

Institutional Review Board

**Policy and
Procedures**

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DEPARTMENT OF HEALTH

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Purpose of the Institutional Review Board (IRB)

The Pennsylvania Department of Health (DOH) IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted or financially supported by the Pennsylvania DOH. The DOH IRB is a group composed of five or more members who work to ensure that research involving human subjects is conducted ethically. Members of this board evaluate the potential risks and benefits to human subjects, as well as methods of informed consent and safeguards put in place for human subjects. By authority vested in it by federal law and regulation, the DOH IRB has the authority to approve, require modifications in or disapprove all research activities that fall within its jurisdiction. Research that has been reviewed and approved by the DOH IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the DOH IRB.

The IRB's purpose is to protect human subjects by making informed determinations on the following topics with respect to research:

- Potential risks to human subjects;
- Potential benefits to human subjects;
- Proper informed consent; and
- Proper safeguards in place for human subjects.

DOH's IRB has been granted a federal-wide assurance by the United States Department of Health and Human Services' Office of Human Research Protections (OHRP) that constitutes a binding commitment to comply with the provisions of 45 CFR 46 to protect the rights and welfare of human research subjects.

Definitions

Conflict of interest¹: A situation that constitutes conflict of interest may exist when any of the following situations exists:

- The reviewer, their spouse, parent, child or close professional associate has a financial interest in the protocol;
- The reviewer, his or her spouse, parent, child or close professional associate serves as officer, director, trustee, employee or professional associate in the organization conducting the research; and

¹ The definition used by the National Institutes of Health

- The reviewer, his or her spouse, parent, child or close professional associate is negotiating or has any arrangements concerning prospective employment or other such associations with the organization conducting the research.

Human subject: This is a living individual² about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual or his or her legally authorized representative (e.g., parents in the case of a minor); and
- Personally identifiable information.

Note: In vitro research and research in animals using already derived and established human cell lines, from which the identity of the donor cannot readily be ascertained by the investigator, are not considered human subject research and do not require review by the IRB.

Minimal risk: The probability and magnitude 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.

Research: This is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

IRB Membership

At any one time, the DOH IRB will be composed of at least five members. Of these members, one must be scientific, one must be from DOH's office of legal counsel, one must be non-scientific and one must not be from DOH. The non-scientific member may be the member who is not from DOH.

Of the five members, one member will be the designated chair. The chair of the IRB has a few more responsibilities than other members of the IRB, such as reviewing adverse event reports.

Though the full IRB is composed of at least five members, a smaller version of the IRB known as the Primary Review Team (PRT) may review applications that fall under certain categories

² A viable fetus meets the definition of a human subject.

of minimal risk research. The PRT will be composed of the IRB chair, the member from DOH's legal counsel and one other member. There are no specifications as to who that other member should be, so the IRB can designate any member as that third member. The IRB may change the third member at its discretion. The specific categories of minimal risk research are specified under federal regulations, and applicants mark whether or not they believe their research falls under these categories on their application. The IRB administrator is not responsible for determining if research falls under these categories. The PRT will determine whether research falls under these categories.

All IRB members will be required to review orientation materials, as well as complete training in human subjects research prior to serving on the IRB. Access to orientation materials and training information will be facilitated by the IRB administrator. All members of the IRB will be required to sign a confidentiality agreement.

IRB Administrator

The IRB administrator is not a voting member of the IRB but, rather, serves to ensure:

- that the information reaches the appropriate people in the IRB; and
- that there is timely communication between the IRB and the research applicant.

The IRB administrator will be the initial point of contact for applicants who are requesting IRB approval. There are several types of forms the IRB administrator may receive. When a form or email is received, it will be distributed to IRB members in accordance with the type of review: expedited, full or exempt. Since primary investigators (PI) often submit IRB applications with the intent of beginning the research relatively soon, it is important to keep the process moving with the IRB members' review and decision process. The IRB administrator will provide reminders to IRB members to assist in the timeliness of a review.

