

**PUBLIC HEALTH
INSTITUTIONAL REVIEW BOARD
Policy & Procedures Manual**



**Oregon Public Health Division
Multnomah County Health Department**

For more information:

<https://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/InstitutionalReviewBoard/Pages/index.aspx>

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Table of Contents

PRINCIPLES	1
PURPOSE	1
AUTHORITY	2
RELATIONSHIPS	3
ADMINISTRATION	3
OTHER HUMAN SUBJECT REVIEW COMMITTEES	3
PRINCIPAL INVESTIGATOR	3
INSTITUTIONAL IRB OFFICIAL	4
FEDERAL REGULATORY AGENCIES	4
PH IRB MEMBERSHIP	4
MANAGEMENT OF THE IRB	5
SELECTING CHAIRPERSON/VICE CHAIR	5
TRAINING OF IRB CHAIR AND MEMBERS	6
COMPENSATION	7
DUTIES OF THE PH IRB COORDINATOR	7
RESOURCES	8
CONFLICT OF INTEREST	8
FUNCTIONS OF THE PH IRB	9
OPERATION OF THE PH IRB	10
MEETINGS	10
REVIEW PROCESS	10
EXEMPTIONS	11
EXPEDITED REVIEW	12
FULL BOARD REVIEW	12
CONTINUING REVIEWS	15
FINDINGS BY FULL BOARD	16
INFORMED CONSENT	17
HIPAA	18
APPEAL OF PH IRB DECISION	19
PH IRB RECORD REQUIREMENTS	19
INFORMATION THE INVESTIGATOR PROVIDES	20
DATA USE AGREEMENTS	20
TRAINING DOCUMENTATION AND RESUMES	20
INITIAL REVIEW QUESTIONNAIRE (IRQ)	21
PROTOCOL/GRANT APPLICATION	21
HIPAA QUESTIONNAIRE	22
CONSENT FORM(S)	22
REQUESTS FOR CHANGE AFTER STUDY COMMENCEMENT	26
UNANTICIPATED PROBLEMS OR ADVERSE EVENTS	26
STUDY CLOSURE	28
NONCOMPLIANCE/COMPLAINTS	28
REFERENCES	30

PRINCIPLES

Research conducted by the Public Health Division (PHD) and the Multnomah County Health Department (MCHD) is guided by codes of ethical principles developed by the scientific community over the last 60 years. One of the earliest, the Nuremberg Code, resulted from a large-scale outbreak of World War II criminal medical experiments on non-German nationals. This code laid out basic principles regarding voluntary consent, the avoidance of unnecessary physical and mental suffering and injury, degree of risk, necessary protections, and vetted qualifications of the investigator. The Nuremberg Code served as the prototype of many later codes and intended to ensure that research involving human subjects would be carried out in an ethical manner. Of particular importance to social science research is the Belmont Report¹ published in April 1979, which lays down the following ethical principles for the protection of human subjects in research:

- 1) Respect for persons: Individuals should be treated as autonomous agents capable of self-determination and individuals with diminished autonomy are entitled to protection;
- 2) Beneficence: The complementary obligations not to harm individuals and to maximize possible benefits and minimize possible harms;
- 3) Justice: The selection of research subjects needs to be scrutinized in order to determine whether some classes are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Furthermore, when the development of therapeutic devices and procedures are involved, the demand that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

The ethical principles from the Nuremberg Code and the Belmont Report were codified in federal regulations in 1981 and amended in 1991 in Title 45, Part 46, of the Code of Federal Regulations (45 CFR 46)². These regulations require peer review for all federally funded research involving human subjects. In addition, they spell out the composition of the review committee and the kind of research that is exempt from review.

PURPOSE

The Public Health Division/Multnomah County Health Department Institutional Review Board (PH IRB) is an administrative body composed of both scientists and non-scientists established to review research studies and ensure that the rights and wellbeing of people who are subjects in research are adequately protected. The PH IRB shall comply with the applicable requirements of 45 CFR 46 and determine whether the criteria set out in 45 CFR §46.111 have been satisfied.

1 See Reference Section for link to complete text

2 See Reference Section for link to Regulation

AUTHORITY

The Public Health Division and Multnomah County Health Department are committed to the concept of ethical research and subsequently review all research involving human subjects, regardless of funding source. The Intergovernmental Agreement #126110 was put in place between the PHD and the MCHD for the purpose of delineating the responsibilities of the PH IRB in reviewing research activities for the MCHD. Both agencies have a Federalwide Assurance³ (FWA) in place with the Office of Human Research Protections (OHRP): PHD FWA #00000520 and MCHD FWA #00004186. Under the terms of these assurances, no human subjects' research may be initiated prior to PH IRB approval. These FWA's designate the OHRP registered PH/MCHD IRB (IRB Registration #00001099) as their IRB which is structured and functioning in accordance with 45 CFR 46.

Human subjects research involving PHD/MCHD employees, data, or sponsorship cannot be conducted without prior approval from the PH IRB. Research projects that involve participation from other institutions must also be approved by that institution's Human Subjects Review Board and documentation of that Board's review and approval must be submitted to the PH IRB.

It is important to note that, the PH IRB is ultimately overseen by the Oregon Public Health Director. While not generally involved, if the PH IRB receives a questionable or controversial protocol or, if research misconduct is at issue, and a final decision maker is needed, then the Director will make the final decision. Since the PH IRB is not charged with making final decisions and is not advising a "public body", the Oregon Public Meetings Law does not apply. (See "The Oregon Department of Justice, Attorney General's 2014 Public Records and Meetings Manual", Section II.B.1.) Consequently, all meeting and study protocol documentation is maintained on a secure member only webpage and will not be made public.

In accordance with 45 CFR §46.109 and 45 CFR §46.113, the PH IRB has the responsibility to review, approve, disapprove or require changes in research projects involving human subjects and the authority to suspend or terminate the approval at a later time in order to protect the subjects' rights. PH IRB review is required for all research with human subjects if any one or more of the following applies:

- The research is sponsored by the PHD or MCHD;
- The research is conducted by or under the direction of an employee or agent of PHD or MCHD in connection with his/her agency responsibilities, or using any property or facility of PHD or MCHD;
- The research involves the use of PHD or MCHD's data;
- The research involves the use of PHD or MCHD's non-public information to identify or contact human research subjects or prospective subjects;
- Funding for the research will be handled through PHD or MCHD, but the research will be done at another location.

³ See Reference Section for link to OHRP FWA Database

The above criteria do not always encompass studies that the PH IRB is asked to review and as the sole IRB for The Division, it must limit the scope of its activities in order to improve efficiency and prioritize the allocation of its limited resources. The Board includes members from The Public Health Division staff, Multnomah County Health Department staff, and select external volunteers with expertise in epidemiologic research, public health interventions, and social and behavioral science (see membership section below). The Board does not have expertise in clinical research or medical interventions. On occasion, researchers may request that the PH IRB review clinical trials or other medical interventions. These are outside the scope of expertise of the IRB members, and thus, need to be reviewed by an IRB with knowledge of the issues related to these types of studies. In other instances, researchers external to governmental public health may request the PH IRB to review their proposed research related to public health interventions. Because of limited resources (and no ability to charge a fee for these services), the PH IRB is unable to review these studies, and these researchers should seek out an external IRB for review.

Research projects already approved by the PH IRB, may be subject to further review and approval by officials of each institution involved. However, 45 CFR §46.112 prohibits institutional officials from approving a research project that has not first been approved by the PH IRB.

