

# Chicago Department of Public Health Institutional Review Board

## Procedures

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### Mission

The Chicago Department of Public Health, through the Institutional Review Board (IRB), monitors research involving the Chicago Department of Public Health (CDPH) patients/clients and staff. Special attention is given to the protection of patients/clients rights, safety and privacy. The IRB guidelines are attached.

This IRB, appointed by the Commissioner, will assure compliance with the Code of Federal Regulations (45 CFR 46, 45CFR 160 & 164 and 21 CFR 50 & 56) for the Protection of Human subjects.

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Terry Mason, M.D., Commissioner  
Chicago Department of Public Health

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Date



# Chicago Department of Public Health Institutional Review Board

## Procedures

### I. Name and Purpose.

The Institutional Review Board (IRB) of the Chicago Department of Public Health (CDPH) is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities under the auspices of the CDPH. This includes CDPH patients as well as other subjects involved in research conducted by CDPH staff members.

The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by federal regulations and CDPH policy. Research reviewed and approved by the IRB may be subject to review and disapproval by other officials at the CDPH. However, no official may approve research if it has been disapproved by the IRB. In addition, IRB approved research is subject to continuing IRB review and must undergo reevaluation at least annually (or more frequently if required by the IRB). All documentation and instructions are posted on the [CDPH Institutional Review Board web site](#).

### II. Definitions

**ADVERSE EFFECT:** An undesirable and unintended, although not necessarily unexpected, result of therapy or other intervention (*e.g.*, headache following spinal tap or intestinal bleeding associated with aspirin therapy).

**ASSENT:** Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research.

**ASSURANCE:** A formal written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy §46.103].

**AUTHORIZED INSTITUTIONAL OFFICIAL:** An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research.

**AUTONOMY:** Personal capacity to consider alternatives, make choices, and act without undue influence or interference of others.

**BELMONT REPORT:** A statement of basic ethical principles governing research involving human subjects issued by the National Commission for the Protection of Human Subjects in 1978.

**BENEFICENCE:** An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm; and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm.

**BENEFIT:** A valued or desired outcome; an advantage.

**COMPENSATION:** Payment or medical care provided to subjects injured in research; does not refer to payment (remuneration) for participation in research.

**CONFIDENTIALITY:** Pertains to the treatment of information that an individual has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission in ways that are inconsistent with the understanding of the original disclosure.

**CONFLICT OF INTEREST:** An IRB member has a conflicting interest if the member is part of the research team submitting the protocol, supervises the research team or may gain financial or other incentives from the protocol.

**DECLARATION OF HELSINKI:** A code of ethics for clinical research approved by the World Medical Association in 1964 and widely adopted by medical associations in various countries. It was revised in 1975 and 1989.

**EMANCIPATED MINOR:** A legal status conferred upon persons who have not yet attained the age of legal competency as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had by virtue of assuming adult responsibilities such as being self-supporting and not living at home, marriage, or procreation.

**EXPEDITED REVIEW:** Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB. Federal rules permit expedited review for certain kinds of research involving no more than minimal risk and for minor changes in approved research [Federal Policy §46.110].

**FULL BOARD REVIEW:** Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present, including at least one member whose primary concerns are in nonscientific areas. For the research to be approved, it must receive the approval of a majority of those members present at the meeting [Federal Policy §46.108].

**GUARDIAN:** An individual who is authorized under applicable state or local law to give permission on behalf of a child to general medical care

**Health Insurance and Accountability Act of 1996 (HIPAA):** The Privacy Rules created by authority of this Act establish a foundation of federal protection for the privacy of health information and the conditions under which protected health information may be used or disclosed by covered entities for research. The Privacy Rules define the mechanisms by which individuals will be informed of uses and disclosures of their medical information and their rights to access information. [Federal Regulation 45CFR 160,164]

**HUMAN SUBJECTS:** Individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under the federal regulations, human subjects are defined as: living individual(s) about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual; or (2) identifiable private information [Federal Policy §46.102(f)].

**INFORMED CONSENT:** A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

**INSTITUTIONAL REVIEW BOARD:** A specially constituted review body established or designated by an entity to protect the welfare of human subjects recruited to participate in biomedical or behavioral research [Federal Policy §§46.102(g),108, 109].