Types of Research Requiring IRB Review

Unless otherwise specified as being exempt from review³, the following research projects involving human subjects require the review of the DOH IRB:

- Research involving grants for which a DOH program is applying;
- Research involving grants awarded by the DOH to grantees;
- Research conducted by the DOH;
- Entities using DOH biological specimens and/or data;
- Entities using DOH protected health information; and

³ For example, the DOH IRB may accept another IRB's review of the proposal.

- Research that is going to be conducted at a DOH licensed/approved nursing home or long-term care facility.

Types of Research Exempt from IRB Review

1. If the principal investigator (PI) has indicated on the IRB application that one of the exemptions applies, and the IRB chair and PRT concur, then the research project need not be reviewed by the full IRB for the following:
 - a. Research conducted in established or commonly accepted educational settings that involves normal educational practices, such as (1) research on regular and special education instructional strategies, or (2) research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods;
 - b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (1) information obtained is recorded in such a manner that human subjects can be identified directly or through identifiers linked to the subjects; and (2) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability or reputation;
 - c. Research involving the collection or study of existing data, documents, records, or pathological or diagnostic specimens if the sources are publicly available and the information is recorded so that individual subjects cannot be identified;
 - d. Research and demonstration projects designed to study aspects of public benefit or service programs, including:
 - Procedures for obtaining benefits or services;
 - Alternatives to programs or procedures; and
 - Changes in methods or levels of payment under the programs; and
 - e. Food quality and taste evaluation studies.
2. The Secretary of Health or their chosen designee retains final judgment as to whether a particular research activity is covered by the exemption policy.

3. The IRB chair should notify the PI in a timely manner when the research proposal has been declared exempt from IRB review.
4. The record must indicate the specific category under which the proposed research is exempt from IRB review.
5. All IRB members must receive a copy of the research summary and the letter to the PI exempting the research proposal from IRB review.

Procedure for Requesting Review

The PI of the research project will be responsible for submitting the project to the DOH IRB for review prior to commencing the research. The procedure is as follows:

1. The PI will complete an Application to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects form. This form may be obtained on DOH's website (www.health.pa.gov).
2. The PI will provide all required documentation to the DOH IRB administrator via email at RA-DHIRB@pa.gov or Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701.
Documentation includes, but is not limited to:

- Completed Application to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects;
- Full research protocol;
- Proposed informed consent documents;
- Relevant grant applications ;
- Relevant data request applications ;
- Investigator's brochure (if available); and
- Subject recruitment materials.

3. In certain types of research, HHS regulations require specific findings on the part of the full IRB, such as in the case of approving:
 - A waiver of obtaining informed consent;
 - Research involving pregnant people, human fetuses or neonates;

- Research involving prisoners; and
 - Research involving children.
4. Once in receipt of the application materials, the IRB administrator will upload the materials into the DOH IRB SharePoint System, which will trigger an email notification to the full IRB, the PRT or the IRB chair based on the research designation chosen by the PI on the application.
 5. The full IRB, the PRT or the IRB chair will review the application based on the designation chosen by the PI on the application. This group will review and make an initial determination of the type of review necessary, then make one of the following decisions:
 - To agree with the PI that their proposal is either exempt from IRB review, eligible for expedited review by the PRT or requires review by the full IRB;
 - To disagree with the PI that their proposal is either exempt from IRB review, eligible for expedited review by the PRT or requires review by the full IRB and to assign the proposal to the appropriate team for review.
 - To require additional information before a determination can be made.

In any case, the full IRB must receive, in a timely manner, copies of the application form and a statement of the determination the PRT has made on the application.

5. In the initial review of a proposal, the IRB chair may seek assistance from persons who have expertise not represented on the IRB. Possible conflicts of interest will be considered before selecting consultants. These persons may provide advice and counsel on the proposal in question but are not voting members of the IRB. Consultants to the IRB will be required to sign a confidentiality agreement.

Informed Consent

Informed consent will be sought from each prospective subject or the subject's legally authorized representative. Informed consent is a process, not just a form. Information must be presented to enable persons to voluntarily decide whether or not to participate as a research subject.