RELATIONSHIPS

The responsibility of ensuring accountability and compliance for research is a shared relationship. The Principal Investigator, research team, PH IRB, and institutional officials hold the responsibility for ensuring respect, trust and support in the review process. All parties are entrusted with the responsibility of protecting the rights and welfare of human research participants by ensuring compliance with the federal regulations during the PH IRB review. The PHD and MCHD are committed to creating an institutional culture that honors and demonstrates this trust and respect.

Administration

The PHD Health Officer & State Epidemiologist in consultation with the Multnomah County Health Officer appoints members of the PH IRB. Selection of members is representative of public and preventive health programs in state and local government as well as higher education, private community health programs and the public. The PH IRB Coordinator reports to the PHD Health Officer & State Epidemiologist and manages the institutional review and approval process for all proposed research activities.

Other Human Subject Review Committees

The PH IRB functions independently of other review committees. However, when protocols engage more than one institution, the Boards may elect to cede oversight to one another on a case-by-case basis as identified in their FWA. The PH IRB may cede oversight to another Board and request annual updates or accept the oversight for another institution. In these instances, authorization agreements between the IRBs will be established and will be available for review by OHRP upon request.

Principal Investigator

A Principal Investigator is the person designated as the individual responsible for the

administrative and programmatic aspects of the proposed project. Although there are no specific degree requirements, the Principal Investigator must be appropriately vetted for technical competence and substantive capabilities (scientific, administrative, and otherwise) to carry out a project.

Institutional IRB Official

The Institutional IRB Official for the PHD is the Health Officer & State Epidemiologist. The Institutional IRB Official for the MCHD is the Health Department Director. These Officials are authorized to act for the institutions and assume overall responsibility for compliance with the federal regulations for the protection of human subjects.

Federal Regulatory Agencies

The Office of Research Integrity (ORI): Reports on possible research misconduct are filed annually with this U.S. Department of Health & Human Services (DHHS) office. It accepts jurisdiction over matters relating to possible fabrication, falsification, or plagiarism in research funded by the Public Health Service (PHS).

OHRP/National Institutes of Health (NIH)/U.S. Food and Drug Administration (FDA): Breaches in scientific integrity, any actions related to adverse events, or any terminations of research by the PH IRB may be reported as they occur. Advice and counsel are sought from the OHRP, NIH, and/or the FDA whenever issues of regulation or guidance require clarification. IRB registration and the Institutions' FWAs are renewed through the OHRP.

PH IRB MEMBERSHIP

The PH IRB consists of a Chair, Vice Chair, primary and alternate members representing public and preventive health agencies engaged in human subjects' research, and members of the community. A majority of PH IRB members must attend meetings, including the Chair or Vice Chair, to achieve a quorum capable of conducting official PH IRB business. A minimum of five members will serve on the Board at any given time. As noted earlier, the PHD Health Officer & State Epidemiologist in consultation with the Multnomah County Health Officer appoints members of the PH IRB. The duration of service is not time limited and the PH IRB Coordinator will check in with each member annually to determine their continued interest in serving on the Board. Members serve at the pleasure of the institutional official and may be relieved of his or her responsibilities for failure to perform PH IRB duties in an appropriate manner.

PH IRB members are selected in accordance with the guidelines established by OHRP and rules established by 45 CFR 46. Members are chosen with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. This includes membership diversity in relation to race, gender, cultural backgrounds, and sensitivity to such issues as community attitudes. There will be at least one member whose primary concern is scientific, at least one member whose primary concern is non-scientific, and one person is not affiliated with either the PHD or the MCHD. The PH IRB will also consist of representatives for prisoners and multicultural communities.

In addition to possessing the professional competence necessary to review scientific and human subjects' research activities, the PH IRB shall also be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable laws, and

standards of professional conduct and practice. The PH IRB will therefore include persons knowledgeable in these areas.

No PH IRB member may participate as a primary or secondary reviewer in the initial or continuing review of any project in which the member has a financial conflict of interest. While these members may be present at meetings to provide information requested by the PH IRB, the member with the conflicting financial interest must abstain from voting.

Individuals with competence in special areas may be invited to assist in the review of issues that require expertise beyond or in addition to that available on the PH IRB. These individuals provide consultation only and do not vote.

Alternate members may substitute for specific primary members during PH IRB meetings. These members must have similar expertise as the primary members for whom they may substitute.

PH IRB members will be assigned research projects to review in preparation for monthly Board meetings. Reviewers will be expected to review study information before the meeting including the Initial Review Questionnaire (IRQ) and/or the Continuing Review Questionnaire (CRQ), protocol, consent form, and other supporting material. If reviewers have specific questions regarding the research, attempts should be made to answer the questions prior to the Board meeting by having the IRB Coordinator speak directly with the Principal Investigator.

MANAGEMENT OF THE IRB

The PH IRB is a part of the Science and Evaluation Unit of the Office of the State Public Health Director and is situated in Suite 930 of the Portland State Office Building located at 800 NE Oregon Street, Portland, Oregon. The PH IRB meets on a monthly basis, the second Friday of every month from 8:30 - 11:00 a.m. Research proposals must be submitted by the application deadline to be considered for Full Board review.⁴ The PH IRB Coordinator shall provide coordination and support services for all PH IRB activities, supporting the Chair, Board, and all investigators and research teams who send research proposals to the PH IRB. All research material will be posted to the secure Public Health IRB Member GovSpace page approximately two weeks prior to the scheduled Board meeting. The PH IRB GovSpace page is secure and may only be accessed by users who have been granted access by the PH IRB Coordinator whom serves as the owner of the page.

The PH IRB Coordinator will maintain records and files of all applications, review activities, meeting proceedings and decisions. PH IRB records will be retained no longer than 10 years after a study is considered closed from further review.

Selecting Chairperson/Vice Chair

All members who have served at least one year on the PH IRB or have a minimum of one year of previous experience working with an IRB or human subjects' research protection regulations are eligible to be Chairperson. The PHD Health Officer & State Epidemiologist and the MCHD Health Officer shall jointly appoint the Chairperson and Vice Chair. These individuals should be highly competent and fully capable of managing the PH IRB and matters brought before it with

⁴ See Reference Section for list of meeting dates and application deadlines

fairness and impartiality. With the mutual consent of the institutional officials, the duration of service of the Chairperson and Vice Chair is not time limited. As with the PH IRB members, the IRB Coordinator will check in with them annually to determine their continued interest in fulfilling these roles.

The responsibilities of the Chairperson and Vice Chair include:

- Play a leadership role in establishing and implementing PH IRB policy;
- Represent the PH IRB in discussions with other organizations and federal authorities;
- Direct the proceedings and discussion of the monthly Board meetings;
- Vote on all protocols reviewed at full committee meetings;
- Understand ethical issues, state law, institutional policy, and federal regulations that are applicable to studies reviewed by the PH IRB;
- Review and sign (or authorize for signature) PH IRB response letters to investigators; and
- In collaboration with the PH IRB Coordinator, promptly review and make decisions regarding submitted research proposals and the investigators' response to Board conditions.

The Chairperson and Vice Chair serve at the pleasure of the institutional officials and may be relieved of their responsibilities for failure to perform the duties in an appropriate manner.

Training of IRB Chair and Members

The PH IRB Coordinator will provide orientation. The institutional policy manual will be provided to each new member. This manual will include sample forms, policies and procedures, and federal regulations. The PH IRB Chair will receive a copy of the IRB Guidebook, "Protecting Human Research Subjects," published by the OHRP.