**LEGALLY AUTHORIZED REPRESENTATIVE:** A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [Federal Policy §46.102(c)].

**MINIMAL RISK:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

**MONITORING:** The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design and subject protections.

**NUREMBERG CODE:** A code of research ethics developed during the trials of Nazi war criminals following World War II and widely adopted as a standard during the 1950s and 1960s for protecting human subjects.

**OFFICE FOR PROTECTION FROM RESEARCH RISKS (OPRR):** The office within the National Institutes of Health, an agency of the Public Health Service, Department of Health and Human Services (DHHS), responsible for implementing DHHS regulations (45 CFR Part 46) governing research involving human subjects.

**PRINCIPAL INVESTIGATOR:** The scientist or scholar with primary responsibility for the design and conduct of a research project.

**PRIVACY:** Control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others.

**Protected Health Information (PHI):** PHI is individually identifiable health information that is maintained or transmitted by a covered entity. PHI cannot be accessed for research without authorization, waiver or exemption.

**PROTOCOL:** The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the treatment regimen(s), and the proposed methods of analysis that will be performed on the collected data.

**RESEARCH:** A systematic investigation (*i.e.*, the gathering and analysis of information) designed to develop or contribute to generalizable knowledge [Federal Policy §46.102(d)].

**RESPECT FOR PERSONS:** An ethical principle discussed in the Belmont Report requiring that individual autonomy be respected and that persons with diminished autonomy be protected.

**REVIEW (OF RESEARCH):** The concurrent oversight of research on a periodic basis by an IRB. In addition to the at least annual reviews mandated by the federal regulations, reviews may, if deemed appropriate, also be conducted on a continuous or periodic basis [Federal Policy §46.108(e)].

**RISK:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (*See also: Minimal Risk.*)

**SPONSOR-INVESTIGATOR:** An individual who both initiates and actually conducts, alone or with others, a clinical investigation. Corporations, agencies, or other institutions do not qualify as sponsor-investigators.

**SURVEYS:** Studies designed to obtain information from a large number of respondents through written questionnaires, telephone interviews, door-to-door canvassing, or similar procedures.

**VOLUNTARY:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity.

### **III. IRB Composition**

The Commissioner of the Chicago Department of Public Health will appoint the IRB chairperson and all other members.

- A. The IRB will consist of a minimum of five members, at least one of whom will not be affiliated with CDPH.
- B. IRB membership will reflect the racial, ethnic, cultural and gender diversity of CDPH and its clients.
- C. There will be at least one member whose primary concerns are in scientific areas.
- D. There will be at least one member whose primary concerns are in nonscientific areas.

### **IV. Standards of Compliance**

All research under the auspices of the CDPH IRB must comply with the tenets of the following:

- A. The Nuremberg Code
- B. The Declaration of Helsinki
- C. The Belmont Report
- D. Department of Health and Human Services (DHHS) 45 CFR 46
- E. Food and Drug Administration (FDA) Regulations at 21 and 50 and 21 CFR 56
- F. Health Insurance and Accountability Act (HIPAA) of 1996 45 CFR Part 160

### **V. IRB Functions and Operations**

- A. Meeting Schedule, Notification of Meetings and Voting
  - 1. The IRB convenes regularly (no less than quarterly) meetings to conduct initial (and other) reviews and other IRB business for research projects according to a preset schedule posted on the Chicago Department of Public Health's web site.
  - 2. IRB members receive written reminders of the meeting date and time prior to the meeting and are asked to return an Attendance Notification form to CDPH to inform the IRB whether or not the member will attend the meeting.
  - 3. A meeting may be held with any number of members present. However, a vote may be taken only if a majority of the members of the IRB are present. At least one member whose primary concerns are non-scientific.
  - 4. The chairperson of the IRB will be counted toward a quorum but will not vote unless there is a tie.
  - 5. No IRB member can participate in an initial review of a research project in which the member has a conflicting interest, except to provide information requested by the IRB. (45 CFR46.107 e)

