
- would compromise the credibility of the research or other funded activity
- otherwise determined to be inappropriate.

The FNIH does not accept anonymous gifts from corporations.

The FNIH reviews gifts for actual or potential conflicts of interest and, if appropriate, alerts or advises its Board of Directors.

Tab Six
Financial Highlights

FINANCIAL HIGHLIGHTS*

FY18-19 Allocation of NIH Support to FNIH+

Office Space	**$345,000**
Unrecovered Program Salary & Benefits	**$250,000**
Partial Operating Costs	**$313,300**
New Staff	**$341,700**
Total	**$1,250,000**

FY 19-20 Allocation of NIH Support to FNIH+

Office Space	**$450,000**
Unrecovered Program Salary & Benefits	**$201,000**
Partial Operating Costs	**$250,000**
New Staff	**$349,000**
Total	**$1,250,000**

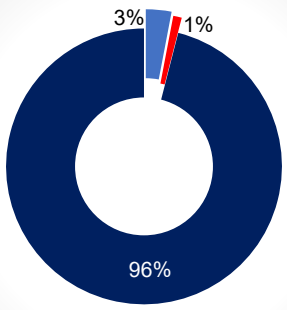
+Expenses Allocable to the NIH Support

Fundraising Summary *

Funds Raised for Active Projects	**$442,056,351**
Active Projects	**126**
Funds Raised for NIH ICs	**$398,605,101**

*Q4 2019 numbers

Funds Transferred to NIH by Category



Total:	**$23,504,795**
Fellowship and Training (3%)	$ 674,515
Events and Awards (1%)	$ 299,109
Research Programs (96%)	$ 22,531,171

Note: Since last years report, the information provided above is based on NIH's fiscal year (October-September) rather than FNIH's fiscal year (January-December).

*Please see attached Audited Financials for a full report.

Tab Seven
2019 Financial Statements and Report of the Independent Auditors

FNIH
Foundation for the
National Institutes of Health

Foundation for the National Institutes of Health, Inc.

Financial Statements

Years Ended December 31, 2019 and 2018

DIXON HUGHES GOODMAN LLP

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DIXON HUGHES GOODMAN LLP

Independent Auditors' Report

Board of Directors
Foundation for the National Institutes of Health, Inc.
North Bethesda, Maryland

We have audited the accompanying financial statements of Foundation for the National Institutes of Health, Inc., which comprise the statements of financial position as of December 31, 2019 and 2018, and the related statements of activities, functional expenses and cash flows for the years then ended, and the related notes to the financial statements.

Management's Responsibility for the Financial Statements
Management is responsible for the preparation and fair presentation of these financial statements in accordance with accounting principles generally accepted in the United States of America; this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error.

Auditors' Responsibility
Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditors' judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity's preparation and fair presentation of the financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion
In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Foundation for the National Institutes of Health, Inc. as of December 31, 2019 and 2018, and the changes in its net assets and its cash flows for the years then ended in accordance with accounting principles generally accepted in the United States of America.

DIXON HUGHES GOODMAN LLP

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Foundation has changed its method of accounting for revenue recognition in accordance with Accounting Standards Codification Topic 606, *Revenue from Contracts with Customers* and ASU 2018-08, Not-for-Profit Entities (Topic 958): *Clarifying the Scope and Accounting Guidance for Contributions Received and Contributions Made,* effective January 1, 2019. The Foundation adopted these standards using a modified retrospective approach and modified prospective approach, respectively. Our opinion is not modified with respect to these matters.

Dixon Hughes Goodman LLP

Richmond, Virginia
May 15, 2020

Foundation for the National Institutes of Health, Inc.
Statements of Financial Position
December 31, 2019 and 2018

	2019	2018
ASSETS		
Current assets:		
Cash and cash equivalents	**$ 29,756,418**	$ 20,568,739
NIH receivable	**500,000**	-
Contributions receivable, net, current portion	**7,811,673**	17,013,499
Accrued interest	**554,097**	465,834
Prepaid expenses and other receivables	**300,636**	249,754
Total current assets	**38,922,824**	38,297,826
Contributions receivable, net, less current portion	**3,642,795**	257,048
Investments	**91,401,689**	102,785,676
Property and equipment, net	**1,574,395**	1,553,424
Total assets	**$ 135,541,703**	$ 142,893,974
LIABILITIES AND NET ASSETS		
Current liabilities:		
Accounts payable and accrued expenses	**$ 10,145,693**	$ 3,884,772
Funds held for others, agency transactions	**-**	1,235,000
Charitable gift annuity	**131,791**	137,937
Total current liabilities	**10,277,484**	5,257,709
Deferred grant revenue	**-**	2,870,167
Advance receipts on conditional contributions	**5,147,362**	3,200,000
Deferred lease incentive	**1,187,019**	1,279,514
Deferred rent liability	**419,548**	383,777
Total liabilities	**17,031,413**	12,991,167
Net assets:		
Without donor restrictions:		
Unrestricted, general	**8,664,974**	6,730,390
Board designated	**12,913,000**	11,337,000
Total without donor restrictions	**21,577,974**	18,067,390
With donor restrictions	**96,932,316**	111,835,417
Total net assets	**118,510,290**	129,902,807
Total liabilities and net assets	**$ 135,541,703**	$ 142,893,974

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Activities
Year Ended December 31, 2019

	Without Donor Restrictions	With Donor Restrictions	Total
Revenue, support and other changes:			
Contributions	$ 528,556	$ 49,298,924	$ 49,827,480
Grants	220,665	-	220,665
In-kind contributions	270,780	-	270,780
Transfers from NIH	500,000	-	500,000
Donated services	50,000	-	50,000
Fundraising event	401,000	-	401,000
Investment and interest income, net	4,003,989	1,193,135	5,197,124
Administrative fee refunded, agency transactions and grants	(50,000)	-	(50,000)
Net assets released from restrictions:			
Satisfaction of indirect cost requirements	4,699,724	(4,699,724)	-
Satisfaction of program restrictions	60,668,032	(60,668,032)	-
Total revenue, support and other changes	71,292,746	(14,875,697)	56,417,049
Expenses:			
Program services:			
Fellowships and training programs	939,134	-	939,134
Memorials, awards and events	575,570	-	575,570
Capital projects	60,340	-	60,340
Research programs	59,558,215	-	59,558,215
Total program services	61,133,259	-	61,133,259
Supporting services:			
Management and general	6,123,632	-	6,123,632
Fundraising	552,675	-	552,675
Total supporting services	6,676,307	-	6,676,307
Total expenses	67,809,566	-	67,809,566
Change in donor designation	27,404	(27,404)	-
Change in net assets	3,510,584	(14,903,101)	(11,392,517)
Net assets, beginning of year	18,067,390	111,835,417	129,902,807
Net assets, end of year	$ 21,577,974	$ 96,932,316	$ 118,510,290

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Activities
Year Ended December 31, 2018

	Without Donor Restrictions	With Donor Restrictions	Total
Revenue, support and other changes:			
Contributions	$ 561,548	$ 57,700,175	$ 58,261,723
Grants	116,338	-	116,338
In-kind contributions	256,859	-	256,859
Transfers from NIH (2018 FY)	750,000	-	750,000
Transfers from NIH (2019 FY)	1,250,000	-	1,250,000
Donated services	60,000	-	60,000
Fundraising event	368,156	-	368,156
Investment and interest income (loss), net	1,030,225	(112,527)	917,698
Administrative fee, agency transactions and grants	64,723	-	64,723
Net assets released from restrictions:			
Satisfaction of indirect cost requirements	4,126,804	(4,126,804)	-
Satisfaction of program restrictions	36,092,304	(36,092,304)	-
Total revenue, support and other changes	44,676,957	17,368,540	62,045,497
Expenses:			
Program services:			
Fellowships and training programs	1,074,653	-	1,074,653
Memorials, awards and events	486,093	-	486,093
Capital projects	852,380	-	852,380
Research programs	34,264,962	-	34,264,962
Total program services	36,678,088	-	36,678,088
Supporting services:			
Management and general	5,436,683	-	5,436,683
Fundraising	515,538	-	515,538
Total supporting services	5,952,221	-	5,952,221
Total expenses	42,630,309	-	42,630,309
Change in donor designation	50,000	(50,000)	-
Change in net assets	2,096,648	17,318,540	19,415,188
Net assets, beginning of year	15,970,742	94,516,877	110,487,619
Net assets, end of year	$ 18,067,390	$ 111,835,417	$ 129,902,807

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Functional Expenses
Year Ended December 31, 2019

	Program Services					Supporting Services			
	Fellowships and Training Programs	Memorials, Awards and Events	Capital Projects	Research Programs	Total Program Services	Management and General	Fundraising	Total Supporting Services	Total
Salaries and benefits	$ 48,372	$ 62,963	$ 13,655	$ 5,588,107	$ 5,713,097	$ 4,074,426	$ 287,798	$ 4,362,224	$ 10,075,321
Stipends	500	111,434	10,000	15,000	136,934	-	-	-	136,934
Programs contracts	769,001	311,109	-	38,977,021	40,057,131	-	-	-	40,057,131
Grant awards	-	-	-	10,519,901	10,519,901	-	-	-	10,519,901
Meetings and travel	93,713	83,422	31,275	2,165,189	2,373,599	76,849	113,135	189,984	2,563,583
Office supplies and expense	2,834	488	1,461	-	4,783	14,902	1,038	15,940	20,723
Telephone	-	-	-	84,140	84,140	95,576	7,776	103,352	187,492
Books and supplies	833	-	1,306	26,077	28,216	8,132	1,192	9,324	37,540
Tuition	-	-	-	3,633	3,633	2,975	-	2,975	6,608
Insurance	-	-	-	101,082	101,082	71,796	-	71,796	172,878
Consultants	-	-	600	1,369,460	1,370,060	289,770	49,910	339,680	1,709,740
Professional fees	1,950	-	-	192,707	194,657	145,940	-	145,940	340,597
Depreciation and amortization	-	-	-	-	-	189,073	-	189,073	189,073
Rent/housing	3,120	-	-	128,877	131,997	432,957	-	432,957	564,954
Recruiting	-	-	-	53,836	53,836	33,471	-	33,471	87,307
Relocation	-	-	-	-	-	398,679	-	398,679	398,679
Temporary services	-	-	-	2,640	2,640	240	-	240	2,880
Dues and subscriptions	-	-	-	18,390	18,390	14,854	-	14,854	33,244
Equipment and rental and maintenance	16,878	-	-	5,939	22,817	40,072	-	40,072	62,889
Printing and photocopying	-	1,385	-	93,562	94,947	48,973	49,088	98,061	193,008
Postage and delivery	-	136	-	115,125	115,261	2,963	3,895	6,858	122,119
Service charges	1,329	1,116	227	6,473	9,145	23,062	1,953	25,015	34,160
Communication	14	3,242	-	76,640	79,896	148,226	30,481	178,707	258,603
Advertising and promotion	-	-	-	14,026	14,026	8,302	2,125	10,427	24,453
Miscellaneous	590	275	1,816	390	3,071	2,394	4,284	6,678	9,749
	$ 939,134	$ 575,570	$ 60,340	$ 59,558,215	$ 61,133,259	$ 6,123,632	$ 552,675	$ 6,676,307	$ 67,809,566

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statement of Functional Expenses
Year Ended December 31, 2018