It is strongly recommended that the Institutional Official's complete Module 1 of the OHRP, "Human Subject Assurance Training". The Human Protections Administrator and the IRB Chair should complete all three modules. This training is located at:

- <https://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>

In addition, the NIH Office of Extramural Research computer based training, "Protecting Human Research Participants," and the CITI human subjects research training "IRB Members" are strongly recommended. These online trainings are located at:

- <https://phrp.nihtraining.com/users/login.php>, and
- <http://www.citiprogram.org> (specific Oregon PHD login instructions can be obtained through the PH IRB Coordinator).

The PH IRB Chair and Coordinator will be encouraged to attend national conferences from which they will provide summary information to PH IRB members. The PH IRB Coordinator will maintain a library of reference material, including videotapes, conference materials and books for use by PH IRB Board members, researchers and their staff.

Compensation

PH IRB members serve as volunteers and are not compensated for their service to the PH IRB.

Duties of the PH IRB Coordinator

- Create and maintain PH IRB policy's, updating and revising as necessary;
- Interpret and apply state laws, federal regulations, institutional policies and guidelines to protect human subjects and to ensure institutional compliance;
- Provide direction to the research team regarding the PH IRB review process including the steps that must be taken prior to submission;
- Provide regulatory and ethical advice to individual research staff in preparation of applications for research proposals involving human subjects and consent documents;
- Provide assistance to both PHD and MCHD program staff in regards to the PH IRB process, including assistance in the development of any required data use agreements being created specifically for research purposes;
- Serve as the Coordinator for the Science and Epidemiology Council which may review projects referred to their "Project Review Team" (PRT) by Center PRT Representatives prior to submission to the PH IRB in order to determine whether the projects involve research or public health practice;
- Ensure research protocols internal to either the PHD or MCHD list a Supervisory Manager as key personnel, effectively designating them as the responsible party overseeing the conduct of the study;
- Ensure research protocols external to the PHD and MCHD have a designated PHD or MCHD "Sponsor" whom completes a scientific merit review of the proposed study prior to its submission;
- Extensively screen new and renewal applications along with any administrative and procedural modification requests;
- Contact and advise investigators in preparation, revision, and completion of these application processes including revisions that must be made to study documentation and conditions that must be met prior to any recommendation being made to the Board or Chair;
- Recommend actions to the PH IRB Chair or Vice Chair including proposal for research to be reviewed by the Full Board, go through an expedited review, be granted conditional approval or full approval, be disapproved, terminated, or closed, or be found exempt from review;
- Prepare meeting agendas and study documentation: assign applications to committee members and prepare material for distribution;
- Be timely in communications regarding protocol reviews with both the Board and research team;
- Keep appropriate programs, data owners and managers informed about the progress of research applications in relation to their data requests from the investigators;

- Prepare correspondence that conveys PH IRB deliberations and contingencies for approval of research activities involving human subjects;
- Review submitted adverse events, ensure prompt reporting to OHRP or FDA if legally required and confirm proper steps have been taken so such events are prevented in the future;
- Create the internal⁵ and external data request process⁶ for those data requests made for research and update as necessary;
- Maintain annual renewal system, prepare and mail reminders and forms and obtain annual financial conflict of interest disclosure forms;
- Prepare final meeting reports and maintain records for all studies;
- Assist in the development and presentation of materials and training programs for staff and Board members on the ethical conduct of research involving human subjects and maintain records and logs of training completion dates for both internal and external research staff;
- Provide information to research subjects on their rights;
- Send monthly expedited review reports to the Board; and
- Maintain active registration of the PH IRB and both FWA's.

Resources

Sufficient resources will be made available for the administrative oversight of the PH IRB as well as to its Board members. This includes, but is not limited to, providing an adequate number of staff with appropriate workspace and equipment, meeting room space, education and training opportunities, and reference material.

CONFLICT OF INTEREST

The PHD has established a Financial Conflict of Interest Policy⁷ in accordance with 42 CFR 50 Subpart F, the purpose of which is to promote the objectivity in research by establishing standards that preserve the integrity of research, protect the rights and safety of research subjects, and prevent bias in the design, conduct, and reporting of research funded under PHS grants or cooperative agreements.

Any PHD employee that serves as an investigator or key personnel and who is planning to participate in PHS-funded research must disclose to the institution any significant financial interest (and those of the investigator's or key personnel's spouse and dependent children) through the submission of an annual disclosure statement.

The PHD Financial Conflict of Interest Officer (FCIO) in collaboration with other institutional officials shall review disclosures to determine whether an investigator has a financial conflict of interest related to PHS-funded research. The FCIO will determine what actions are necessary to manage the conflict. Such measures will be reported to the PH IRB. If the actions required to manage the conflict result in revisions to the research protocol or disclosing information to a

⁵ See Reference Section for Internal Data Request Process Map

⁶ See Reference Section for External Data Request Process Map

⁷ See Reference Section for link to Policy

research subject, investigators must submit revised material to the PH IRB for review and approval.

Federal regulations do not allow an IRB member to participate in the initial or continuing review of any project in which the IRB member has a conflicting interest. Such members will not participate in the review except to provide information requested by the PH IRB. These members must abstain from any vote with respect to such a project.

FUNCTIONS OF THE PH IRB

All research involving human subjects, unless exempt under one of the specific criteria set forth in 45 CFR 46, must be reviewed by the PH IRB for compliance with federal regulations. Research that is submitted to the PH IRB by an investigator requesting an exemption will be reviewed carefully by the PH IRB Coordinator and Chair to determine if the research qualifies as such.

In order to approve research, the PH IRB must ensure that the following requirements are satisfied:

- Risks to human subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits to subjects, if any, and the importance of knowledge that may reasonably be expected to result;
- Selection of subjects is equitable;
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative;
- The informed consent is adequate and appropriately documented;
- When appropriate, adequate provision is made for monitoring the data collected and the data collection process to ensure the safety of the subjects;
- When appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data; and
- When subjects are likely to be vulnerable to coercion or undue influence and/or are defined in 45 CFR 46, subparts B, C, or D as a vulnerable population, appropriate safeguards have been included in the study to protect the rights and welfare of the subjects.

After initial review, the PH IRB will determine whether an approved study must be reviewed more often than annually and investigators will be notified. At the time of continuing review, investigators will be required to verify that no changes have occurred to the study (without prior PH IRB approval) since the previous PH IRB review. Investigators are allowed to submit changes for approval at the same time as their submission for continuing review, if the timing of both coincides.

Prompt reporting of any changes to the research study or design, must be reported and approved by the PH IRB, including changes in study personnel. Failure to report changes will be classified as a protocol violation and the research study will be suspended until the Board has reviewed and

approved the changes. Changes may only be initiated without PH IRB review and approval when necessary to eliminate immediate hazards to the human subjects.

Investigators are required to promptly report any adverse events or unanticipated problems involving risks to subjects. These events, along with any serious or continuing noncompliance with federal regulations, requirements, or determinations of the PH IRB; and any suspension or termination of other IRB approvals will be promptly documented by the PH IRB and appropriate notification will be sent to institutional officials and federal agencies.

It is the investigator's responsibility to ensure that PH IRB approval does not lapse during the course of the research study, however the IRB Coordinator will send out reminders approximately six weeks ahead of the expiration. Protocols will be reviewed no less than annually. The continuation of research after a protocol's PH IRB approval has lapsed is a violation of both institutional policy and federal regulations. When PH IRB approval expires, a formal notice of expiration will be sent explaining that the continuing review paperwork is now due within two weeks' time. It will be explained that OHRP does not consider expiration to be a suspension or termination of PH IRB approval, however, approval must be sought as soon as possible in order to continue the research. If the study is active and open to enrollment, all research activities must cease. No new subjects may be enrolled in the study, data cannot be collected from those who have already consented, and analysis of identifiable data, documents, or specimen should be halted. If the study is active but closed to enrollment, data analysis may continue, however, it is asked that any long-term follow up of those enrolled subjects be brought to a stand-still. If the paperwork is not received by the given date, reviews will be shortened to every six months.