The informed consent form should include each of the following elements in language that is clear and understood by the subjects:

- A statement that the study involves research

- An explanation of the purposes of the research and the expected duration of the subject's participation
- A description of the procedures to be followed and identification of any experimental procedures
- A description of any reasonably foreseeable risks or discomforts to the subject
- A description of any benefits to the subject or to others that may reasonably be expected from the research
- A disclosure of appropriate alternative procedures or courses of treatment that might be advantageous to the subject
- A statement describing the extent to which confidentiality of records identifying the subject will be maintained
- A thorough explanation in any instances in which protected health information may be divulged, if the organization conducting the research is designated as a covered entity (as defined by the Health Insurance Portability and Accountability Act of 1996)
- Signed subject authorizations for use of protected health information OR an IRB waiver of authorization (see page 11) in addition to informed consent forms for all research that will be performed by a covered entity (as defined by the Health Insurance Portability and Accountability Act of 1996) occurring after April 14, 2003
- For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs
- An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, as well as whom to contact in the event of a research-related injury to the subject
- A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled
- A statement from the subject or other method to demonstrate that the subject is fully informed
- A signature of the subject or the subject's legally authorized representative and the current date

Conditional or Deferred Approval

The DOH IRB may set conditions under which a protocol can be conditionally approved or deferred, including:

1. When the IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are relevant to the determinations made by the IRB, IRB approval of the proposed research should be deferred pending review of the responsive material by the IRB.
2. IRB staff should notify the PI in a timely manner that the research proposal has been reviewed and conditions must be met before final approval is granted. The PI should be given specific written guidance as to the conditions of approval.
3. When the IRB stipulates specific revisions requiring only simple concurrence by the PI, the IRB chair or designee may subsequently approve under an expedited review procedure. If the requested revisions are more technical or complicated in nature, as determined by the IRB chair, the full IRB must approve.

Human Subject Research and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The Privacy Rule of HIPAA restricts the ways in which Covered Entities⁴ (CE) can use and disclose protected health information (PHI) for research purposes. CEs may not use or disclose PHI for research purposes, except as follows:

- With the written authorization of each research participant;
- After an IRB has granted a Waiver of Authorization;
- For reviews preparatory to research (e.g., to assess the feasibility of a study);
- For research on deceased persons;
- When the information to be obtained is part of a limited data set that has been stripped of direct identifiers; and
- When the information has been de-identified to meet the standards included in the HIPAA regulations.

⁴ Health care providers that transmit health information electronically in connection with covered transactions (including diagnosis, treatment, mitigation or prevention of disease), health plans and health care clearinghouses

Issuance of a Waiver of Authorization under the Health Insurance Portability Act of 1996 (HIPAA)

The DOH IRB may issue a waiver of authorization at the request of the PI subsequent to review by the IRB's PRT. Documentation of the waiver must include all of the following:

- A statement identifying the IRB and the date on which the waiver of authorization was issued and whether the waiver was granted on an expedited basis or after deliberation of the full IRB
- A statement that the IRB has determined that the waiver satisfies the following criteria:
 - The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the presence of the following elements:
 - An adequate plan to protect the PHI from improper use and disclosure;
 - An adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of research, unless there is justification for retaining the identifiers or such retention is required by law; and
 - Adequate written assurances that the PHI will not be reused or disclosed, except as required by law, for authorized oversight of the research or for other research for which the use or disclosure would be permitted by HIPAA regulations.
 - The research could not practicably be conducted without the waiver and access to and use of the PHI.
- A description of the PHI the IRB has determined to be necessary
- The signature of the IRB chair

Continuing Review of IRB Approved Research Projects

PIs who have already been approved by the DOH IRB will submit the Continuing Review of Approved Research to the Pennsylvania Department of Health's Institutional Review Board for Review of Research Project under the Federal Policy for the Protection of Human Subjects, at least annually. These documents provide the IRB with an update about the current status of research projects that have already received IRB approval. Every project is required to submit a request for continuing review at least once per year, but the IRB may require projects to submit continuing review forms more frequently.

1. A completed Continuing Review of Approved Research to the Pennsylvania Department of Health's Institutional Review Board for Review of Research Project under the Federal Policy for the Protection of Human Subjects, which can be obtained

on DOH's website (www.health.pa.gov), and any other documents submitted by the PI should be sent to the IRB administrator via email to RA-DHIRB@pa.gov or mail Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701).