	Program Services					Supporting Services			
	Fellowships and Training Programs	Memorials, Awards and Events	Capital Projects	Research Programs	Total Program Services	Management and General	Fundraising	Total Supporting Services	Total
Salaries and benefits	$ 49,988	$ 60,175	$ 82,437	$ 4,433,468	$ 4,626,068	$ 3,921,523	$ 173,868	$ 4,095,391	$ 8,721,459
Stipends	500	110,997	10,000	15,250	136,747	-	50,000	50,000	186,747
Programs contracts	892,062	128,568	602,282	16,512,076	18,134,988	-	-	-	18,134,988
Grant awards	-	-	-	9,744,585	9,744,585	-	-	-	9,744,585
Meetings and travel	105,345	174,089	31,854	1,180,650	1,491,938	68,194	104,943	173,137	1,665,075
Office supplies and expense	1,433	1,389	30	-	2,852	18,497	481	18,978	21,830
Telephone	-	-	-	70,723	70,723	88,559	7,356	95,915	166,638
Books and supplies	3,612	-	-	14,692	18,304	8,498	-	8,498	26,802
Tuition	-	-	-	674	674	2,177	-	2,177	2,851
Insurance	-	-	-	104,525	104,525	69,968	-	69,968	174,493
Consultants	-	-	118,420	1,665,555	1,783,975	233,850	95,113	328,963	2,112,938
Professional fees	-	-	-	132,198	132,198	153,052	-	153,052	285,250
Depreciation and amortization	-	-	-	-	-	173,807	-	173,807	173,807
Rent/housing	9,172	-	-	131,886	141,058	408,696	-	408,696	549,754
Recruiting	-	-	-	8,767	8,767	80,865	-	80,865	89,632
Temporary services	-	503	-	3,151	3,654	2,268	450	2,718	6,372
Dues and subscriptions	-	-	-	10,492	10,492	12,495	-	12,495	22,987
Equipment and rental and maintenance	10,851	-	-	8,985	19,836	40,287	-	40,287	60,123
Printing and photocopying	-	2,472	2,005	38,352	42,829	20,757	46,472	67,229	110,058
Postage and delivery	-	28	1,071	99,499	100,598	3,805	6,965	10,770	111,368
Service charges	1,645	325	176	6,611	8,757	22,200	2,080	24,280	33,037
Communication	45	5,047	8	80,054	85,154	90,075	13,244	103,319	188,473
Advertising and promotion	-	-	-	1,438	1,438	6,052	4,873	10,925	12,363
Miscellaneous	-	2,500	4,097	1,331	7,928	11,058	9,693	20,751	28,679
	$ 1,074,653	$ 486,093	$ 852,380	$ 34,264,962	$ 36,678,088	$ 5,436,683	$ 515,538	$ 5,952,221	$ 42,630,309

See accompanying notes.

Foundation for the National Institutes of Health, Inc.
Statements of Cash Flows
Years Ended December 31, 2019 and 2018

	2019	2018
Cash flows from operating activities:		
Change in net assets	**$ (11,392,517)**	$ 19,415,188
Adjustments to reconcile change in net assets to net cash (used) provided by operating activities:		
Depreciation and amortization	**189,073**	173,807
Contributions restricted for long-term purposes	**(259,681)**	(109,617)
Net realized and unrealized (gain) loss on investments	**(2,558,778)**	979,685
Deferred lease incentive amortization	**(92,495)**	(92,495)
Change in assets and liabilities:		
Contributions receivable	**5,816,079**	5,709,465
NIH receivable	**(500,000)**	500,000
Accrued interest	**(88,263)**	(262,015)
Prepaid expenses and other receivables	**(50,882)**	(78,047)
Accounts payable and accrued expenses	**6,260,921**	180,313
Funds held for others, agency transactions	**(1,235,000)**	(5,626)
Charitable gift annuity	**(6,146)**	(6,256)
Advance receipts on grants	**(2,870,167)**	(76,906)
Advance receipts on conditional contributions	**1,947,362**	2,765,000
Net cash (used) provided by operating activities	**(4,840,494)**	29,092,496
Cash flows from investing activities:		
Furniture and equipment acquisitions	**(210,044)**	(73,954)
Sales and maturities of investments	**98,377,402**	90,642,144
Purchase of investments	**(84,434,637)**	(123,567,801)
Net cash provided (used) by investing activities	**13,732,721**	(32,999,611)
Cash flows from financing activities:		
Deferred rent liability	**35,771**	282,341
Contributions restricted for investment in permanent endowment	**259,681**	109,617
Net cash provided by financing activities	**295,452**	391,958
Net increase (decrease) in cash and cash equivalents	**9,187,679**	(3,515,157)
Cash and cash equivalents, beginning of year	**20,568,739**	24,083,896
Cash and cash equivalents, end of year	**$ 29,756,418**	$ 20,568,739

See accompanying notes.

Notes to Financial Statements

1. Organization and Nature of Activities

Foundation for the National Institutes of Health, Inc. (Foundation) is a not-for-profit organization, whose mission is to support the National Institutes of Health (NIH) in its mission, and to advance collaboration with biomedical researchers from universities, industry, and nonprofit organizations.

2. Summary of Significant Accounting Policies

Basis of accounting

The financial statements of the Foundation have been prepared on the accrual basis of accounting and, accordingly, reflect all significant receivables, payables, and other liabilities.

Basis of presentation

The Foundation reports information regarding its financial position and activities according to two classes of net assets: without donor restrictions and with donor restrictions.

- Net assets without donor restrictions – not subject to donor-imposed restrictions and may be expended for any purpose in performing the primary objectives of the organization. These net assets may be used at the discretion of the Foundation's management and the board of directors.
- Net assets with donor restrictions – subject to stipulations imposed by donors, and grantors. Some donor restrictions are temporary in nature; those restrictions will be met by actions of the Foundation or by the passage of time. Other donor restrictions are perpetual in nature, whereby the donor has stipulated the funds be maintained in perpetuity.

Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Accordingly, actual results could differ from those estimates.

Cash and cash equivalents

For purposes of the financial statement presentation, cash and cash equivalents includes all cash on hand, demand accounts, and highly-liquid investments with original maturities of three months or less, excluding temporarily uninvested money market funds held in brokerage accounts.

Investments

Investments are reported at market value. Realized gains or losses are recognized upon sale or disposal. Interest income is recorded on the accrual basis. Dividends are recorded on the ex-dividend date. Unrealized gains and losses, due to market fluctuations during the year, are recognized at year-end.

Contributions and other receivables

Unconditional contributions receivable that are expected to be collected within one year are recorded at net realizable value. Unconditional contributions to be collected in more than one year are recorded at net present value, which approximates fair value. Conditional contributions receivable are recognized when the conditions on which they depend are substantially met. Credit risk for contributions receivable is concentrated, as a significant amount of contributions receivable are received from a few donor organizations. Other receivables are stated at net realizable value and are deemed fully collectible by management.

Allowance for uncollectible receivables

Contributions receivable are stated at unpaid balances, less an allowance for doubtful accounts. Management has established an allowance for uncollectible contributions receivable based on a review of historical collections. Receivables are considered delinquent if full principal payments are not received in accordance with the contractual terms. It is the Foundation's policy to charge off uncollectible accounts receivable when management determines the receivable will not be collected. Amounts recorded as other receivables are deemed to be fully collectible by management. Accordingly, an allowance has not been recorded for those receivables.

Property and equipment

Property and equipment purchases are recorded at cost. Depreciation is computed using the straight-line method based on the following estimated useful lives:

Furniture and equipment	3 - 5 years
Leasehold improvements	15 years

The Foundation's policy is to capitalize furniture and equipment purchased with a cost of $1,000 or more. Donated equipment is recorded at fair value at the date of contribution.

Deferred rent and incentives

Deferred rent is recorded and amortized to the extent the total minimum rental payments allocated to the current period on a straight-line basis exceed or are less than the cash payments required. Deferred leasehold incentives are recorded and amortized over the life of the lease.

New accounting pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09, *Revenue from Contracts with Customers* (Topic 606), which replaced most existing revenue recognition guidance in U.S. GAAP. The ASU also required expanded disclosures relating to the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The Foundation adopted the new standard effective January 1, 2019, the first day of the Foundation's fiscal year using the modified retrospective approach. There was not a material impact on the financial statements as a result of the adoption.

During 2019, the Foundation adopted ASU No. 2018-08: *Not-for-profit Entities (Topic 958): Clarifying the Scope and the Accounting Guidance for Contributions Received and Contributions Made*. The Update addresses the evaluation of whether transactions should be accounted for as contributions (nonreciprocal transactions) or as exchange (reciprocal) transactions, and determining whether a contribution is conditional. The Foundation adopted the Update as of January 1, 2019 under the modified prospective method. There was not a material impact on the financial statements as a result of the adoption.

Contributions

Contributions received are recorded as net assets without donor restrictions or net assets with donor restrictions, depending on the existence and/or nature of any donor-imposed restrictions. When a restriction expires (that is, when a stipulated time restriction ends or purpose restriction is accomplished), net assets with donor restrictions are reclassified to net assets without donor restrictions and reported in the statements of activities as net assets released from restrictions. Grants and contributions considered to be nonexchange transactions that include donor-imposed conditions are recognized as revenue when the condition is met. Funds received by the Foundation for conditional contributions are recorded as a liability until the conditions are met.

Grant revenues

Amounts received under grant awards are considered exchange transactions and are recognized as unrestricted revenue when the related expenses are incurred. Unexpended amounts received are recorded as deferred grant revenue. Expenditures in excess of receipts are recorded as grants receivable.

Agency transactions

The Foundation recognizes a liability equal to the fair value of assets received by the Foundation for which the donor stipulates that the assets are to be used on behalf of the donor or another entity (the beneficiary) or to be transferred to another entity.

Transfers from NIH revenue recognition

Transfers from NIH are recognized as revenue in the year they are approved.

Fundraising event revenue recognition

Amounts received to attend the annual award ceremony are considered exchange transactions as a reciprocal benefit is received by the attendees. The revenues associated with this event are recognized at a point in time, on the date of the event, at which time the Foundation's performance obligation is satisfied. There are no elements of variable consideration, contract costs, or significant financing components associated with this revenue.

Functional expenses

The costs of providing program and other activities have been summarized on a functional basis in the financial statements. Accordingly, certain costs have been allocated among program services and supporting services benefited. Such allocations are determined by management on an equitable basis.

The expenses that are allocated include the following:

Expense	Method of Allocation
Salaries and benefits	Time and effort
Stipends	Time and effort
Program contracts	Time and effort
Grant awards	Time and effort
Meetings and travel	Time and effort
Office supplies and expense	Time and effort
Telephone	Headcount/Time and effort
Books and supplies	Headcount/Time and effort
Tuition	Time and effort
Insurance	Headcount
Consultants	Time and effort
Professional fees	Time and effort
Depreciation	Time and effort

Rent and housing	Square footage
Recruiting	Time and effort
Relocation	Time and effort
Temporary services	Time and effort
Dues and subscriptions	Time and effort
Equipment and rental	Headcount/Time and effort
Printing and photocopying	Time and effort
Postage and delivery	Time and effort
Service charges	Time and effort
Communications	Time and effort
Advertising and promotion	Time and effort
Miscellaneous	Time and effort

Income taxes

The Foundation is exempt from federal income taxes under Section 501(c)(3) of the Internal Revenue Code; accordingly, the accompanying financial statements do not reflect a provision or liability for federal and state income taxes. The Foundation has determined that it does not have any material unrecognized tax benefits or obligations as of December 31, 2019 and 2018.

Subsequent events

In preparing these financial statements, the Foundation has evaluated events and transactions for potential recognition or disclosure through May 15, 2020, the date the financial statements were available to be issued.

Subsequent to the balance sheet date, the World Health Organization declared the outbreak of COVID-19, a novel strain of Coronavirus, a pandemic. The coronavirus outbreak is disrupting supply chains and affecting production and sales across a range of industries. The extent of the impact of the outbreak on the Foundation's operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, impact on the Foundation's donors, employees and vendors, and governmental, regulatory and private sector responses. The financial statements do not reflect any adjustments as a result of the subsequent increase in economic uncertainty.

The Foundation carries a significant balance of equity securities. As of the date the financial statements were available to be issued, the economic uncertainty caused by the outbreak has resulted in a severe decline in the value of equity securities, including many of those held by the Foundation.

Recently issued accounting standards

Leases

In February 2016, the FASB issued ASU 2016-02, *Leases*. Under the new standards, lessees will need to recognize a right-of-use asset and a lease liability for virtually all their leases (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. For income statement purposes, the FASB continued the dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied to current lease accounting. Extensive quantitative and qualitative disclosures will be required to provide greater insight into the extent of revenue and expense recognized and expected to be recognized from existing contracts. The new standard will be effective for the Foundation on January 1, 2021, and the Foundation is currently evaluating the effect this accounting standard may have on its financial statements.