When paperwork is not received within six weeks of the formal notice of expiration, the study will be officially terminated. If PH IRB approval of a research study is terminated, all research activities must end. Subjects currently participating in the study and/or the PHD and MCHD Programs and Data Owners will be notified that the study has been terminated and all data collection and transfers must cease. Procedures for withdrawal of enrolled subjects must consider the rights and welfare of the subjects. If follow-up of subjects is required by the PH IRB, current participating subjects will be informed, and any adverse events or unanticipated problems will be reported to the PH IRB and to the sponsor.

OPERATION OF THE PH IRB

Meetings

The PH IRB meets on the second Friday of every month from 8:30 - 11:00 a.m. Meetings are held in Suite 918 of the Portland State Office Building located at 800 NE Oregon Street, Portland, Oregon. These meetings are designed to discuss previous meeting minutes, protocol deviations, adverse events, substantive revisions to previously approved research that are likely to increase risk to subjects or significantly affect the nature of the study, and medium-to-high risk protocols needing either an initial or continuing review. The PH IRB Coordinator will develop the Board meeting agenda and material for review. All documentation will be posted to the PH IRB Member secure GovSpace page approximately two weeks prior to the scheduled Board meeting.

Review Process

Materials for review must be submitted approximately six weeks prior to the meeting date to allow for processing and timely distribution to Board members. In order to facilitate the review process, the material is extensively screened by the PH IRB Coordinator to determine whether the research can be classified as Exempt⁸, meets an Expedited Review⁹ category, or shall be referred for Full Board Review. Continuing Reviews¹⁰ will be conducted no less than annually and must be preceded by receipt of appropriate progress reports from the investigator, including available study-wide findings. In addition, careful attention will be paid to distinguishing public health practice from public health research. To assist in this effort, the PH IRB has adopted the following guidelines:

- “Defining Public Health Research and Public Health Non-Research” established and revised by CDC in July, 2010¹¹; and
- “Public Health Practice vs. Research: A Report for Public Health Practitioners Including Cases and Guidance for Making Distinctions,” published by the Council of State and Territorial Epidemiologists on May 24, 2004.¹²

During the pre-screening of an application, every attempt will be made by the PH IRB Coordinator to ensure the application’s documentation is complete, consistent, and compliant with both state laws and federal rules and regulations. This preliminary review should help investigators focus on problem areas in the research protocol, design, and supplemental documentation. Studies that do not qualify as exempt, or do not fall under an expedited review category, will be reviewed by the full IRB at a regularly scheduled meeting.

Studies internal to the PHD or MCHD must list a Supervisory Manager as key personnel on their Initial Review Questionnaire¹³, effectively designating them as the responsible party overseeing the conduct of the of the study throughout its duration. Studies external to the PHD and MCHD must have a designated PHD or MCHD “Sponsor”. This sponsor does not need to be working on the actual investigation; rather, their sponsorship acknowledges their familiarity with the project including their ability to vouch for its scientific and research merit and integrity. The “Sponsor” will be required to fill out the “Scientific Merit Pre-IRB Review Tool” which is located in the “OHA Public Health Division Pre-IRB Review Process for External Projects” document¹⁴ and provide their signature of approval on the Initial Review Questionnaire. In special cases, sponsorship may be adequately covered by the review of a PHD/MCHD Program specific Advisory Committee or Review Group. In these cases, the PH IRB Coordinator will request documentation of the Program’s review including minutes, correspondence to the investigator, and the official resulting determination.

⁸ See Reference Section for Exempt Categories

⁹ See Reference Section for Expedited Review Categories

¹⁰ See Reference Section for Continuing Review Questionnaire

¹¹ See Reference Section for Policy

¹² See Reference Section for link to Report

¹³ See Reference Section for form

¹⁴ See Reference Section for document

Exemptions

Research applications that are submitted by an investigator claiming an exemption under 45 CFR §46.101, will be reviewed by the PH IRB Coordinator who will make recommendations to the Chair or Vice Chair for final determination regarding exempt status. If applicable, the researcher will receive a memo stating that the research is exempt and to notify the PH IRB if changes are made in the study design.

If an investigator decides to modify a research application that has already been deemed exempt, they must submit a modification request in case the requested amendment changes the study in such a manner that it is no longer exempt and requires review. If the PH IRB is not notified of any revision requests for three years from the original exempt determination, the IRB Coordinator will contact the investigator to check the status of the study. If no changes have occurred in those three years, per 45 CFR §46.115, the PH IRB will no longer track the study nor keep record of it and will send all study documentation to State Archives.

Expedited Review

The PH IRB Coordinator may conduct an initial or continuing review of a research protocol that appears to fall under an expedited review category. Due to time constraints, if needed, the Coordinator may assign the review of such a protocol to one or more Board members, with the permission of the PH IRB Chair. Members shall use the Expedited Review Form and submit to the PH IRB Coordinator upon completion. The IRB Coordinator will forward their own, or that of the assigned Board members', recommendation to the Chair. This recommendation will include a summary of the general purpose of the study, its specific aims, the scientific design and merit, and its ultimate goal. The summary will outline the procedures to be followed including the recruitment of subjects and protection of their data. Risks and benefits, costs and compensation, informed consent or assent and possible authorization, will all be explained in great detail.

The IRB Coordinator will request proof of human subjects' research training and copies of all the key personnel CV's in order to further vet the teams' qualifications. If federally funded, all key personnel who are employed by the Public Health Division or are completing a substantive portion of the project as subcontractors and are therefore accountable to the PHD for its outcomes and compliance matters, will be asked to disclose any financial conflicts of interest on an annual basis by completing the Public Health Division's Financial Conflict of Interest Disclosure Statement¹⁵. If neither of the former apply and the researchers are all from an outside institution, the P.I. must provide evidence that the institution is in compliance with 42 CFR 50, Subpart F and that appropriate disclosures have been made.

The Coordinator will summarize a recommendation for approval or otherwise and draft a formal decision memo to send to the Chair or Vice Chair. Investigators will be notified by both electronic and paper mail that the study was reviewed and approved under an expedited review category, if applicable. Minor changes to previously approved research during the period for which approval is granted may also be approved using expedited review; however, completion of the Expedited Review Form will not be necessary in these instances. Board members will be kept advised of all research protocols and project revisions approved through an expedited review process on a monthly basis via electronic mail.