2. Continuing review of every IRB approved project is required at least annually by the DOH IRB. Continuing review should be substantive and meaningful. The IRB chair should review the new proposal. If there are no changes to the proposal, the IRB chair may approve. If changes have been made to the proposal, the PRT must review and make a decision as to whether the proposal must be brought before the full IRB.
3. Certain types of research may be reviewed more often than annually. The IRB should make this determination at the time of initial review and designate how often the projects will be reviewed. The types of research that may require more than annual review include:
 - Projects with a high risk to benefit ratio;
 - Research on vulnerable populations (includes children and the elderly); and
 - Projects conducted by PIs who have previously failed to comply with HHS regulations or the determinations of an IRB.
4. In seeking continuing review, the PI should submit the following documentation to the IRB:
 - The completed Continuing Review of Approved Research to the Pennsylvania Department of Health's Institutional Review Board for Review of Research Project under the Federal Policy for the Protection of Human Subjects;
 - The complete protocol, including any modifications since the last review;
 - The number of subjects accrued during the period since the last IRB review;
 - A summary of recent relevant literature;
 - A summary of adverse events and any unanticipated problems involving risks to subjects;
 - A list of any subject withdrawals since the last review;
 - Lists of any complaints about the research since the last review;
 - A summary of interim findings;
 - A listing of amendments or modifications to the research since the last review;
 - Any relevant multi-center trial reports; and
 - A copy of the current informed consent document and any newly proposed consent document.

Protocol Change to an IRB Approved Research Project

If a PI whose project was already approved by the DOH IRB needs to change the protocol from their initial DOH IRB application, they will submit the Change of Protocol Application to the Pennsylvania Department of Health Institutional Review Board for the Approval of Protocol Change of Research Project under the Federal Policy for the Protection of Human Subjects.

1. A completed Change of Protocol Application to the Pennsylvania Department of Health Institutional Review Board for the Approval of Protocol Change of Research Project under the Federal Policy for the Protection of Human Subjects, which can be obtained on DOH's website (www.health.pa.gov), and any other documents submitted by the PI should be sent to the IRB administrator via email to the RA-DHIRB@pa.gov or mail to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701. Change of protocol request forms and any other documents submitted by the PI should be sent to each member of the PRT by the IRB administrator
2. The PI is responsible for promptly notifying the IRB of proposed changes in research activity. Such changes may not be initiated without IRB review and approval except to eliminate immediate hazards to the human subject(s).
3. The review of proposed protocol changes must be conducted by the full IRB except where an expedited review is deemed to be appropriate under HHS regulations 45 CFR 46.110 (b)(2). The IRB chair may decide to approve the revised protocol using the expedited procedure if the changes are not substantive and pose no danger to the human research subjects.
4. Each revision to a research protocol must be incorporated into the original written proposal with revision dates noted on each page. This practice ensures there is only one complete protocol.

Adverse Events Reporting

When an unanticipated event that effects human subjects happens during a project that was already approved by the DOH IRB, a PI must submit an adverse event form. An adverse event form, which can be obtained on DOH's website (www.health.pa.gov), and any other

documents submitted by the PI should be sent to the IRB administrator via email to the RA-DHIRB@pa.gov or mail to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701.

1. The PI is responsible for promptly notifying the IRB chair and other appropriate Department of Health/Department of Health and Human Services officials of any unanticipated risks to the subject, noncompliance with IRB policies and determinations, and any suspension or termination of any IRB approval.
2. The IRB administrator should disseminate the information regarding the event to all IRB members and coordinate the response of the IRB to the PI.
3. The IRB chair shall determine whether the adverse event warrants a meeting of the full IRB and act accordingly. The IRB shall make a determination on whether IRB approval should be withdrawn and notify the PI accordingly.

Research Approved by Another IRB

If the research project has been approved by another institutional review board, the PI can request that the DOH IRB accept the approval of the other institution's IRB.