3. Availability and Liquidity

The following represents the Foundation's financial assets at December 31:

	2019	2018
Financial assets:		
Cash and cash equivalents	**$ 29,756,418**	$ 20,568,739
NIH receivable	**500,000**	-
Contributions receivable, net, current portion	**7,811,673**	17,013,499
Investments	**91,401,689**	102,785,676
Total financial assets	**129,469,780**	140,367,914
Less amounts not to be used within one year:		
Net assets with donor restrictions	**96,932,316**	111,835,417
Legacy Fund established by the board	**1,601,000**	1,550,000
Quasi endowment established by the board	**10,412,000**	8,887,000
	108,945,316	122,272,417
Financial assets available to meet general expenditures over the next twelve months	**$ 20,524,464**	$ 18,095,497

The Foundation's goal is to maintain financial assets to meet one year of Supporting Services (approximately $8 million). As part of its liquidity plan, excess cash is invested in short-term investments, including money market accounts and high-quality fixed income securities with a maximum maturity of 3 years.

4. Concentration of Credit Risk

Financial instruments that potentially subject the Foundation to concentration of credit risk consist of cash transaction accounts. The Foundation places its cash transaction accounts with high credit quality financial institutions. At December 31, 2019 and 2018, the Foundation had deposits in excess of the amount insured by the Federal Deposit Insurance Corporation (FDIC). The Foundation has not experienced any losses in such accounts and management believes it is not exposed to any significant credit risk on cash and cash equivalents.

5. Property and Equipment

Major classes of property and equipment consisted of the following:

	2019	2018
Furniture and equipment	**$ 935,548**	$ 1,041,295
Leasehold improvements	**1,387,425**	1,387,425
	2,322,973	2,428,720
Accumulated depreciation and amortization	**(748,578)**	(875,296)
	$ 1,574,395	$ 1,553,424

6. Investments

Investments as of December 31, 2019, are summarized as follows:

	Cost	Market Value
Money market funds	**$ 3,254,540**	**$ 3,254,540**
U.S. government bonds	**71,883,010**	**72,119,707**
Exchange traded funds	**1,774,338**	**1,947,293**
Mutual funds	**12,793,415**	**14,080,149**
	$ 89,705,303	**$ 91,401,689**

The following schedule summarizes the investment return and its classification for 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Interest and dividends	**$ 2,382,347**	**$ 435,987**	**$ 2,818,334**
Realized gain (loss)	**345,963**	**(385)**	**345,578**
Unrealized gain	**1,455,667**	**757,533**	**2,213,200**
Investment fees	**(179,988)**	**-**	**(179,988)**
Total investment return	**$ 4,003,989**	**$ 1,193,135**	**$ 5,197,124**

Investments as of December 31, 2018, are summarized as follows:

	Cost	Market Value
Money market funds	$ 3,231,655	$ 3,231,655
U.S. government bonds	87,831,681	87,965,203
Exchange traded funds	1,595,842	1,499,212
Mutual funds	10,950,208	10,089,606
	$ 103,609,386	$ 102,785,676

The following schedule summarizes the investment return and its classification for 2018:

	Without Donor Restrictions	With Donor Restrictions	Total
Interest and dividends	$ 1,709,521	$ 347,637	$ 2,057,158
Realized gain	366,349	503,162	869,511
Unrealized loss	(885,870)	(963,326)	(1,849,196)
Investment fees	(159,775)	-	(159,775)
Total investment return	$ 1,030,225	$ (112,527)	$ 917,698

7. Contributions Receivable

Contributions receivable at December 31, were as follows:

	2019	2018
Receivable in less than one year	**$ 7,826,673**	$ 5,703,499
Receivable in one to five years	**3,746,667**	11,865,000
Total unconditional contributions receivable	**11,573,340**	17,568,499
Discounts to net present value	**(103,872)**	(282,952)
Allowance for uncollectible contributions receivable	**(15,000)**	(15,000)
Net unconditional contributions receivable	**$ 11,454,468**	$ 17,270,547

The discount rate used on long-term contributions receivable was 2.25% in 2019 and 2018.

8. Conditional Contributions Receivable

As of December 31, the Foundation had the following contributions receivable subject to donor conditions:

	2019	2018
Conditioned upon the funder not notifying the Foundation by a specific date that they do not wish to fund the program:		
Comprehensive Cellular Vaccine Immune Monitoring Consortium	**$ 766,745**	$ 3,245,488
Developing Leads to Shorten Duration of TB Chemotherapy	**-**	1,464,744
Using Biomarkers to Predict TB Treatment Duration	**3,159,480**	5,800,002
Lurie Prize in Biomedical Research	**200,000**	300,000
Support functions for Vector-based Control of Transmission Research	**-**	262,225
Pew Latin American Fellows Awards	**183,750**	199,500
Lifespan Connectome Project	**-**	580,645
Transitional Support for Gene Drive Research	**-**	1,850,599
Efficacy of Heterodimeric IL-15 Treatment Regimens in Reducing SIV Reservoir	**765,405**	765,405
Biomarkers Consortium Novel Cardiac Biomarkers in the General US Population	**-**	25,000
Conditioned upon meeting certain milestones and/or the funder not cancelling:		
NIH Medical Research Scholars Program	**180,000**	210,000
Follicular Lymphoma Research Fund	**-**	20,000
Alzheimer's Disease Neuroimaging Initiative-3	**2,511,683**	5,280,000
Accelerating Medicines Partnership: RA, SLE & Related Autoimmune Disorders	**-**	690,000
Biomarkers Consortium Treatments Against Rheumatoid Arthritis and Effect on FDG PET-CT	**60,000**	226,250
Biomarkers Consortium Advanced Metrics and Modeling with Volumetric CT for Precision Analysis of Clinical Trial Results	**-**	308,333
Longitudinal Proteomic Changes in CSF from ADNI: Towards Better Defining the Trajectory of Prodromal and Early Alzheimer's Disease	**-**	22,000
Amgen NIH Scholars Program	**335,000**	502,500

Pamela Anne Cafritz Renal Cell Carcinoma Award	**200,000**	300,000
Biomarkers Consortium Osteoarthritis Biomarkers Qualification	**1,041,000**	1,345,500
Structure-based Vaccine Design Against HIV-1	**-**	125,000
Biomarkers Consortium Inflammatory Markers for Neurodegenerative and Mood Disorders	**477,000**	477,000
Partnership for Accelerating Cancer Therapies	**36,000,000**	36,150,000
Accelerating Medicines Partnership: Parkinson's Disease	**-**	6,000,000
NCTN Data Archive De-Identification Project	**60,000**	60,000
Biomarkers Consortium ctDNA Reference Standards	**980,542**	774,122
Chemotherapeutic Impact on the Immune MicroEnvironment Project (ChIIME)	**1,250,000**	1,250,000
Participation of Native American Students in the National Institute for Neurological Disorders and Stroke (NINDS)	**60,000**	120,000
Non-Invasive BioMarkers of MetaBolic Liver DiseasE (NIMBLE) (Project is not yet launched)	**6,545,888**	6,545,888
Understanding NHP protection against TB induced by Intravenous BCG	**916,656**	916,656
Single Cell Mass Accumulation Rate (MAR) Biomarker for Drug Efficacy (Multiple Myeloma Leukemia)	**-**	272,000
LungMap	**1,576,862**	-
CAR-T	**1,318,544**	-
ADNI – Amyloid PET Early Frames Add on Study	**100,000**	-
Biomarkers Consortium – Plasma Abeta project	**1,000,717**	-
2019 NINDS/CNS Getch Scholar	**300,000**	-
iUFV (Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine)	**674,943**	-
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**3,499,008**	-
Mucosal Healing in Ulcerative Colitis	**420,000**	-
GeneConvene Global Collaborative	**17,764,694**	-
	$ 82,347,917	$ 76,088,847

Since these represent conditional contributions receivable, they are not recorded as contributions receivable and contribution revenue until donor conditions are met.

9. Board Designated Net Assets

The Board of Directors has established three board designated funds as follows at December 31:

	2019	2018
Endowment Fund	**$ 10,412,000**	$ 8,887,000
Contingency Fund	**900,000**	900,000
Legacy Fund	**1,601,000**	1,550,000
	$ 12,913,000	$ 11,337,000

10. Net Assets with Donor Restrictions

As of December 31, net assets with donor restrictions were available for the following purposes:

	2019	2018
Fellowships and Training Programs:		
Amgen Scholars Program	**$ 150,177**	$ 147,803
Dean R. O'Neill Renal Cell Cancer Research Fund	**181,482**	210,452
Dr. Edward T. Rancic Memorial Fund	**6,648**	6,515
Dr. John L. Barr Memorial Fund for Cancer Research	**686**	686
Neva Fund	**28,144**	27,880
NIH Medical Research Scholarship Program	**1,007,706**	1,618,803
NOB Fund	**7,152**	7,652
Norman P. Salzman Memorial Award and Lecture in Virology	**231,690**	208,444
Robert Whitney Newcomb Memorial Lecture and Internship	**1,288,012**	1,129,261
Sallie Rosen Kaplan Fellowship for Women Scientists in Cancer Research	**185,984**	58,738
Swanson Family Fellowship in Generic Thyroid Benign Chorea and IgA Deficiency (TTF-1)	**92,500**	92,500
Notkins biomedical Research Fund	**200,000**	200,000
Memorials, Awards and Events:		
2019 Alzheimer's Disease-Related Dementia (ADRD) Summit	**-**	87
2017 AD Caregiving Summit	**44,717**	44,717
Adam J. Berry Memorial Fund	**6,770**	5,992
Breast Cancer Summit 2	**65,198**	65,198
Carcinoid Summit Workshop	**17,594**	17,594
Celebrating 50 Years of Brain Research: New Discoveries, New Hope	**171,451**	171,451
Dr. Anita Roberts Memorial Fund	**24,150**	32,238
Dr. Jane M. Sayer Vision Research Lecture and Award	**272,169**	252,485
Edna Williams Curl & Myron R. Curl Endowment for Multiple Sclerosis Research	**66,790**	65,458
Human Genome Exhibition	**9,325**	17,481
John Laws Decker Memorial Fund	**2,325**	2,279
Kovler Prize for Excellence in Science Journalism	**198,781**	-
Lurie Prize	**100,000**	100,000
MRSP 2019-2020	**205,040**	-
Pamela Ana Cafritz	**196,960**	197,000
Polio Conference	**40,698**	40,698
Stephen E. Straus Award	**100,489**	105,475
Capital Projects:		
Edmond J. Safra Family Lodge Bricks and Mortar	**79,759**	79,759
Edmond J. Safra Family Lodge All Programs	**24,212**	16,175
Edmond J. Safra Family Lodge GSK Endowment	**371,673**	77,188
Edmond J. Safra Family Lodge Weinberg Endowment	**259,391**	87,874
Edmond J. Safra Family Lodge Gallin Endowment	**109,188**	106,689
Tracy's Toy Box	**7,941**	7,941
Research Partnerships:		
Accelerating Medicines Partnership Membership	**565,930**	1,026,605
Accelerating Medicines Partnership: Type 2 Diabetes	**8,006,894**	10,795,122
Accelerating Medicines Partnership: Alzheimer's	**4,159,605**	11,444,566
Accelerating Medicines Partnership: Rheumatoid Arthritis and Lupus	**4,254,460**	7,213,091
Accelerating Medicines Partnership: Parkinson’s Disease	**9,915,954**	2,914,828
ADNI - Amyloid PET Early Frames Add on Study	**652,500**	347,585
ADNI - Optimization of Alzheimer’s Disease Cognitive Measures Project	**15,980**	15,980
Alzheimer's Disease Neuroimaging Initiative – 3	**3,509,396**	7,971,047