B. List of Required Initial Review Materials Distributed Prior to IRB Meetings

1. Applicants will submit 10 copies of the proposed research project to CDPH at least two weeks prior to the IRB meeting in order to be reviewed. The application will include all of the following items (45 CFR 46.111.):
  - a. the completed latest version of the CDPH Submission Form for Research Involving Human Subjects signed by principal investigator and the institutional sponsor.
  - b. a copy of the proposed informed consent document in all relevant languages (if applicable).
  - c. the full study protocol including a detailed description on the method to be used to secure informed consents of human subjects and any study instruments.
  - d. a description of how subjects will be recruited (if applicable), including brochures, advertisements intended to be seen or heard by potential human subjects.
  - e. any relevant grant information including other IRB approvals and project sponsorship.
2. IRB members will receive the research project proposal and the documents listed above ten days before the IRB meeting.
3. IRB members conduct in-depth reviews of each proposal and pertinent documents for discussion at the next meeting.

C. IRB Review of Research. Possible IRB Actions in the Review of Research:

1. Full review: Review of proposed research at a convened meeting at which a majority of the membership of the IRB are present.
  2. Expedited Review of proposed research by the IRB chair or a designated voting member or group of voting members rather than by the entire IRB.
  3. Exemption from review
  4. Continuing review
1. IRB Review of Protocols
- a. In its deliberations, the IRB will determine if the proposed research complies with acceptable ethical standards and values. No research project may be approved unless:
    - (i) There is a valid informed consent form, unless a waiver has been granted or the project meets the criteria for exemption.
    - (ii) Confidentiality is assured and HIPAA compliant. This includes secure storage of all records; this requires that all computer records of research subjects will contain no names or personal identifiers, unless specifically authorized by the CDPH IRB.
    - (iii) The individuals conducting the research, notably the principal investigators are known to be competent, including documentation of IRB training.

- (iv) If the principal investigator is not a CDPH employee, then a CDPH sponsor is required and must acknowledge his or her sponsorship in writing.
- (v) The applicant has complied with the Standard uses and disclosures for research purposes of 45 CFR 164. 508.

b. The IRB considers the following questions in its deliberations and review of protocol.

- (i) Does the proposed research project have scientific value?
- (ii) Does the proposed research project have scientific validity?
- (iii) Does the proposed research project pose an inappropriate risk to research study participants? (For adults appropriate risk is where a balance of risk and individual or general benefit is present and for children where the risk of participation is comparable to the risks of daily living for that group of children.)
- (iv) How does the proposed research project minimize anticipated risks to subjects?
- (v) Are the possible risks to subjects reasonable in relation to anticipated benefits and the importance of the resulting knowledge?
- (vi) Is the selection of subjects equitable?
- (vii) Are additional safeguards in place to protect subjects who may be vulnerable to undue influence or coercion?
- (viii) Will research study participants or their legally authorized representatives provide informed consent?
- (ix) Are study participants likely to agree to provide written informed consent? Are alternatives presented?
- (x) Is there evidence of adequate monitoring of data collected to ensure the confidentiality of research study participants.
- (xi) Are there adequate provisions to protect the privacy of research study participants and to maintain confidentiality of the data.

2. IRB Review of Informed Consent Requirements.

- a. Consent Protocol: The IRB will review informed consent protocol submitted to ascertain the process that the project will use to assure that:
  - (i) research study participant or legally authorized representative affix his or her signature to the consent form showing the date that the form is signed witnessed and translated when appropriate.
  - (ii) research study participants will be given essential information in language understandable by research study participants and his/her representatives prior to being asked for written consent (see checklist on website).
  - (iii) research study participant fully understand the research including purpose, risks, benefits and alternatives to participation; and
  - (iv) language and cultural barriers to informed consent are understood and addressed.