1. The PI must complete an Application to the Pennsylvania Department of Health's Institutional Review Board for Approval of Research Project under the Federal Policy for the Protection of Human Subjects form, which can be obtained on DOH's website (www.health.pa.gov), and any other documents submitted by the PI should be sent to the IRB administrator via email to RA-DHIRB@pa.gov or mail to Department of Health, Health Research Office, Health and Welfare Building, Room 833, 625 Forster St., Harrisburg, PA 17120-0701. The proposal will undergo review by the IRB's PRT.
2. IRB staff will notify the PI in writing if the IRB has decided to accept the approval of the other institution's IRB. If the IRB deems it appropriate, it may designate a third party to observe the research project and/or require additional IRB reviews on a more frequent basis than annually.
3. If the IRB PRT decides that it will not accept the review of the other institution's IRB, a decision will be made by the PRT as to whether the proposal will undergo expedited or full review by the full IRB.

4. Unless specified otherwise in the IRB's approval letter, the PI will request the IRB's review on an annual basis thereafter, until completion of the project.
5. The PI is responsible for promptly notifying the IRB of proposed changes in research activity. Such changes may not be initiated without IRB review and approval except to eliminate immediate hazards to the human subject(s). The IRB chair may decide to approve the revised protocol using the expedited procedure if the changes are not substantive and pose no danger to human research subjects. Each revision to a research protocol must be incorporated into the written proposal. See section "Protocol Change to an Approved IRB Project."
6. The research projects approved by this IRB are subject to the Department of Health's "Policy Regarding Procedures for Dealing with and Reporting Possible Misconduct in Science" as reviewed and revised Jan. 31, 1997; more recent policies will take precedence when completed. This document shall be sent to the PI with the IRB's approval.

Conflicts of Interest

1. No IRB member may participate in the IRB's review of a project in which he or she has a conflict of interest, except to provide information to the IRB. Conflict of interest is defined as any situation that creates the potential for bias leading to the possibility of improper decision-making. Potential conflict of interest indicators include, but are not limited to:
 - a. When an IRB reviewer is a PI, co-PI or a member of the support staff for the project;
 - b. When an IRB reviewer stands to gain materially based on the approval status of a proposal; and
 - c. In other situations where there may be the appearance of impropriety.
2. IRB members are expected to interpret this section conservatively if there is any doubt and to err on the side of recusal on the grounds of conflict of interest. The IRB chair may request that a reviewer with a possible conflict of interest recuse him or herself to prevent the appearance of impropriety.
3. A discussion about conflict of interest on any of the proposals to be considered will be a permanent part of the IRB meeting agenda. IRB members expressing a conflict of

interest should not be present in the meeting room when the IRB is deliberating about the project. The meeting minutes should reflect the nature of the conflict.

4. IRB members who are employees of the Commonwealth of Pennsylvania must also comply with the Governor's Code of Conduct, Executive Order 1980-18.

IRB Review in Emergency Situations

HHS regulations do not permit human subject research activities to be started, even in an emergency, without prior IRB review and approval.

IRB Records

1. The IRB shall maintain adequate documentation of IRB activities for **THREE** years from the date of the end of the research period. Documentation includes the following:
 - Copies of proposals, scientific evaluations, consent documents, progress reports, reports of adverse events
 - Minutes of meetings that reflect:
 - Attendance and the presence of a quorum;
 - Separate deliberations, actions and votes for each protocol undergoing initial or continuing review by the full IRB;
 - Voting, including the number voting for, against or abstaining;
 - Basis for requiring changes in or disapproving research;
 - Written summary of discussion of controversial issues and resolution
 - Records of continuing review activities
 - Copies of correspondence between the IRB and PIs
 - List of IRB members
 - Policies and procedures for the IRB
 - Statements of significant new findings provided to subjects
2. There are instances in which HHS regulations require specific findings on the part of the IRB, such as in the case of approving:
 - A waiver of obtaining informed consent;
 - Research involving pregnant women, human fetuses or neonates;
 - Research involving prisoners; and
 - Research involving children.

Specific findings must be clearly and fully documented in the minutes of the meeting, including protocol-specific information justifying each IRB finding.

3. All IRB records will be maintained in the Health Research Office in the Health Innovation Deputate; these records are separate from the records for the Tobacco Settlement funded research (under Act 77 of 2001).