A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**1,209,047**	-
Biomarker Consortium	**3,055,502**	2,651,567
Biomarkers Consortium: Atherosclerosis Computer Modeling	**366,852**	596,504
Biomarkers Consortium: Autism Spectrum Disorder	**70,426**	563,194
Biomarkers Consortium: Beta Cell Clinical Trial	**-**	30,720
Biomarkers Consortium: Bone Quality Project	**46,221**	310,391
Biomarkers Consortium: CABP-Skin Infection	**19,736**	19,736
Biomarkers Consortium: CSF-Based Biomarkers in AD	**-**	10,838
Biomarkers Consortium: HABP/VABP Working Group	**3,747**	20,863
Biomarkers Consortium: HD-SCA in CRC (High Definition Single Cell Analysis of Blood and Tissue Biopsies	**37,895**	161,037
Biomarkers Consortium: Inflammatory Markers for Neurodegenerative and Mood Disorders	**364,482**	456,637
Biomarkers Consortium: Kidney Safety	**32,971**	34,196
Biomarkers Consortium: Longitudinal CSF Proteomics	**92,704**	113,292
Biomarkers Consortium: MRD Project	**1,065,511**	1,174,882
Biomarkers Consortium: Novel Cardiac Biomarkers in the General US Population	**181,670**	387,122
Biomarkers Consortium: OA BMxQ	**1,174,758**	1,342,168
Biomarkers Consortium: Placebo Data Analysis Project in AD	**-**	13,154
Biomarkers Consortium: Target BMx	**308,375**	413,793
Biomarkers Consortium: Vol-PACT	**421,623**	1,439,628
Biomarkers Consortium: PACT Implementation	**13,331,809**	21,015,886
Bradley Charitable Gift Annuity	**17,518**	24,808
Cancer Research Fund	**1,432,348**	644,690
Cancer Research Major Gift	**4,737,225**	4,737,225
Charles A. Sanders Legacy Fund	**1,352,218**	1,380,269
Chemotherapeutic Impact on the Immune MicroEnvironment	**89,618**	696,699
Comprehensive Cellular Vaccine Immune Monitoring Consortium (CVIMC)	**2,713,591**	2,284,976
Consensus Pathway for Gene Drive in Mosquitoes	**187,673**	205,385
ctDNA Reference Standards	**561,721**	464,467
Development of a Second Generation Broadly Neutralizing Antibody (2GVRC01)	**-**	35,678
Deeda Blair Research Initiative Fund for Disorders of the Brain	**387,361**	200,318
Essential Strategies to Combat Ebola in West Africa: Social Mobilization and Communications	**652**	-
Effects of Moderate Drinking	**-**	418,372
Eliminate Dengue	**3,320**	3,320
Epilepsy Research in the Laboratory of Kareem Zaghloul, M.D., Ph.D	**148,212**	148,212
FDG-PET Lung/Lymphoma	**-**	14,599
FNIH Travel support for NIH Scientists	**412,816**	590,539
Follicular Lymphoma Research Fund	**2,700**	20,700
GeneConvene Global Collaborative	**5,305,808**	-
Gilead HIV Cure Grants	**1,890,104**	1,237,109
Gramlich Melanoma Research Trust	**200,751**	178,606
Grand Challenges in Global Health	**-**	119,258
HIT-TB	**-**	26,676
iUFV (Combining Epitope-Based Vaccine Design with Informatics-Based Evaluation to Obtain a Universal Influenza Vaccine)	**1,061,655**	-
Kidney Cancer Research	**106,042**	100,298
Lifespan Connectome Project	**-**	180,003
Lung Cancer Master Protocol (LungMAP)	**1,615,637**	1,448,758
Mucosal Healing in Ulcerative Colitis	**200,000**	-
Multiple Myeloma Accumulation Rate (MAR)	**136,000**	136,000

NCTN Data Archive De-Identification Project	**79,671**	276,773
Non-Invasive Biomarkers of Metabolic Liver Disease	**6,117,104**	6,319,682
OPIOIDS Stakeholder	**100,000**	100,000
Partnership for Accelerating Cancer Therapies	**3,693**	79,376
Plasma Abeta Project	**1,000,717**	-
PREDICT-TB	**763,866**	1,535,173
Rapid identification of individuals with viable adult female worms of Onchocerca volvulus: a means to the end	**81**	80
Sarcopenia 2	**-**	78,203
SHORTEN-TB	**100,261**	203,453
Solarz Memorial Fund	**19,276**	264,345
Spiromic Project	**3,396**	3,396
Structure-Based Vaccine D	**26,575**	33,622
Support functions for VCTR	**1,969,908**	511,289
The Lowy Cancer Research Support Fund	**3,812**	13,182
Transitional Support Gene Drive Research	**1,683,282**	3,322,342
Tuberculosis Vaccine	**81,821**	2,422,497
Other Temporarily Restricted Programs	**369,182**	494,940
Total Temporarily Restricted Net Assets	**93,504,465**	108,642,245
Perpetual Endowments:		
Edmond J. Safra Family Lodge:		
GlaxoSmithKline Endowment Fund	**1,500,000**	1,500,000
Harry and Jeanette Weinberg Endowment at the Edmond J. Safra Family Lodge	**830,894**	830,894
Sallie Rosen Kaplan Fellowship for Women Scientists in Cancer Research	**707,771**	707,772
CarMollNat Muscular Dystrophy Endowment	**39,186**	54,506
Futures Fund	**350,000**	100,000
Total Perpetual Endowments	**3,427,851**	3,193,172
	$ 96,932,316	$ 111,835,417

11. Endowments

The Foundation's endowments consist of individual donor-restricted endowment funds established for a variety of purposes and board designated endowments. Net assets associated with endowment funds are classified and reported based on the existence or absence of donor-imposed restrictions.

Interpretation of relevant law

The Board of Directors of the Foundation has interpreted the Maryland State Prudent Management of Institutional Funds Act (SPMIFA) as requiring the preservation of the fair value of the original gift as of the gift date of the donor-restricted endowment funds absent explicit donor stipulations to the contrary. As a result of the interpretation, the Foundation retains in perpetuity (a) the original value of the gifts donated to the permanent endowment, (b) the original value of subsequent gifts to the permanent endowment, and (c) accumulations to the permanent endowment made in accordance with the direction of the applicable donor gift instrument at the time of the accumulation to the fund. Donor-restricted amounts not retained in perpetuity are subject to appropriation for expenditures by the Foundation in a manner consistent with the standard of prudence prescribed by SPMIFA. The Foundation considers the following factors in making a determination to appropriate or accumulate donor-restricted endowment funds:

1. The duration and preservation of the fund

2. The purposes of the Foundation and the donor-restricted endowment fund
3. General economic conditions
4. The possible effect of inflation and deflation
5. The expected total return from income and the appreciation of investments
6. Other resources of the Foundation
7. The investment policies of the Foundation

The endowment net asset composition, by type of fund, was as follows as of December 31, 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Board-designated endowment funds	$ 10,412,000	$ -	$ 10,412,000
Donor-restricted endowment funds:			
Original donor-restricted gift amount and amounts required to be maintained in perpetuity by donor	-	3,427,851	3,427,851
Accumulated investment gains	-	1,057,654	1,057,654
Total endowment funds	$ 10,412,000	$ 4,485,505	$ 14,897,505

The changes in endowment assets were as follows for 2019:

	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, beginning of year	$ 8,887,000	$ 3,627,811	$ 12,514,811
Investment return:			
Investment income	-	129,593	129,593
Net appreciation (realized and unrealized)	-	576,307	576,307
Total investment return	-	705,900	705,900
Contributions	-	263,682	263,682
Additional board designation	1,525,000	-	1,525,000
Appropriation of endowment assets for expenditure	-	(111,888)	(111,888)
Endowment net assets, end of year	$ 10,412,000	$ 4,485,505	$ 14,897,505

The endowment net asset composition, by type of fund, was as follows as of December 31, 2018:

	Without Donor Restrictions	With Donor Restrictions	Total
Board-designated endowment funds	$ 8,887,000	$ -	$ 8,887,000
Donor-restricted endowment funds:			
Original donor-restricted gift amount and amounts required to be maintained in perpetuity by donor	-	3,193,172	3,193,172
Accumulated investment gains	-	434,639	434,639
Total endowment funds	$ 8,887,000	$ 3,627,811	$ 12,514,811

The changes in endowment assets were as follows for 2018:

	Without Donor Restrictions	With Donor Restrictions	Total
Endowment net assets, beginning of year	$ 7,968,000	$ 3,952,726	$ 11,920,726
Investment return:			
Investment income	-	117,481	117,481
Net depreciation (realized and unrealized)	-	(384,712)	(384,712)
Total investment return	-	(267,231)	(267,231)
Contributions	-	113,217	113,217
Additional board designation	919,000	-	919,000
Appropriation of endowment assets for expenditure	-	(67,504)	(67,504)
Transfers	-	(103,397)	(103,397)
Endowment net assets, end of year	$ 8,887,000	$ 3,627,811	$ 12,514,811

Return objectives and risk parameters

The Foundation has adopted investment and spending policies for endowment assets that attempt to maximize long-term results, consistent with a prudent level of risk while seeking to maintain the purchasing power of the endowment assets. Endowment assets include those assets of donor-restricted funds that the Foundation must hold in perpetuity or for a donor-specified period or purpose. Under this policy, as approved by the Board of Directors, the endowment assets are invested to maximize long-term results, consistent with a prudent level of risk. The goal is to produce a return on the assets to support the programmatic purposes, while also achieving growth of principal in order to maintain real purchasing power. This approach helps assure that gifts to endowment funds keep pace with inflation and always support the designated activity.

Strategies employed for achieving objectives

To satisfy its long-term rate-of-return objectives, the Foundation relies on a total return strategy in which the investment returns are achieved through both capital appreciation (realized and unrealized) and current yield (interest and dividends). The Foundation targets a diversified asset allocation that balances fixed-income and equity-based investments to achieve its long-term return objectives within prudent risk constraints.

12. Grant Revenue

The Foundation receives a portion of its support under certain grants and contributions that may be audited by the donors and the ultimate determination of allowable costs is determined by such audits.

13. In-Kind Contributions

Telephone expense, on-line communication costs, and some office space for the Foundation are donated by NIH. The value of the telephone expense, value of the on-line communication costs, and estimated rental value of the office space, has been reflected in the accompanying financial statements as in-kind contributions with a like amount recorded as telephone expense, communications expense, or rent/housing expense. For 2019 and 2018, these in-kind contributions from NIH of $270,780 and $250,908, respectively, are reflected in the financial statements.

Various other items were donated during 2018 in the amount of $5,951.

14. Donated Services

The Foundation receives benefit from services donated by NIH, which include various administrative and technical services performed by NIH employees. The estimated value of these services is based on the hourly rate and average benefit amount of the NIH employees. The estimated amount of these services has been reflected in the accompanying financial statements as donated services with a like amount recorded as salaries and benefits expense.

The Foundation also receives benefit from donated legal services. The value of these services has been reflected in the financial statements as donated services with a like amount recorded as professional fees expense.

For 2019 and 2018, donated services of $50,000 and $60,000, respectively, are reflected in the financial statements.

15. Retirement Plan

The Foundation has a retirement plan through TIAA-CREF. The plan calls for a mandatory contribution of at least 2% of annual salary from participating employees and an additional contribution of 10% of annual salary from the Foundation. Retirement plan expense for 2019 and 2018 was $762,039 and $661,485, respectively.

16. Concentration of Revenue

For 2019 and 2018, the Foundation received approximately 35% and 25%, respectively, of its revenue from contributions and grants from the Bill and Melinda Gates Foundation.

17. Relationship with the Foundation for Advanced Education in the Sciences, Inc.

The Foundation was established under legislation that authorized it to be the sole entity responsible for soliciting funds on behalf of NIH and to conduct specific other activities that support NIH in its mission. Certain of the activities described in the legislation are conducted by the Foundation for Advanced Education in the Sciences, Inc. (FAES) under a Memorandum of Understanding (MOU) with the Foundation. This MOU preserves the prerogatives conferred on the Foundation by its authorizing legislation but also allows the FAES to carry on its current activities under the authority of the Foundation.