¹⁵ See Reference Section for form

Full Board Review

The Full Board review process shall be carried out at least every 12 months for each research activity that does not meet expedited review criteria or is not exempt from review, meaning it presents medium to high risk. Convened meetings will be held in which a majority of the members of the PH IRB are present, including one member whose primary concerns are non-scientific. Approval by a majority of those members present represents approval from the PH IRB. The Board shall consider the following factors in reviewing a research application:

- **SIGNIFICANCE:** Study objectives must be clearly specified and if there is preliminary data to justify the research, the Board must be made aware. The Board must feel confident that the scientific merit of a proposal justifies its risk to benefit ratio.
- **BENEFITS/RISKS:** The Board will review the potential risks, discomforts, hazards, and inconvenience of participation in research protocols. Probability, magnitude, and duration of the risks involved will all be addressed. Precautions that are being taken to avoid or minimize the potential risks will also be examined. Direct benefits expected for the subjects involved as well as the community at large must be explained. It is important for the Board to have a strong understanding of the risk to benefit ratio in order to determine its acceptability.
- **EQUITABLE SELECTION OF SUBJECTS:** The PH IRB will take into account the purpose of the research, the setting in which the research will be conducted, and whether subjects selected to participate are members of the population most likely to benefit from the research. The Board will ensure appropriate inclusion and exclusion criteria are in place in order to justify the human subject's research ethically. Poorly specified criteria may result in inadvertent exclusion of eligible research subjects and an imbalanced or inappropriate enrollment of research subjects. Women and members of minority groups should be included in all research projects involving human subjects, unless a clear and compelling reason exists that inclusion of such subjects is inappropriate with respect to the health of the subjects or the purpose of the research. The PH IRB will be particularly cognizant of the special problems that may arise in research involving vulnerable populations, such as children, prisoners, pregnant women, cognitively impaired persons, and economically or educationally disadvantaged persons. When some or all of the subjects are likely to be vulnerable to coercion or undue influence, the Board will require additional safeguards be included in the study to protect their rights and welfare. All federal regulations defined in 45 CFR part 46, subparts B, C, and D will be followed when research includes the targeted inclusion of any of these vulnerable populations. The PH IRB Coordinator will assist the researchers in deciphering whether any of these populations are targeted and/or incidentally included. Due to the extensive and lengthy review required for inclusion of prisoners in research, it is important that the PH IRB communicates that this extra federally mandated protection is not intended for individuals who have ever served time in prison over their lifetime. The protection is in place, rather, for any subject that is a prisoner directly involved in the research during their incarceration or their records are being noted as that of a prisoner.
- **COMPENSATION/COSTS:** Compensation or reimbursement offered must be reasonable and non-coercive. Adequate provisions must be in place to avoid out-of-pocket expenses and costs by the research subject if insurance denies payment.
- **VOLUNTARY AND INFORMED CONSENT:** All subjects, adults or children, must be fully informed in advance of the degree of risk involved in their participation and, insofar as

possible, given an explanation of the nature and consequences of the proposed research. Methods of securing cooperation of subjects should be specified in advance as clearly as possible. No coercion may be used to obtain or maintain cooperation. Adult subjects or their legally authorized representative must express consent to participate in writing. If the subject is under the age of 18, informed consent must be obtained in writing from the subject's parent or legal guardian. Subjects over seven years of age must give their assent. All subjects, adults and children alike, must be assured that they may choose to withdraw from the research at any time without penalty. Request for a waiver of consent or its documentation may be considered by the PH IRB in accordance with 45 CFR 46.

- **PROCEDURES:** The Board will be well informed on the timing and setting of the study along with the qualifications of those conducting the research. Consistency among study documentation will be examined thoroughly to ensure uniformity of all written procedures regarding informed consent, protection of subjects, confidentiality of data, and written results. The Board is required to evaluate whether the study procedures are consistent with sound research design that minimizes risks to the subjects.
- **ANALYSIS:** Protocols must contain well-conceived, well-formulated, and appropriate plans for interpretation of data and statistical analyses.
- **CONFIDENTIALITY AND PRIVACY:** All information gathered on subjects or provided by them via questionnaires, tests, and interviews must be kept confidential. Adequate provisions must be present to protect the privacy of subjects and to maintain the confidentiality of their data. Published accounts of such data must not reveal the identity of the subject.
- **RESEARCH DESIGN:** The Board may return to the applicant proposals involving human subjects that it feels are unlikely, through faulty design, to yield accurate and scientifically meaningful data.
- **CODES AND STANDARDS:** In their review process, the Board will consider the degree to which proposed research conforms to the prevailing social codes and moral standards of the community or cultural group involved.

Each project requiring Full Board Review is extensively screened and vetted by the IRB Coordinator prior to the study documentation being posted on the PH IRB Member GovSpace page. Projects include both initial proposals and continuing reviews. The Coordinator will assign further review to two members of the PH IRB identified as the primary and secondary reviewers. The two designated reviewers are responsible for reviewing protocols assigned to them and sending questions for clarification or revision requests to the research team through the PH IRB Coordinator, prior to the Full Board review. Primary and secondary reviewers are asked to use the Reviewer Summary form(s) and should be prepared to present the following information during the Board meeting:

- Purpose;
- Specific Aims and Ultimate Goal;
- Scientific Merit;
- Study Design;

- Subject Characteristics;
- Vulnerable Populations;
- Risks/Benefits;
- Costs/Compensation;
- Consent/Assent Process;
- Requested Waivers;
- Privacy/PHI Confidentiality;
- Data Use, Transfer, and Protection;
- Genetic/Tissue Banking;
- Retention/Destruction of Data;
- Miscellaneous issues; and
- Recommendation.

All Board members will receive the following documents to prepare for the Board meeting:

- Initial Review Questionnaire (IRQ), Continuing Review Questionnaire (CRQ); or Project Revision/Amendment Form (PRAF)
- Complete protocol;
- Copy of grant application, if federally supported;
- Recruitment flyer(s);
- Information letters to participants including follow-up;
- Consent and Authorization form(s);
- Scripts, including screening and follow-up (both oral and written);
- Questionnaire, survey, and/or interview instrument(s);
- Information management or flow chart, if indicated;
- Drug brochure for IND studies;
- Medical chart review forms, if applicable;
- Other IRB's correspondence, if applicable; and
- Personnel CV's and proof of HSR training.

If Spanish-speaking subjects will be included, translated documents will be requested. The Principal Investigator(s), Study Coordinator, and any other study personnel are encouraged to attend the meeting and participate in the discussion. Prior to the Board vote however, the research team will be asked to exit the room. Certification of PH IRB review and approval, or otherwise, will be forwarded through the PH IRB Coordinator to the research investigator and

institutional officials. It is the investigators responsibility to send appropriate material to federal departments for research sponsored by such institutions.

Continuing Reviews

Continuing reviews are a way to monitor and ensure that continuing safeguards are in place to protect the rights and welfare of study participants. Intermittent review of findings will allow the Board to determine if the benefits and risks associated with the research have changed. Therefore, continuing review of research must be substantive and meaningful.

In the case of continuing reviews requiring a Full Board review, Board members will receive a status report on the progress of the research during a regularly scheduled Board meeting, including:

- Number of subjects enrolled, withdrawn, and whom remain in follow-up;
- Breakdown of subjects race, ethnicity, gender, and sex, if known;
- Summary of adverse events and any unanticipated problems involving risks to subjects or others and any complaints about the research since the last review;
- Summary of any relevant literature, interim findings, and amendments or modifications to the research since the last review;
- Any relevant multi-center trial reports;
- Any other relevant information, especially information about risks associated with the research; and
- A copy of the current informed consent document and any newly proposed changes.

Board members will also receive all material previously reviewed in addition to any changes. In the case of extremely large projects, the primary and secondary reviewers will receive complete file documentation, while other Board members will receive the CRQ, previously approved IRQ, protocol, consent and if applicable, questionnaire.