- b. Consent Forms: The IRB will review consent forms to assure that they include the following essential statements:
    - (i) an explicit statement that the project involves research
    - (ii) a clear explanation of the purpose of the project
    - (iii) an explanation of the expected duration of research study participant's participation
    - (iv) a description of the procedures to be followed
    - (v) identify any products or procedures that are experimental
    - (vi) a description of any reasonably foreseeable risks or discomforts to research study participants
    - (vii) a description of any benefits to research study participants or to others that may be reasonably expected from the proposed research
    - (viii) disclosure of any appropriate alternative procedures or course of treatment, if any exists, that may be advantageous to research study participants
    - (ix) full explanations of the confidentiality of any records that identify research study participants will be maintained and any circumstances under which governmental agencies or funders may inspect the record
    - (x) for research involving more than minimum risk an explanation of whether any compensation and/or medical treatment are available if research study participants is injured and if so where to get further information; adverse events should be reported to the IRB immediately
    - (xi) who to contact in the event of further questions about the research, who to contact about the rights of subjects and who to contact if research study participants suffers an injury. The contact is the Office of the CDPH IRB at (312) 747-9415.
    - (xii) An explanation that participation is voluntary, that refusal to participate in any part of the research will not result in any penalty or loss of benefits that research study participants is otherwise entitled, and that research study participants can discontinue participation at any time without penalty or loss of benefits.
    - (xiii) The consent form will conform to the requirements for HIPAA authorization for research within the consent form or as a separate document.
- 3 IRB Action on Exemption from Review. Applicants may submit an Application for Exemption From Human Subjects Review using the CDPH form signed by the principal investigator and institutional sponsor.
- a. The IRB will review the full research proposal and instruments to determine if the project meets the criteria for exemption.
  - b. The IRB will document the specific category that justifies the decision to exempt the proposed category from review.

- c. Research activities in which the only involvement of human subjects will be in one or more of the following categories will be exempt from review.
- (i) Research conducted in established or commonly accepted educational settings involving normal educational practices such as: research on regular and special education instructional or research on the effectiveness of or the comparison among instructional, techniques, curricula, or classroom management methods.
  - (ii) Research involving the use of educational tests (cognitive, diagnostic aptitude, achievement) survey procedures, interview procedures or the observation of public behavior unless: Information obtained is recorded in such a manner that human subjects can be identified, directly through identifiers linked to research study participants;
  - (iii) Any disclosure of human subjects' responses could place them at risk of civil or criminal standing or be damaging to research study participant's financial standing, employability or reputation. Research involving survey or interview procedures is not exempt from human subject review if children are involved. Research involving observations of public behavior of children as subjects is exempt only if the investigator does not participate in the activities being observed.
  - (iv) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) survey procedures, interview procedures or the observation of public behavior that is not exempt under "iii" above:
  - (v) The human subjects are elected or appointed public official or candidates for public office or Federal statue without exception requires that the confidentiality of the research and thereafter
  - (vi) Research involving the collection or study of: Existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified directly or through identifiers linked to research study participants.
  - (vii) Research and demonstrations projects which are conducted by subjected to approval of governmental department or agency heads and which are designed to study, evaluate or otherwise examine:
  - (viii) Public benefit or service programs; Procedures for obtaining benefits or services under those programs.
  - (ix) Possible changes or alternatives to those programs or procedures; or
  - (x) Possible changes in methods or levels of payment for benefits or services under those programs.
  - (xi) Taste and food quality evaluation and consumer acceptance studies.

#### 4. IRB Action on Expedited Review

Applicants may request that a project is granted an expedited review in cases where the research involves no more than minimal risk or when there are minor changes to a previously approved process.

- a. An expedited initial review of research projects may be conducted by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among the members of the IRB.
- b. An expedited review may be conducted when minimal risk exists and when the probability of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- c. In reviewing the research, the reviewer may exercise all of the authorities of the IRB, except the reviewers may not disapprove the research. A research activity may be disapproved only after full IRB review in accordance with the non-expedited procedures.
- d. The IRB chairperson will present to the full IRB board research proposals approved under the expedited procedure and any discussion will be entered into the IRB minutes.