18. Fair Value of Financial Instruments

Accounting Standards Codification (ASC) Topic 820 provides a framework for measuring fair value. That framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (level 1 measurements) and the lowest priority to unobservable inputs (level 3 measurements). The three levels of the fair value hierarchy are described below:

Level 1 Inputs to the valuation methodology are unadjusted quoted market prices for identical assets or liabilities in active markets that the Foundation has the ability to access.

Level 2 Inputs to the valuation methodology include:

- Quoted prices for similar assets or liabilities in active markets;
- Quoted prices for identical or similar assets or liabilities in inactive markets;
- Inputs other than quoted prices that are observable for the asset or liability;
- Inputs that are derived principally from or corroborated by observable market data by correlation or other means.

If the asset or liability has a specified (contractual) term, the level 2 input must be observable for substantially the full term of the asset or liability.

Level 3 Inputs to the valuation methodology are unobservable and significant to the fair value measurement.

The asset or liability's fair value measurement within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of observable inputs and minimize the use of unobservable inputs.

Following is a description of the valuation methodologies used for assets measured at fair value.

U.S. government bonds; exchange traded funds:

Valued at quoted market price per number of units/shares held at year-end.

Equity mutual funds; bond mutual funds

Valued at net asset value (NAV) of shares held at year-end.

All assets have been valued using a market approach. Fair values for assets in Level 2 are calculated using quoted market prices for similar assets in markets that are not active. There were no changes in the valuation techniques during the current year.

The preceding methods described may produce a fair value calculation that may not be indicative of net realizable value or reflective of future fair values. Furthermore, although the Foundation believes its valuation methods are appropriate and consistent with other market participants, the use of different methodologies or assumptions to determine the fair value of certain financial instruments could result in a different fair value measurement at the reporting date.

The following sets forth by level, within the fair value hierarchy, the Foundation's assets at fair value as of December 31, 2019 and 2018:

	Assets at Fair Value as of December 31, 2019			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. government bonds	**$ 72,119,707**	**$ -**	**$ -**	**$ 72,119,707**
Equity mutual funds	**10,890,405**	**-**	**-**	**10,890,405**
Bond mutual funds	**3,189,744**	**-**	**-**	**3,189,744**
Exchange traded funds	**1,947,293**	**-**	**-**	**1,947,293**
Total investments	**$ 88,147,149**	**$ -**	**$ -**	**$ 88,147,149**

	Assets at Fair Value as of December 31, 2018			
	Level 1	**Level 2**	**Level 3**	**Total**
U.S. government bonds	$ 87,965,203	$ -	$ -	$ 87,965,203
Equity mutual funds	6,491,923	-	-	6,491,923
Bond mutual funds	3,597,683	-	-	3,597,683
Exchange traded funds	1,499,212	-	-	1,499,212
Total investments	$ 99,554,021	$ -	$ -	$ 99,554,021

19. Conditional Grant Awards

As of December 31, 2019, the Foundation has authorized conditional scientific grants under the following programs:

	2019	**2018**
Accelerating Medicines Partnership: Type 2 Diabetes	$ **1,819,974**	$ 2,712,069
Accelerating Medicines Partnership: Parkinson's Disease	**333,431**	-
A-Plus Trial (NICHD Global Network) Multi-site Efficacy and Safety Trial of Intrapartum Azithromycin in LMICs	**2,082,140**	-
Biomarkers Consortium – HD-SCA in CRC Project	**-**	100,000
Using Biomarkers to Predict TB Treatment Duration	**2,743,406**	5,609,994
Developing Leads to Shorten Duration of TB Chemotherapy	**-**	1,383,390
Transitional Support for Gene Drive	**-**	348,323
Biomarkers Consortium – Cardiac Troponin Project	**43,454**	221,136
Biomarkers Consortium – Bone Quality Project	**55,000**	-
Biomarkers – Target BMx	**355,333**	482,078
LungMaP (Lung Cancer Master Protocol)	**50,000**	50,000
Osteoarthritis (OA) Biomarkers Qualification (OA BMxQ)	**151,329**	98,432
Accelerating Medicines Partnership: Alzheimer's Disease	**4,159,250**	3,934,043
Efficay of Heterodimeric IL-15 Treatment Regimens	**1,741,317**	1,741,317
Understanding the Mechanisms of Intravenous BCG-induced Protection against TB in NHP	**803,722**	1,701,200

NIH Travel for Gates (FNIH Travel support for NIH Scientists)	**139,739**	279,739
Comprehensive Cellular Vaccine Immune Monitoring Consortium	**2,625,249**	4,552,057
Structure-based Vaccine Design against HIV-1	**-**	108,333
	$ 17,103,344	$ 23,322,111

These authorized awards would become a liability to the Foundation in the future, if the grantees meet certain conditions, including the Foundation's satisfaction with and approval of progress reports.

20. Lease

In January 2017, the Foundation entered into a new lease agreement with Hines USVF North Bethesda Place LP for a fifteen-year period which expires October 31, 2032. This lease is effective November 2017 and contains a rent abatement period for the first seven months.

In June 2019, the Foundation entered into a new lease agreement with Hines USVF North Bethesda Place LP for a twelve-year period which expires October 31, 2032. This lease is effective January 2020 and contains multiple rent abatement periods.

Rent expense was $564,954 and $549,754, respectively, for 2019 and 2018.

The future minimum lease payments required under the operating lease for the years ending December 31, are as follows:

2020	$ 707,122
2021	847,247
2022	722,172
2023	618,939
2024	919,084
Thereafter	7,644,035
	$ 11,458,599

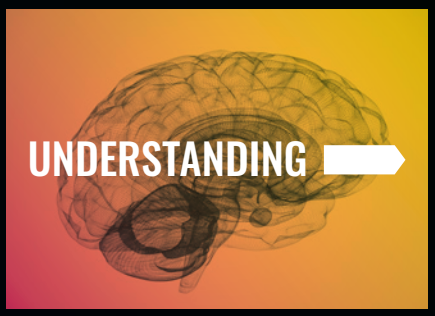
21. Risks and Uncertainties

The Foundation invests in various investment securities. Investment securities are exposed to various risks, such as interest rate, credit and overall market volatility risks. Due to the level of risk associated with certain securities, it is at least reasonably possible that changes in the values of investment securities will occur in the near term and such changes could materially affect the Foundation's account balances and amounts reported in the statements of financial position.

Enclosure
2019 FNIH Summary Annual Report

FNIH
Foundation for the
National Institutes of Health

RESEARCH BRINGS US ONE STEP CLOSER TO



2019 ANNUAL REPORT

IMPACT HIGHLIGHTS

AS WE EMBARK ON A NEW DECADE, THE FOUNDATION FOR THE NATIONAL INSTITUTES OF HEALTH (FNIH) IS PROUD TO CONTINUE SUPPORTING THE FIELD OF BIOMEDICAL RESEARCH. PRESENTED HERE ARE A FEW SIGNIFICANT MILESTONES FROM THE PAST DECADE RESULTING IN MEANINGFUL IMPACT IN HEALTH WORLDWIDE.

CREATED the infrastructure for unparalleled public-private partnerships to accelerate development of new treatments for chronic diseases like Alzheimer's disease, type 2 diabetes, rheumatoid arthritis, lupus and Parkinson's disease, by sharing data publicly to advance the science and establish a model for progress.

Read about it: fnih.org/AMP

QUALIFIED the first clinical safety biomarker ever in the history of the U.S. Food and Drug Administration (FDA), leading to improved detection of drug-induced acute kidney injury in clinical trials.

Read about it: fnih.org/kidneysafety

DEVELOPED the first-ever evidence-based criteria to diagnose sarcopenia, which will promote the generation of better therapies to treat this condition.

Read about it: fnih.org/sarcopenia

REVEALED that exposures to pathogens in children in low-resource settings leads to significant shortfalls in child development — even in the absence of symptoms of any disease — through a paradigm-shifting study.

Read about it: fnih.org/MAL-ED

PIONEERED the use of a master protocol for clinical trials in oncology, leading to rapid acceleration of cancer drug testing, extending treatment access to hundreds of cancer patients and paving the way for master protocol use in other disease areas.

Read about it: fnih.org/Lung-MAP

DEAR FRIENDS,

IT HAS BEEN SAID THAT SCIENCE IS A VERB: A DYNAMIC PROCESS OF DISCOVERY, INNOVATION AND TRANSLATION.

Put in action, science can solve some of the greatest health challenges facing the world today. Research brings us one step closer to doing just that. The exploration taking place now in research laboratories supported by the National Institutes of Health (NIH) and at the NIH has enabled a more profound scientific understanding of disease than ever before. These new insights lead to novel methods and techniques that facilitate breakthroughs in the ways we diagnose, treat and prevent disease. Such groundbreaking approaches, in turn, make possible practical solutions for health challenges faced by people across the globe.

In these pages, you will see examples of biomedical research moving the needle forward. In 2019, the FNIH launched initiatives that anticipate patients' response to cancer treatment, ease the burden of diagnosis of a common, deadly liver disease and improve the tuberculosis vaccine — to name just a few. These stories illustrate the unique and crucial role of the FNIH: building and managing cross-sector alliances, convening key stakeholders to tackle complex challenges, investing in the future of scientific leadership, and sharing the results of our collaborations to advance knowledge among the research community.

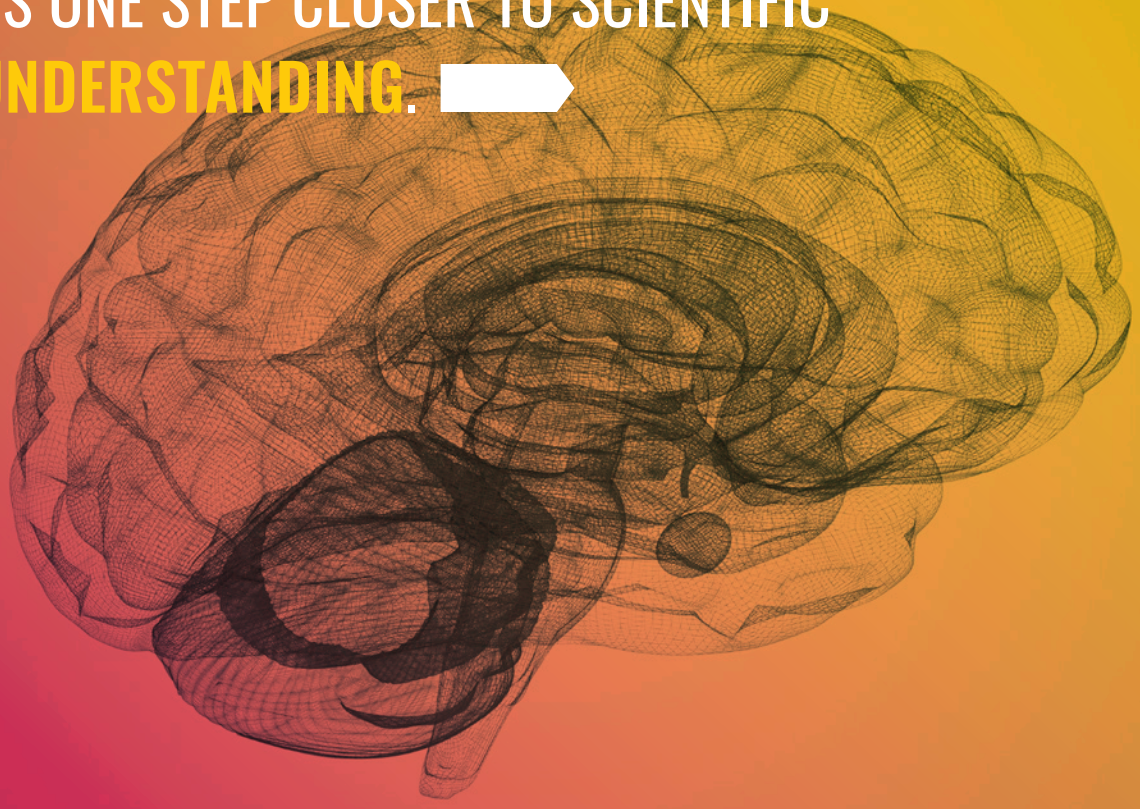
There is no better example of the importance of our work than our support of the NIH in its urgent and heroic efforts to combat COVID-19 through clinical trials for vaccines and treatments. It has never been clearer that public-private partnerships are critical to solving humanity's most pressing public health challenges. Collaborations with partners from industry, government, not-for-profit organizations, foundations and individual donors leverage generosity, dedication and expertise to move toward the types of health care solutions that will make a huge difference in all of our lives.