Findings by Full Board

Projects screened by the Full IRB may be classified as approved, approved with conditions, deferred, disapproved, or not human subjects research:

- **APPROVED:** Researcher will receive a memo stating the project is approved for a specified amount of time however, the Principal Investigator is required to notify the PH IRB of any changes to the research protocol and applicable documents prior to implementation. The date of the Board meeting at which the protocol was considered and judged to be acceptable without changes is the date of approval. In the memo, researchers will be notified of whether their study will need to be reviewed by the Full Board again the following year or if it was determined that all future reviews may be expedited.
- **APPROVED WITH CONDITIONS:** Researcher will receive a memo stating that the project has been approved subject to a number of conditions. The memo will outline additional information and/or documentation that is needed, revision requests to current paperwork, and the timeline in which these conditions must be met. Conditional approval does not mean

approved; it means that the PH IRB believes it is possible that the study may be approved upon completion of the conditional items. Conditional issues responded to by investigators will be reviewed by the PH IRB Coordinator and recommendations for further changes may be identified. The PH IRB Coordinator may seek additional review by the primary and secondary reviewers. Upon determination that the investigator has complied with conditions, the PH IRB Coordinator will recommend approval to the PH IRB Chair for concurrence. A final IRB approval letter will be sent to the investigator and at that time, the study may begin. The approval date is the date of the original IRB meeting at which the “minor revisions required” determination was made, even in the event that it may take several months to receive the revisions from the investigators.

- **DEFERRAL:** Researcher will receive a memo stating that the Board does not believe the research team fulfilled the requested conditions sent by the IRB Coordinator prior to the scheduled meeting. This will include a list of conditions that must be met and documentation that must be received by a designated deadline to ensure a Full Board review can take place during the next scheduled meeting.
- **DISAPPROVED:** Researcher will receive written notification of disapproved status. This communication will include statements about problems identified in forms or procedures and what corrective actions, if any, are needed. Investigators may not enroll any subjects for a study that has been disapproved by the PH IRB.
- **NOT HUMAN SUBJECTS RESEARCH:** If the Chair, Vice Chair, or the Board determine the protocol submitted is not human subjects research, investigators will be notified by a memo noting that if any changes occur to the study design, it should be brought forward for reconsideration.

Informed Consent

In accordance with 45 CFR 46, the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent or waive the requirement to obtain informed consent altogether. The PH IRB must find and document that:

- The research involves no more than minimal risk;
- The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- The research could not practicably be carried out without the waiver or alteration; and
- Whenever appropriate the subjects will be provided with additional pertinent information after participation.

Nothing in this policy regarding consent is intended to limit the authority of a physician to provide emergency medical care, to the extent the physician is permitted to do so under applicable federal, state or local law.

The PH IRB may waive the requirement for the documentation of consent if it finds that:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;
- The research presents no more than minimal risk;

- The research involves no procedure for which written consent is normally required outside of the research context; and
- The research could not practicably be carried out without the waiver or alteration.

HIPAA

With the passage of the Health Insurance Portability and Accountability Act's (HIPAA) Privacy Rule, subjects must authorize a covered entity to use and/or disclose their protected health information (PHI). The Privacy Rule does not apply to all research, it only applies to covered entities, which researchers may or may not be. To gain access for research purposes to PHI created or maintained by covered entities, the researcher may have to provide supporting documentation on which the covered entity may rely in meeting the requirements, conditions, and limitations of the Privacy Rule. The OHA is a hybrid entity meaning it is a covered entity but performs business activities that include both covered and non-covered functions, and it designates its health care components as provided in the Privacy Rule. Effective July 1, 2011 The Authority designated specific divisions or programs of The Authority as health care components and part of the covered entity portion of the agency based on specific criteria. The following divisions or programs were designated as health care components and part of the covered entity because each division or program could meet the definition of a covered entity in the HIPAA Privacy Rule if the division or program were its own separate legal entity:

- The Authority in its capacity as the state Medicaid agency for the administration of the Medicaid program under Title XIX of the Social Security Act;
- The Children's Health Insurance Program under Title XXI of the Social Security Act;
- The medical assistance program as described in ORS Chapter 414;
- The high-risk pools administered by the Oregon Medical Insurance Pool Board and the Office of Private Health Partnerships;
- The Family Health Insurance Assistance Program established in ORS Chapter 414;
- The Health Care for All Oregon Children Program (also known as the Healthy Kids program);
- The Breast and Cervical Cancer Program;
- The Wise Woman Program;
- The Oregon State Hospital;
- Blue Mountain Recovery Center;
- The Public Health laboratory;
- The Authority's Privacy Officer; and
- Staff associated with responding to complaints about potential HIPAA compliance issues.

Effective April 1, 2014, to comply with changes made effective by the HIPAA Omnibus Rule, The Authority designated the following additional divisions or programs as part of the health care component of the covered entity portion because they perform business associate functions

on behalf of the covered entity component of OHA:

- The Office of Health Analytics;
- The CCare Program;
- The Babies First Program;
- The Oregon Transitional Reinsurance Pool administered by the Oregon Medical Insurance Pool Board; and
- CaCoon and the FamilyNet ORCHIDS data collection and reporting system.

For purposes of the PH IRB, if a covered entity is in any way involved in the research, either by requesting or disclosing PHI, HIPAA's Privacy Rule will be applied.

Appeal of PH IRB Decision

If an investigator chooses to appeal a PH IRB decision, he or she must send a written statement with the reasons for appeal to the PH IRB Chair. Copies of the statement will be distributed to all Board members and the research project will be scheduled for re-review. After discussion of the project and the reason for appeal, the PH IRB will formally vote. A project may not be reconsidered after a subsequent disapproval unless significant changes are made.

PH IRB RECORD REQUIREMENTS

The PH IRB Coordinator is responsible for preparing and maintaining adequate documentation of PH IRB activities including:

- All research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved consent documents and survey instruments, and reports of injuries to subjects or breaches of protocol;
- Records of initial and continuing review and review of additions, revisions, and amendments to the protocol or consent forms;
- Progress reports submitted by investigators and statements of significant new findings provided to subjects, if applicable;
- Resulting publications or presentations;
- Agendas and minutes of PH IRB meetings which contain sufficient detail to show:
 - attendance at the meetings;
 - actions taken by the PH IRB and the vote on these actions including the number of members voting for, against, or abstaining;
 - the basis for requiring changes, deferring or disapproving research;
 - a summary of any discussion of controverted issues and their resolutions; and
 - the recommended frequency and type of continuing review.
- PH IRB roster; and

- All correspondence between the PH IRB and investigators, including e-mails and formal memos.

The records required by this policy shall be retained for ten years after the study is closed from further PH IRB review.

INFORMATION THE INVESTIGATOR PROVIDES

All investigators should carefully review the following requirements for submission of applications to the PH IRB. Submission of incomplete application packets will result in delay of the review and approval process. PH IRB protocols must reflect what is actually done in the research. Once the PH IRB has approved a protocol for a particular project, the investigator is bound to follow that procedure. If the investigator decides to change the protocol, he or she must receive approval from the PH IRB prior to initiating the change. Also, any problems involving risks or injuries to subjects as a result of the research must be reported immediately to the PH IRB.

Data Use Agreements

When PHD or MCHD data is requested for research, the PH IRB Coordinator will direct the investigator to first contact the Program to see if disclosure of the data is possible, and if so, what the program requires in order to agree upon its release. There is substantial paperwork required for PH IRB review and to be as efficient as possible, the IRB requires research teams to check with data owners first.

Requirements for data contracts are program specific. Some programs have a written policy requiring a formal program review of the proposal to determine whether or not the data can be disclosed for the purpose of the research and whether or not a data use agreement (DUA) should be in place. If a program requires DUAs for data disclosure, which is highly recommended (and required in the case of a limited data set in which the Privacy Rule applies), required HIPAA elements and statements must be included if a covered entity is involved. It is ultimately up to the PH or MCHD program to guarantee the DUA is appropriately written and signed by the requestor.