#### 5 IRB Action on Consent waiver

The IRB may approve a consent process that does not contain all of the elements (listed in “2b” above) or waive entirely the requirement to get informed consent, if the investigator is able to justify the following to the IRB minutes:

- a. The research could not be carried out without the waiver or alteration
- b. When appropriate, participants will be provided with additional pertinent information after participation.
- c. No more than minimal risk to the participant is involved and the rights and welfare of the participant will not be affected
- d. To obtain a waiver for research that requires the disclosure of any protected health information the applicant must provide the following
  - (i) For reviews preparatory to research, the researcher must provide representations that:
    - (a) The use or disclosure is sought solely to review PHI as necessary to prepare a research protocol or for similar purposes preparatory to research;
    - (b) No PHI will be removed from CDPH by the researcher in the course of the review; and
    - (c) The PHI for which use or access is sought is necessary for the research purposes.
  - (ii) For research on decedent’s information the researcher must provide.
    - (a) Representation that the use or disclosure is solely for research on the PHI information of decedents,
    - (b) Documentation of the death of such individuals, and
    - (c) Representation that the PHI for which use or disclosure is sought is necessary for the research purposes.

- e. Documentation of waiver approval. If the waiver is approved the IRB will provide the following documentation:
  - (i) A statement that the IRB has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:
    - (a) The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals, based on, at least. The presence of the following elements:
      - (A) An adequate plan to protect the identifiers from improper use and disclosure;
      - (B) An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
      - (C) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by law;
    - (b) The research could not practicably be conducted without the waiver or alteration.
    - (c) The research could not practicably be conducted without access to and use of the PHI.
  - (ii) A brief description of the PHI for which use or access has been determined to be necessary by the IRB.
  - (iii) A statement that the alteration or waiver of authorization has been reviewed and approved by the IRB under either normal or expedited review procedures; and
  - (iv) The documentation of the exemption must be signed by the chair or other member, as designated by the chair, of the IRB.
- f. Retention of Records. The research records will be kept for at least six years or for three years after the study is complete, whichever is longer. At that time the records will be destroyed or identifying information removed from the study results. Any research information in the medical record will be kept. (CFR46.115)

## 6. IRB Action on Conditional Approvals of Initial Reviews

The IRB may approve research projects conditionally in the following situations:

- a. When the convened IRB requires clarifications or modifications regarding the protocol or informed consent documents. IRB approval of the proposed research will be deferred pending receipt of the requested material by the convened board.
- b. When the convened IRB stipulates specific revisions that requires simple concurrence by the investigator. The IRB chair or another member designated by the chair may then subsequently approve the revised research protocol on behalf of the IRB under an expedited review procedure.

## 7. IRB Action on Continued Review of Research

- a. The Institutional Review Board of the Chicago Department of Public Health will continue to review each human subjects research, at least annually, in a manner consistent with the Department of Health and Human Services regulations at 45 CFR 46.108(b) and 46.115(a)(2). The investigator will submit 2 copies of the original (approved) application together with 10 copies of the progress report. In conducting continuing review of research not eligible for expedited review, all IRB members shall at least receive and review a protocol summary and a status report on the progress of the research, including:
  - (i.) the number of subjects accrued;
  - (ii.) a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review; (the IRB will be notified promptly of any adverse events or any change in the protocol)
  - (iii) any relevant multi-center trial reports;
  - (iv) a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
  - (v) any other relevant information, especially information about risks associated with the research; and
  - (vi) a copy of the current informed consent document and any newly proposed consent document
- b. At least one member of the IRB (i.e., a primary reviewer) shall receive a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, any IRB member also shall have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.
- c. When reviewing the current informed consent documents, the IRB should ensure that the proposed consent documents are current.
- d. Any significant new findings that may relate to the subject's willingness to continue participation are provided to the subject in accordance with HHS regulations at 45 CFR 46.116(b)(5).
- e. The minutes of the IRB meetings will reflect the separate deliberations, actions and votes for each protocol undergoing continuing review by the convened IRB.
- f. Where local investigators are participating in multi-center trials of human subjects research, the IRB may rely on a current statement from the Data and Safety Monitoring Board (DSMB), Data Monitoring Committee (DMC), another similar body or sponsor whose responsibilities include review of adverse events, interim findings and relevant literature.
- g. The IRB will review research initially approved under expedited review in the manner outlined in this section.