Above all, we wish to highlight our gratitude for *your* partnership and support in carrying out the mission of the FNIH. Just as research brings us one step closer, research brings us *together* around the shared desire to achieve our grandest, most transformative goals for human health.

Steven M. Paul, M.D.
Chairman

Maria C. Freire, Ph.D.
President and Executive Director

EXPLORATION AND DISCOVERY BRING US ONE STEP CLOSER TO SCIENTIFIC **UNDERSTANDING.**



CATALYZING COLLABORATION TO TRANSFORM PARKINSON'S DISEASE RESEARCH

"THE COMBINATION OF MANY DATA SETS COULD ALLOW RESEARCHERS GREATER POWER TO ANALYZE POTENTIAL BIOMARKERS FOR PARKINSON'S DISEASE."

Walter Koroshetz, M.D., Director of the National Institute of Neurological Disorders and Stroke

Each year in the United States, an estimated 50,000 people will receive the devastating news of a diagnosis with Parkinson's disease. Second only to Alzheimer's disease as the most common age-related neurodegenerative disorder, Parkinson's disease affects approximately half a million Americans, a number that is expected to triple over the next 50 years as the population ages.

Parkinson's disease and its hallmark symptoms of tremors and stiffness are unfortunately very well-known to many people. Yet there is much left to learn about the disorder as researchers work to understand the underlying causes, to better predict the disease and its progression, and to develop more effective treatments for patients.

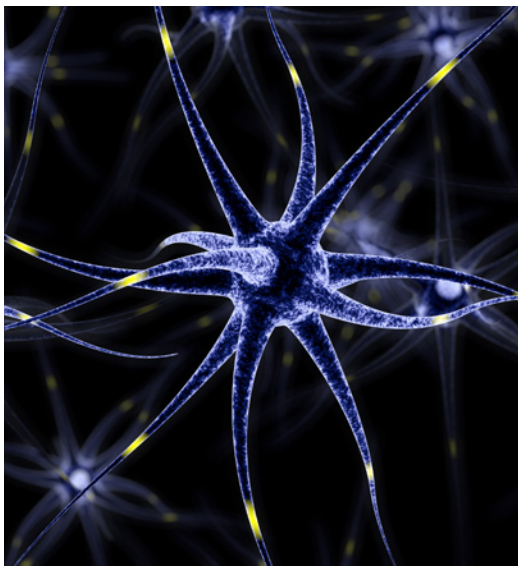
Enter AMP PD, the Accelerating Medicines Partnership for Parkinson's Disease. A public-private partnership between NIH, biomedical and pharmaceutical companies and a not-for-profit organization, managed by the FNIH, AMP PD is one of the AMP collaborations uniting sectors to transform research in high-priority disease areas such as Alzheimer's disease, type 2 diabetes, and rheumatoid arthritis and lupus. AMP PD will revolutionize the field of Parkinson's disease research through its alliance of experts working to identify and validate promising treatment targets for the disease, with the ultimate goal of improving outcomes for patients.

In 2019, AMP PD launched a groundbreaking data portal to grant researchers working on Parkinson's disease unprecedented access to the de-identified health information of more than 4,000 people. Such access allows scientists to study and analyze complex data sets at a scale previously unthinkable.

The first step was harmonizing the data, a crucial process that ensures the information is entered in an accurate, consistent way and that enables the comparison of data from many different sources. Looking forward, this establishes the standard for harmonized databases.

"AMP PD is a true example of the whole being greater than the sum of its parts. The combination of many data sets could allow researchers greater power to analyze potential biomarkers for Parkinson's disease," says Walter Koroshetz, M.D., director of the National Institute of Neurological Disorders and Stroke. "This effort follows other AMP programs which have the shared goal of changing the way we go about the business of studying disease."

Read more at fnih.org/amp-pd.

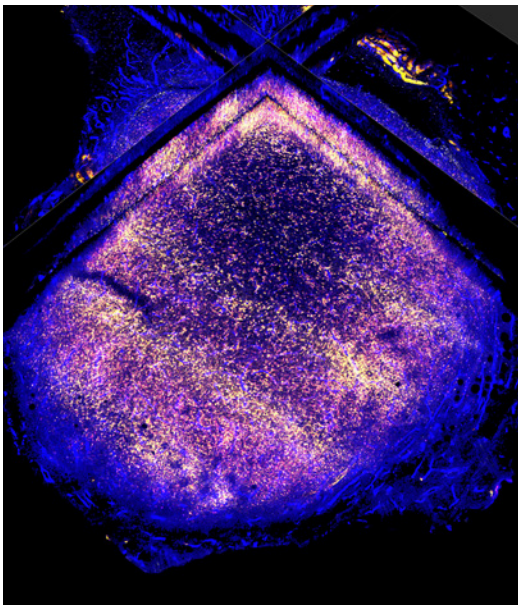


3D illustration of neurons in the brain.

BETTER PREDICTING A PATIENT'S RESPONSE TO CANCER TREATMENT

SCIENTIFIC EVIDENCE SUGGESTS THAT INTRODUCING CHEMOTHERAPY BEFORE IMMUNOTHERAPY — OR DOING BOTH AT THE SAME TIME — CAN ALTER THE MICROENVIRONMENT, IMPROVING THE ODDS OF SUCCESSFUL TREATMENT.

Every tumor adapts to its unique place of growth within the body. These changes create complex ecosystems, each made up of different kinds of cells. The interactions within these microenvironments can be analyzed to determine how cancer progresses and how it is affected by anti-cancer treatments. A deeper understanding of these processes will shed light on how two common forms of cancer treatment — immunotherapy and chemotherapy — might best be used in concert to improve health outcomes for cancer patients. The need for that better understanding is why the FNIH launched a project called Chemotherapeutic Impact on the Immune Microenvironment, or ChIIME.



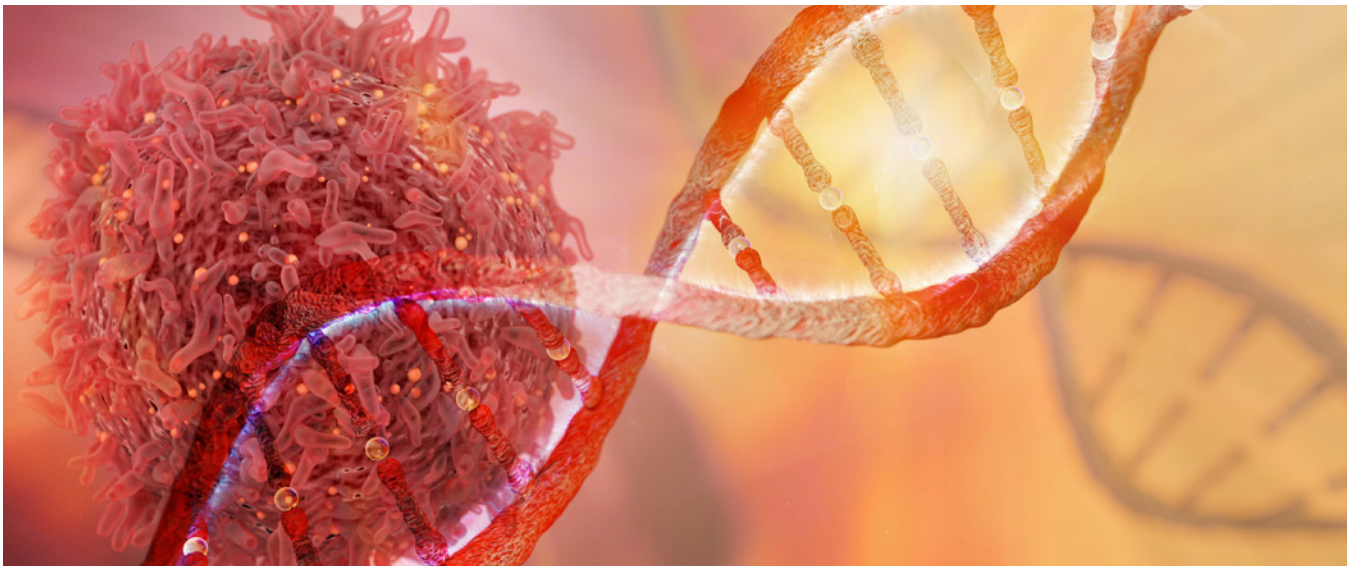
Transparent tumor tomography image of the tumor microenvironment from mouse model for HER2-positive breast cancer. *Credit: National Cancer Institute / University of Chicago Comprehensive Cancer Center*

The fastest-growing type of cancer treatment is immunotherapy, which stimulates the body's natural immune system to attack cancer cells. It has shown great success for some kinds of cancers and some patients, but not all. Scientific evidence suggests that introducing chemotherapy before immunotherapy — or doping both at the same time — can alter the microenvironment, improving the odds of successful treatment.

Led by experts from the FNIH, the National Cancer Institute (NCI), the FDA, academia and industry, the ChIIME project uses a cutting-edge technology called single nucleus RNA sequencing to analyze the microenvironment of breast cancers that are particularly resistant to most therapies. The analysis technique allows for a clearer picture of all cell populations in the microenvironment, interactions among different cells and features that explain tumor cells' responses to treatment. Studying breast cancer samples in this way, scientists will learn more about the effects of chemotherapy on different kinds of cells, including immune cells.

Ultimately, the insights gleaned from this investigation will be used to develop biomarkers that inform therapeutic decisionmaking. The knowledge will help to guide the ways that therapies are designed and assigned to patients, potentially leading to new and better treatment options for people with cancer.

Read more at fnih.org/chiime.



DNA strand and cancer cell.

STANDARDIZING THE ASSESSMENT OF GENETIC TESTS USED TO TRACK CANCER

As a cancerous tumor progresses and grows in a person's body, it often sheds cells. These cells are broken down in the body, releasing material into the bloodstream, including DNA known as circulating tumor DNA, or ctDNA. This ctDNA can be studied by scientists to determine genetic mutations in the tumor that can be targeted for treatment. These mutations can also help explain a tumor's resistance to treatment.