In special cases, the PH IRB will allow researchers to submit IRB paperwork prior to DUAs being put into place if several program's data are being sought for purposes of the research. It is understood that obtaining accurate DUAs from several different programs and/or entities is time consuming and therefore the IRB will review the research prior to each of them being confirmed. Researchers who request this be done must understand however, that obtaining PH IRB approval does not mean all programs will disclose data and the research, for that reason may not be plausible. The PH IRB will request a copy of all DUAs for the study's file and will copy relevant data owners on all subsequent correspondence regarding the status of the study.

Training Documentation and Resumes

In order to further assess their qualifications, all listed study personnel on PH IRB approved studies must complete required human subjects research training every three years and provide the PH IRB Coordinator with copies of their CV's. The PH IRB Coordinator has set up and

maintains PHD account with the University of Miami's Collaborative Institutional Training Initiative (CITI).

All PHD and MCHD staff serving as Principal Investigators or Co-P.I.s on any active study will be required to complete the "PH Principal Investigators & Co-P.I.s" Basic Course. The completion report will be sent to the PH IRB Coordinator and kept on file for three years. At that time the researchers will be asked to take the Refresher course. All PHD and MCHD staff serving as other key personnel will be required to complete the "PH Other Key Personnel" Basic Course and after three years, be asked to take the Refresher Course. Special exceptions will be made if study team members have already completed a certified human subject's research training with an external institution and they are able to provide the PH IRB with documentation of its completion. At the time of its expiration, the study members will be asked to complete the PH IRB specific CITI training.

All external researchers will be asked to provide documentation of their completion of human subject's research training from their own institution for PH IRB records.

Initial Review Questionnaire (IRO)

A detailed overview of the proposed research project, this questionnaire is required along with the protocol or grant application. Investigators must adequately document the provisions in place for protecting the rights and welfare of the research subjects as well as ensuring that all pertinent laws and regulations are followed.

Protocol/Grant Application

The study protocol is the formal document that establishes the conditions under which the research is to be conducted. The protocol should include the following information:

- Investigators and collaborators;
- Background and description including specific scientific aims and hypotheses;
- Description of preliminary studies results;
- Research methods and procedures;
- Statistical/analytical methods to be used;
- Adverse event reporting and monitoring including a description of the Data Safety Monitoring Board, if applicable (e.g. membership, frequency of reviews and reports, etc.);
- Security measures in place to protect the subjects' data and privacy;
- Approximate number of subjects involved and related study population information, including:
 - Inclusion and exclusion criteria;
 - Justification for the involvement of any special/vulnerable populations;
 - Potential risks and benefits associated with participation;
 - Alternatives, if any, available should the subject not participate;
 - Recruitment methods;

- Consent procedures (how is it obtained and how the process is structured);
 - Procedures for documenting informed consent and if applicable, assent;
 - Explanation for requests for waivers, if applicable; and
 - Compensation and/or costs to subjects for their participation.
- Flow Chart

HIPAA Questionnaire

With the passage of the HIPAA Privacy Rule, subjects must authorize the use or disclosure of their PHI. This federal regulation establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. The Privacy Rule also defines the means by which individuals will be informed of uses and disclosures of their medical information for research purposes, and their rights to access information about them held by covered entities. A valid Privacy Rule Authorization (Authorization) is an individual's signed permission that allows a covered entity to use or disclose the individual's PHI for the purposes, and to the recipient(s), as stated in the Authorization form. The Privacy Rule requires that this form pertain only to a specific research study, not to non-specific research or to future, unspecified projects. If an Authorization for research is obtained, the actual uses and disclosures made must be consistent with what is stated in the Authorization. The Authorization focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed. The IRB Coordinator will ensure all required core elements and required statements stipulated in the Privacy Rule are included in the form.

Under the Privacy Rule, covered entities are permitted to use and disclose protected health information for research without individual authorization under limited circumstances. These include:

- Waiver for minimal risk;
- The use or disclosure is solely to prepare a research protocol or for similar purposes preparatory to research;
- The use or disclosure being sought is solely for research on the protected health information of decedents and is necessary for the research;
- The information meets HIPAA's standards for de-identification; and
- The information is disclosed as a limited data set, and the covered entity obtains a DUA entered into by both the covered entity and the researcher.

In those cases in which a waiver of authorization is sought, the PH IRB asks for great detail regarding the data being requested and the protections being put in place. If a waiver is being sought, the relevant PH IRB HIPAA Questionnaire¹⁶ must be submitted.

Consent Form(s)

Unless the PH IRB has determined that a waiver of consent is applicable to a given study, federal regulations require that informed consent be sought from each potential subject or a legally

¹⁶ See Reference Section for link to forms

authorized representative of the subject. This must be documented through the use of a PH IRB date-stamp approved consent form. If the study has been reviewed and approved by more than one IRB, the PH IRB will allow only one IRB's date-stamp of approval to be present on the form, in order to avoid conflicting expiration dates.

The PH IRB Coordinator will review the document extensively to ensure all required elements along with required references to state laws, if applicable, are included and arranged appropriately throughout the form prior to the document being reviewed by the Board. The Board members' role in reviewing the proposed informed consent process is to ensure participants are informed about the voluntary nature of their consent to participate in the research. It must be guaranteed that the entire consent process takes place in such a manner that the research subjects' informed, voluntary decision to participate is not compromised and the document must communicate the necessary information in a meaningful, understandable way.

Federal regulations require that the following information be provided to each research subject:

- Purpose – Subjects must be told that the activity involves research, given an explanation of the purpose of the study, and told why they are being invited to participate.
- Procedures – A description of the procedures to be followed during the course of the research and the expected duration of the subject's participation must be included in the consent form. In addition, identification of any procedures that are experimental is necessary.
- Risks – Subjects must be informed about any foreseeable risks or discomforts associated with the study. This would include any clinical procedures, laboratory tests, psychological discomfort, and/or potential loss of confidentiality.
- Benefits – A description of any potential benefits of participating in the research must be disclosed, compensation does not pertain. If no direct benefit is expected for the subjects, that must be stated. If benefits are likely for society at large, they must be explained.
- Alternatives – Disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subjects.
- Confidentiality – Subjects must understand how identifying information about them will be maintained and what efforts investigators will take in keeping the information from being disclosed. If a Certificate of Confidentiality (CoC) is being sought, language must be inserted explaining the protections it will offer if granted. If the CoC is granted after initial PH IRB approval, a Project Revision Request must be submitted to update the language on the form demonstrating that the protection is in fact in place.
- Compensation – For research involving more than minimal risk, an explanation is needed as to whether any compensation is granted. If injury occurs, an explanation as to whether any medical treatments are available and, if so, what they consist of, and where further information can be obtained. The consent form and process cannot contain any exculpatory language that makes it appear that subjects are being asked to waive their legal rights.
- Contacts – Explanation of whom to contact for answers to pertinent questions about the research, research subject's rights, and whom to contact in the event of a research-related injury to the subject.
- Participation – A statement must be provided that explains participation is voluntary, refusal

to participate or discontinuation of participation at any time will involve no penalty or loss of benefits to which the subject is otherwise entitled.

When appropriate, the following additional elements of informed consent shall be provided to subjects:

- A statement that the particular treatment or procedure may involve risk to the subject which is currently unforeseeable;
- Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
- Any additional costs to the subject that may result from participation in the research;
- The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
- A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
- The approximate number of subjects involved in the study.

Assent for Children

In addition to obtaining consent from parents or guardians for subjects under the age of 18 to participate in research, the assent of children must be sought whenever the child is capable of understanding an explanation and purpose of the study. Children between the ages of 7 and 17 years are generally considered capable of giving assent.