- h. When reviewing research under an expedited review procedure, the IRB Chair (or designated IRB member) should receive and review all of the above-referenced documentation listed in previous section and report on all of the expedited reviews at the next meeting.
- i. In general, research that did not qualify for expedited review on initial review will not qualify for expedited review at the time of continuing review, except in the following limited circumstances:
  - (i) the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects; OR
  - (ii) where no subjects have been enrolled and no additional risk have been identified; OR
  - (iii) where the remaining research activities are limited to data analysis.
  - (iv) unless more frequent review is specified during the initial review, each study protocol must undergo continued review within one year of the initial review

#### 8. Determination of the date for continued review

- a. Where the IRB reviewed and approved a protocol without any conditions or where the approval of the protocol was contingent on specific minor conditions the IRB Chair or designee subsequently verified the continued review must occur within one year of the date of the convened meeting of the IRB that provided initial approval.
- c. Where the IRB reviewed a protocol and had serious concerns or lacked significant information that required IRB review at subsequent convened meetings, the continued review must occur within one year of the date of the subsequent convened meeting that provided initial approval.
- d. Because there are no grace periods beyond the expiration date of the IRB approval provided in the HHS regulations, any protocol that has not properly received continued review prior to the expiration date must halt unless the IRB finds it is in the best interests of individual subjects to continue participation in the research interventions or interactions. Enrollment of new subjects cannot occur after the expiration of the IRB approval.
- e. In order to prevent disruption of a study protocol, the principal investigator or CDPH sponsor should properly submit the protocol, including all information required in II (a)(1), for continued review 45 days prior to the expiration date of the IRB approval.

#### VI IRB Reporting to Investigators and Institutions.

The Chair will send a letter to the Principal Investigator within two weeks of the IRB's review and determination.

- a. The letter will include the IRB's findings, actions, and requests for modification or clarification.
- b. The letter will also include reporting requirements and any conditions.
- c. A copy of the letter is kept on file at CDPH.

- d. All other communication with the Principal Investigator or CDPH sponsor by IRB members will be documented in writing. Such communication may include requests for additional information or clarification.
- e. At the request of the Chair these communications may be forwarded to the IRB, filed at CDPH and/or forwarded to the Commissioner.

#### VII. IRB Review Procedures for Research that Requires More than Annual Review

All research proposals are reviewed at least annually until a final report is submitted. However, as part of an initial or continuing review disposition a more frequent review may be required. Examples of this include but are not limited to:

- a. Research proposals involving vulnerable populations such as pregnant women, infants and children, prisoners and terminally ill patients.
- b. Research proposals involving significant physical, medical or mental risk to the subjects.
- c. Research proposals involving an investigator inexperienced in IRB procedures.
- d. Research proposals involving an investigator who has experienced problems in compliance with IRB regulations and procedures.

#### VIII. IRB Verification Process to Evaluate Material Changes in Research

In accordance with HHS regulations at 45 CFR 46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate under HHS regulations at 45 CFR 46.110(b).

- a. The IRB will review at the earliest possible occasion reports of unanticipated consequences of approved research or any changes in research procedure.
- b. Any proposed protocol changes must be sent in written form to the IRB for formal review. The written version must be incorporated into the original research protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents, which then supersede the previous one.
- c. To clarify, if the changes are relevant to the consent process, a revised consent form would also need to be included. The investigator may not implement such changes until the IRB has approved the revised protocol.
- d. The IRB will determine the types and extent of outside sources used to review compliance for each project separately.

- e. If the IRB determines that a complete review of a project by outside experts is necessary, the principal investigator or sponsor will pay for all associated costs.
- f. Below are listed projects that may require periodic review by outside sources. This list is not comprehensive and the IRB reserves that right to use outside sources to review compliance for any project for any reason.
  - (i) Complex projects deemed by the IRB to involve unusual levels or types of risk to subjects.
  - (ii) Projects conducted by any investigator who previously has failed to comply with all IRB requirements.
  - (iii) Projects where concern about possible material changes occurring without IRB approval have been raised based upon information provided in continuing review reports or from other sources.
- g. Expedited review of minor changes may be possible under the following conditions:
  - (i) The changes are determined to involve no more than minimal risk
  - (ii) The changes do not impact the informed consent process
  - (iii) The changes do not involve different human subject populations
  - (iv) The changes do not involve the process of maintaining confidentiality