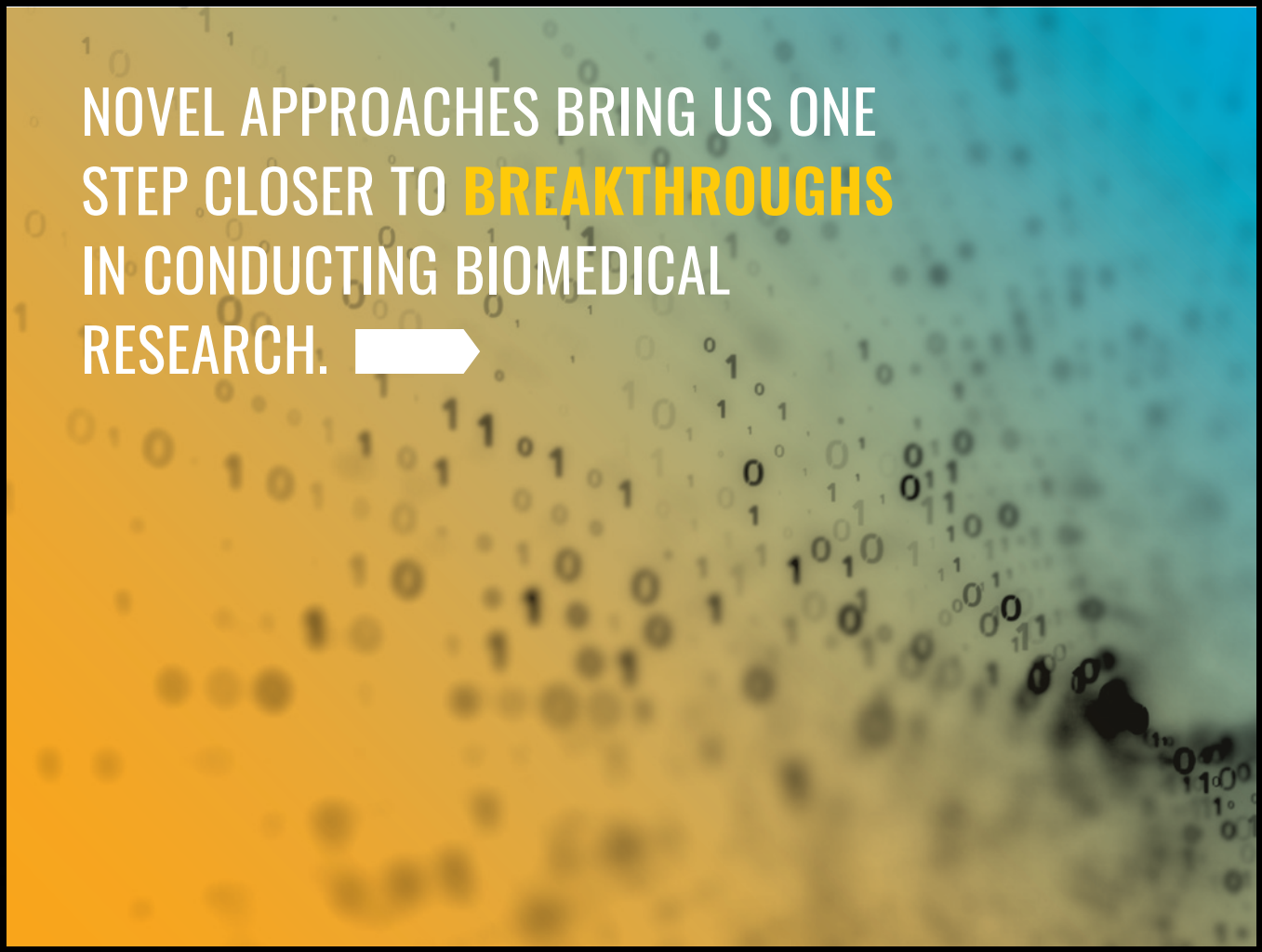
Because of the many uses of ctDNA and the simple way in which it is obtained — through a blood sample — a host of technological advances have been developed to analyze it. This has been highly beneficial in providing crucial diagnostic information to doctors, patients and cancer researchers, but the proliferation of technologies gives rise to a lack of standardization. Hospitals and laboratories across the country are capturing and analyzing ctDNA but lack a uniform set of universally recognized standards to guide interpretation of the results. The same sample can be interpreted very differently by different scientists, making it difficult to fully understand or trust any given test.

In 2019, the FNIH launched a project called Identification and Validation of ctDNA Quality Control Materials. A partnership spanning the public, private and academic sectors, the ctDNA project will develop much-needed universal standards. The project will create a set of quality-control materials meant to provide assurance that all testing steps were correctly performed, allowing for comparison of samples across different hospitals and laboratories and better enabling accurate results.

Once successfully developed and disseminated, these quality-control materials will help lay the groundwork for more effective clinical research, as well as faster regulatory approval of new testing technologies and how they might be used to help patients. The project is likely to lay a foundation for the development of protocols to test other genetic material in the future, with implications that could reach far beyond even those for people with cancer.

Read more at fnih.org/ctDNA.

A PARTNERSHIP SPANNING THE PUBLIC, PRIVATE AND ACADEMIC SECTORS, THE ctDNA PROJECT WILL DEVELOP MUCH-NEEDED UNIVERSAL STANDARDS.


NOVEL APPROACHES BRING US ONE
STEP CLOSER TO BREAKTHROUGHS
IN CONDUCTING BIOMEDICAL
RESEARCH.

IMPROVING THE PATIENT EXPERIENCE IN DIAGNOSING A DEADLY LIVER DISEASE

According to the American Liver Foundation, roughly 5 percent of U.S. adults — or 16.5 million people — are affected by a type of liver disease called NASH: non-alcoholic steatohepatitis. Characterized by buildup of fatty tissue in the liver, NASH continues to increase in prevalence alongside rising rates of obesity and type 2 diabetes. Unfortunately, NASH does not present symptoms until a patient is in the later stages of the disease; when left untreated, the disease can cause permanent damage. Currently, the disease can only be diagnosed through a painful, invasive and expensive liver biopsy. To properly diagnose NASH, and to help doctors identify patients at risk of dire health complications, better, less invasive and more reliable diagnostic tools are needed.

In 2019, the FNIH Biomarkers Consortium launched the Non-Invasive Biomarkers of Metabolic Liver Disease (NIMBLE) project to replace the current standard for diagnosing NASH with a patient-friendly, non-invasive approach. The NIMBLE team will compare promising new imaging-based and blood-based biomarkers individually and in combination against liver biopsies to identify a reliable, widely deployable, non-invasive marker to more easily diagnose NASH and monitor patient responses to treatments. Armed with this knowledge, physicians for the first time will be able to identify more effectively those patients who are most likely to progress to serious complications like liver failure or cancer.

"There is a broad consensus on the need to validate safe and simple approaches to replace biopsy for diagnosis and staging, and as a way to monitor the liver health of patients with NASH over time," says Gail Cawkwell, of partner Intercept Pharmaceuticals. "We will get there faster if academic institutions, patient groups, drug developers, regulators and public health agencies all work together to pool our data, resources and knowledge." Morris J. Birnbaum, of partner Pfizer, says, "NIMBLE has the potential to galvanize the entire field in our pursuit of an accurate, scalable, non-invasive tool for the diagnosis and staging of NASH."

A breakthrough discovery in the diagnosis and monitoring of NASH is an essential goal for the research community, potentially helping patients with this deadly, yet invisible, disease.

Read more at fnih.org/NIMBLE.

"NIMBLE HAS THE POTENTIAL TO GALVANIZE THE ENTIRE FIELD IN OUR PURSUIT OF AN ACCURATE, SCALABLE, NON-INVASIVE TOOL FOR THE DIAGNOSIS AND STAGING OF NASH."

Morris J. Birnbaum
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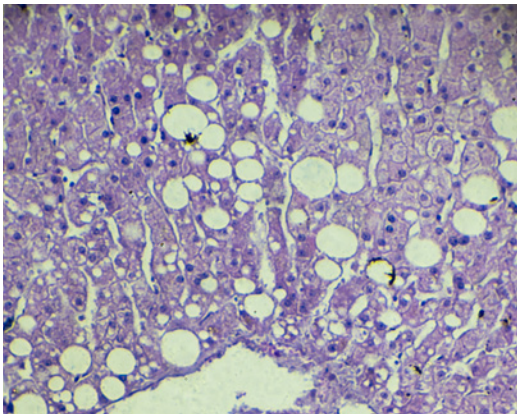

Liver fatty degeneration in microscopy.

Dr. Yasmine Belkaid at the 2019 FNIH Award Ceremony.

INVESTING IN THE FUTURE OF SCIENTIFIC LEADERSHIP

BY TRANSFORMING THE UNDERSTANDING OF THE MICROBIOME'S CRITICAL FUNCTION IN HUMAN HEALTH, DR. BELKAID'S RESEARCH PAVES THE WAY FOR YET FURTHER BREAKTHROUGHS IN DISEASE DIAGNOSTICS AND MANAGEMENT.

One of the many ways the FNIH accelerates progress is through investment in the creativity of exceptional scientists. The organization bestows three prizes each year to recognize outstanding partners and contributors to advancing biomedical research.

LURIE PRIZE IN BIOMEDICAL SCIENCES

The Lurie Prize in Biomedical Sciences is an annual prize made possible by a gift from philanthropist Ms. Ann Lurie, recognizing outstanding achievements made by a promising young scientist. In May, the FNIH honored Yasmine Belkaid, Ph.D., of the National Institute of Allergy and Infectious Diseases (NIAID) for revolutionizing our understanding of microbes in the gut and skin.

Dr. Belkaid's groundbreaking work has shed light on the interaction between the microbiome and the immune system, as well as the crucial implications of this interaction for human health. Her research is focused on using microbes to develop novel strategies to prevent and treat diseases such as psoriasis, Crohn's disease, allergies and autoimmune diseases. By transforming the understanding of the microbiome's critical function in human health, Dr. Belkaid's research paves the way for yet further breakthroughs in disease diagnostics and management.

Read more at fnih.org/LuriePrize.

TRAILBLAZER PRIZE FOR CLINICIAN-SCIENTISTS

The Trailblazer Prize was established in 2018 to highlight the essential role of early career clinician-scientists in spurring innovation in patient care.

In October, Dr. James Kochenderfer of NCI was announced as the prize winner for pioneering the development of immunotherapies that leverage chimeric antigen receptor (CAR) T-cells to treat blood cancers. His work led to the first approval by the FDA of a CAR T-cell therapy for lymphoma. He also headed the first clinical trials focused on a specific antigen for the treatment of multiple

myeloma. Dr. Kochenderfer's work is a premier example of how clinical science has the potential to create life-saving breakthroughs in the treatment of cancer.

Funding for the Trailblazer Prize is provided by the Gallin Fund at the FNIH.

Read more at fnih.org/TrailblazerPrize.

CHARLES A. SANDERS, M.D., PARTNERSHIP AWARD

Each year, the FNIH bestows the Charles A. Sanders, M.D., Partnership Award to recognize people and/or organizations that have made significant contributions to the organization's efforts to build, implement and nurture public-private partnerships in support of the mission of the NIH. In 2019, the FNIH proudly honored the Doris Duke Charitable Foundation and Jane Sayer, Ph.D., for their steadfast support of NIH training and awards programs to foster the research community and for their ongoing work to further the Foundation's mission.

Funding for the Charles A. Sanders, M.D., Partnership Award is provided by the Charles A. Sanders Legacy Fund of the FNIH.

Read more at fnih.org/SandersPartnership.

CONVENING LEADERS TO CHART THE PATH TO PROGRESS

Next-generation breakthrough therapies require the construction of diverse alliances to identify the best ways to treat and serve patients worldwide. The FNIH specializes in convening key stakeholders from wide-ranging sectors to identify and tackle scientific challenges and knowledge gaps to propel research forward.

As one example, in September, the FNIH hosted the 11th International Forum on Rheumatoid Arthritis (RA): Pathogenesis and Emerging Therapeutic Strategies, or IFRA 2019. The meeting brought together major scientific leaders from industry and academia in Asia, Europe and the United States, including NIH Director Dr. Francis Collins. The group represented a global consortium with a shared collective goal of accelerating discovery and innovation in RA.

A chief outcome of the meeting was laying the foundation for a future International RA Collaborative Network building on the work of existing initiatives, such as the Accelerating Medicines Partnership for RA and lupus, to foster transformative studies and facilitate international collaboration. An article published in the *Annals of the Rheumatic Diseases* lays out the session's overarching themes and provides a vision for the path forward.

Trailblazer Prize finalists Ami S. Bhatt, M.D., Ph.D.; James Kochenderfer, M.D.; Evan Macosko, M.D., Ph.D.; and Giovanni Traverso, M.B., B.Chir, Ph.D. at the FNIH Annual Fall Board Dinner.


BREAKTHROUGH APPROACHES BRING
US ONE STEP CLOSER TO PRACTICAL
SOLUTIONS TO HEALTH CHALLENGES
FACED BY PEOPLE WORLDWIDE.

DEVELOPING BETTER VACCINES TO PREVENT TUBERCULOSIS WORLDWIDE

The global burden of tuberculosis (TB) is staggering: Around the world, one person infected with the disease dies every 18 seconds. According to the World Health Organization, TB is "the leading cause of death from a single infectious agent," killing more people worldwide than HIV/AIDS or any other infectious disease. The need for new approaches to target and end the global TB epidemic is clear.

The only existing vaccine for TB, called Bacillus Calmette Guerin (BCG), is commonly administered to newborns. While the vaccine confers important health protections to infants and young children, its effects wear off over time, so that adolescents and adults may not be safeguarded against the disease.

In 2019, the FNIH announced the TB Vaccine project, funded through a grant from the Bill & Melinda Gates Foundation. Researchers at NIAID and the University of Pittsburgh are setting out to study whether the way the BCG vaccine is administered could make a difference in its long-term protective effects. The vaccine is currently delivered intradermally, or injected into the skin. Could intravenous delivery, or injection directly into the vein, better prevent TB?

The researchers will test intravenous injection in animal models to see if that technique better activates white blood cells that can help to trigger a powerful, long-lasting immune response. Using cutting-edge immune cell analysis, radiologic imaging, microbiology and pathology analyses, the scientists will learn more about the biological mechanisms of protection. Ultimately, the project's goal is to use the study's findings to inform a TB vaccine design of the future, bringing the world that much closer to solving this global public health affliction.

Read more at fnih.org/TBvaccine.

USING CUTTING-EDGE IMMUNE CELL ANALYSIS, RADIOLOGIC IMAGING, MICROBIOLOGY AND PATHOLOGY ANALYSES, THE SCIENTISTS WILL LEARN MORE ABOUT THE BIOLOGICAL MECHANISMS OF PROTECTION.

FILLING A NEED OF THE NATION'S LEADING RESEARCH CENTER

At the NIH Clinical Center — the nation's premier hospital solely devoted to clinical investigation — patients are considered "active partners in medical discovery," participating in experimental trials carried out by NIH institutes to receive treatment for their conditions and ultimately benefit scientific progress. The extensive list of research breakthroughs coming out of the NIH Clinical Center includes the first cures for childhood leukemia and Hodgkin's disease using chemotherapy, the first blood tests for AIDS and hepatitis, and the first gene therapy, to name just a few. To support such resource-intensive endeavors, the FNIH established the Clinical Center In-Kind Drug Donation Program to donate pharmaceuticals to the NIH Clinical Center. The program, which has provided nearly $16 million in drugs and therapeutics to the NIH since 2008, was supported in 2019 by a major gift from Horizon Therapeutics plc. "The generosity of the program has been a major boon to our patients and our program," says Dr. Steven Holland, Director, Division of Intramural Research at NIAID.

To learn more, visit fnih.org/DrugDonation.

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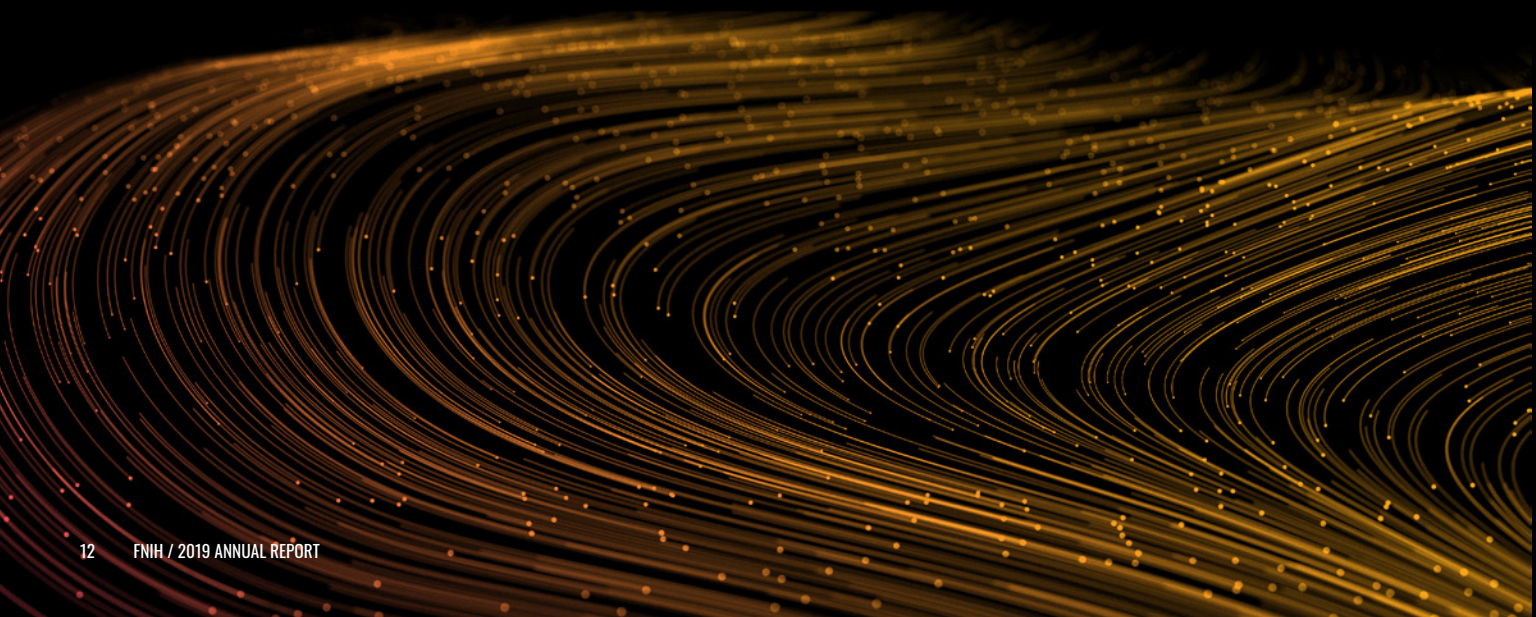

WAYS TO GIVE

SPOTLIGHT ON: THE FNIH FUTURES FUND

Virtually all of the funds raised by the FNIH support specific projects to advance crucial biomedical research goals. During public health emergencies, or to seed new discoveries, the Foundation is called upon to assist the NIH in its response to new and emerging priorities. In such cases, the ability to access flexible funding is of paramount importance. In 2018, the Board of Directors established the Foundation's first endowment, the FNIH Futures Fund. Supported by an inaugural gift from Dr. Steven and Jann Paul, the endowment marks a turning point in the Foundation's history, providing the flexibility to advance critical research projects and drive the innovation that promotes life-saving biomedical progress.

To learn more about the FNIH Futures Fund, please contact Robert Balthaser at rbalthaser@fnih.org.

"WE ARE PROUD TO SUPPORT THE FNIH FUTURES FUND, ALLOWING THE FNIH TO MORE NIMBLY RESPOND TO NEW CHALLENGES AND ENSURING ITS ABILITY TO CONTINUE CREATING A HEALTHIER FUTURE FOR ALL OF US."

Dr. Steven and Jann Paul

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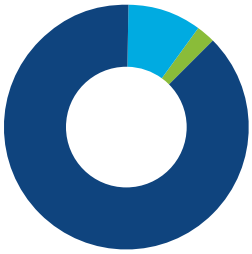
REVENUE AND SUPPORT	2019	2018
Contributions	$ 49,827,480	$ 58,261,723
Grants	220,665	116,338
Administrative costs	(50,000)	64,723
Transfers from NIH	500,000	2,000,000*
Investment income	5,197,124	917,698
In-kind contributions	270,780	256,859
Donated services	50,000	60,000
Fundraising event	401,000	368,156
Total revenue and support	**$ 56,417,049**	**$ 62,045,497**

EXPENSES AND CHANGES IN NET ASSETS	2019	2018
Program services		
Fellowships and training programs	$ 939,134	$ 1,074,653
Memorials, awards and events	575,570	486,093
Capital projects	60,340	852,380
Research programs	59,558,215	34,264,962
Total program services	**$ 61,133,259**	**$ 36,678,088**
Supporting services		
Management and general	$ 6,123,632	$ 5,436,683
Fundraising	552,675	515,538
Total supporting services	**$ 6,676,307**	**$ 5,952,221**
Total expenses	**$ 67,809,566**	**$ 42,630,309**
Change in net assets	$ (11,392,517)	$ 19,415,188
Net assets beginning of year	$ 129,902,807	110,487,619
Net assets at end of year	**$ 118,510,290**	**$ 129,902,807**

2019 EXPENSES



87.8%
Research Programs

9.8%
Management and Fundraising

2.3%
Education and Events

**This figure reflects transfers from NIH for 2018 and 2019 federal government fiscal years.*

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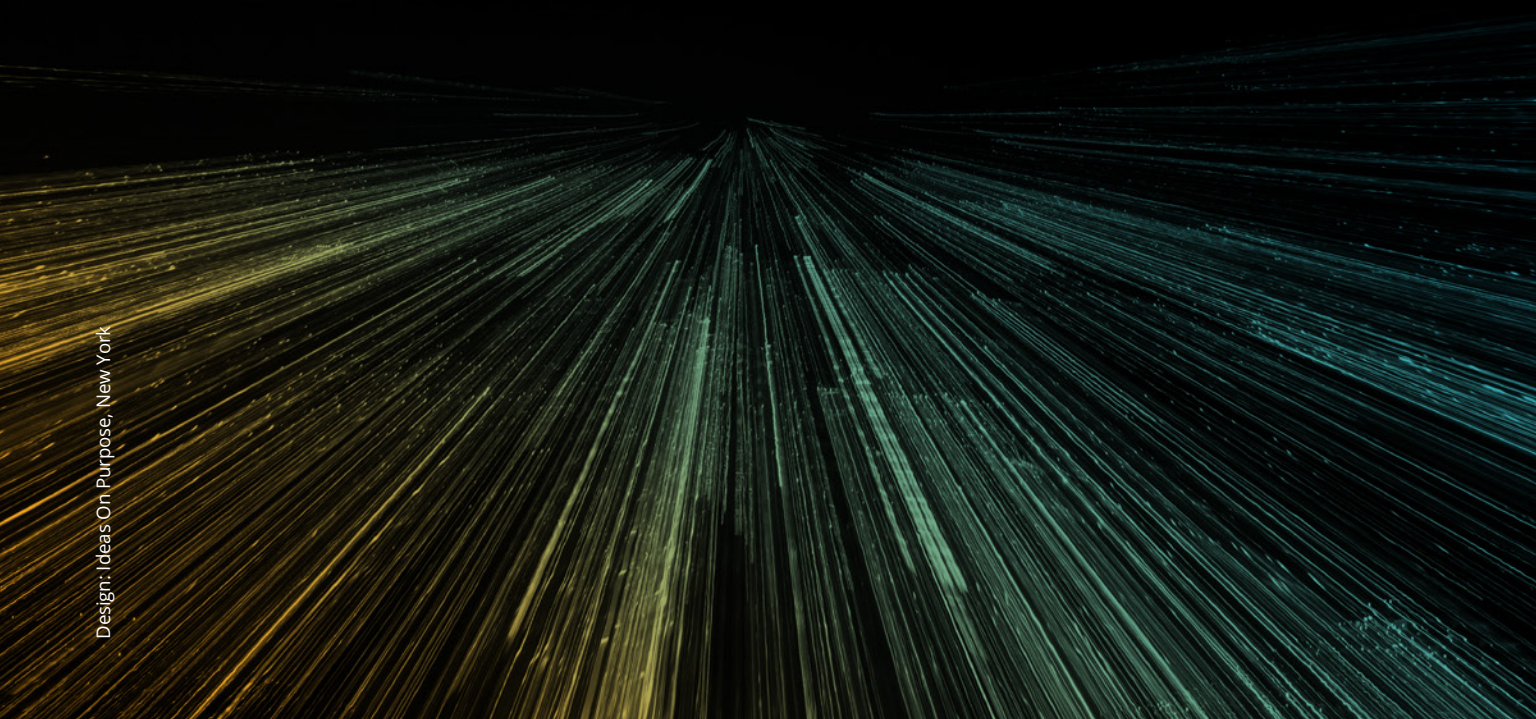

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