When subjects under the age of 18 are pregnant or have children, and their participation in the research is related to the minor as a parent and not just as an individual, the requirement to obtain parental consent (of the minors' parents) is not necessary if it is determined that the study poses minimal risk.

Informed Consent for Genetic Research

In 1995, the Oregon Legislative Assembly enacted a comprehensive Genetic Privacy Act¹⁷. The intent of the law, as set forth in ORS 192.533, is to protect the genetic privacy of all Oregonians. This law was enacted in order to prevent any citizen in Oregon from experiencing insurance or employment discrimination on the basis of medically indicated genetic testing.

All proposed genetic research, including anonymous research, or research otherwise exempt from PH IRB approval, must first be submitted to an IRB for explicit approval or determination that the research is anonymous or otherwise exempt. Researchers must disclose to the IRB the intended use of human DNA samples, genetic tests, or other genetic information for every proposed research project, including their use in anonymous or otherwise exempt research.

Specific elements to be contained in a consent form for obtaining genetic information include:

¹⁷ See Reference Section for link to complete text of Act and administrative rules

- The name of the individual whose DNA sample is to be tested;
- The name of the individual, company, or organization requesting the genetic test for the purpose of obtaining genetic information;
- A statement signed by the individual whose DNA sample is to be tested indicating that he/she authorizes the genetic test;
- A statement that specifies the purpose of the test and the genetic characteristic for which the DNA sample will be tested;
- Explain that the genetic test is voluntary, the individual may choose not to have his/her DNA sample tested, and he/she has the option of withdrawing consent at any time;
- Explain the risks and benefits of having the genetic test, including a description of Oregon law provisions pertaining to individual rights with regard to genetic information and the confidential nature of the genetic information; a statement of potential consequences with regards to insurability, employability, and social discrimination if the genetic test results or genetic information become known to others; the implications of both positive and negative test results; and the availability of support services, including genetic counseling;
- Inform the individual that it may be in his/her best interest to retain his/her DNA sample for future diagnostic testing, but that he/she has the right to have his/her DNA sample promptly destroyed after completion of the specific genetic test which was authorized;
- Inform the individual about the implications, including potential insurability, of authorizing disclosure to a third party payer that the genetic test was performed, and that he/she has the option of paying the cost of the genetic test out of pocket rather than filing an insurance claim;
- Ask the individual whether he/she has any further questions, and if so, provide the individual with the opportunity to ask them and receive answers from either a genetic counselor or another person who is sufficiently knowledgeable to give accurate, understandable, and complete answers;
- Request that the individual read, complete, sign and date the consent form; and,
- Provide the individual with a copy of the completed form for his/her personal records.

Elements of Coded Research under Oregon Law

Genetic research in which the DNA sample and/or genetic information is coded must satisfy the following requirements:

- For DNA samples or genetic information obtained on or after June 12, 2003, the subject has granted informed consent for the specific research project or has consented to genetic research generally;
- The research has been approved by an IRB subsequent to the investigators disclosure of potential risks associated with the coding to the Board;
- The code is:
 - Not derived from individual identifiers;

- Kept securely and separately from the DNA samples and/or genetic information; and
- Not accessible to the investigator unless specifically approved by the IRB.
- Data are stored securely in password protected electronic files or by other such means with access limited to necessary personnel;
- The data are limited to elements required for analysis and meets the criteria in 45 CFR §164.514(e) for a limited data set; and
- The investigator is a party to the Data Use Agreement as provided by 45 CFR §164.514(e) for limited data set recipients.

Requests for Changes after Study Commencement

Investigators must promptly report any changes in the research activity to the PH IRB for review and approval prior to being implemented. Changes may only be implemented prior to PH IRB notice when necessary to eliminate apparent immediate hazards to the human subjects.

Revisions are divided into two types:

- **Minor Revisions** – changes in the protocol that are no more than minimal risk, or risks to subjects are not increased, and/or the revision is not a significant alteration of the study design. Such revisions may include, but are not limited to, changes to the number of participants included in the study population, addition or deletion of research team members, change in contact information related to the study, change to the amount or frequency of blood draws, or addition of non-sensitive questions to a questionnaire.
- **Substantive Revisions** – changes in the protocol that involve increased risk to subjects or significantly affect the nature of the study. Such changes may include, but are not limited to, changing or adding a study drug, revisions to the recruitment plan, adding or revising eligibility criteria, adding a research site, changing the P.I., updating the consent form to include a newly identified side effect related to a study drug, or the addition of a brand new research arm to the study.

The Principal Investigator must submit the Project Revision/Amendment form¹⁸ to the PH IRB Coordinator. The revision request must identify the assigned PH IRB tracking number, research title, and the description and justification for the proposed change(s). The affected documents must also be attached to the form (e.g. revised consent form, protocol, IRQ etc.). Changes must be highlighted or submitted in a “tracked changes” format for ease of review.

In the case of minor revisions, the PH IRB Chair may approve through an expedited review. All major revisions will be forwarded to the Full Board and reviewed at a regularly scheduled Board meeting. Failure to report changes for review and approval will be considered a protocol violation and may result in the suspension of the research study. Investigators must report violations using the Protocol Deviations/Violations Form¹⁹.

Unanticipated Problems or Adverse Events

¹⁸ See Reference Section for copy of form

¹⁹ See Reference Section for copy of form

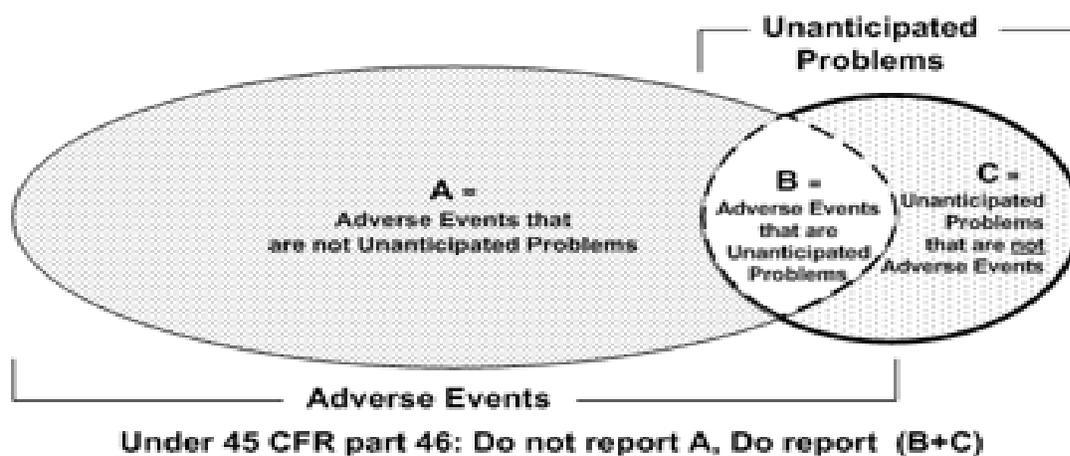
Unanticipated problems include any incident, experience, or outcome that meets **all** of the following criteria:

1. Unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied;
2. Related or possibly related to participation in the research; and
3. Suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The Principal Investigator shall immediately report any unanticipated problem involving risks to a research subject as a result of their participation in the study to the PH IRB using the Unanticipated Problem Report form.²⁰ Outcomes of such a report may include changes to the study.

Adverse events include any untoward or unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research. Typically, such events occur with biomedical research, however, it is possible for them to occur in social and behavioral research as well.

Distinguishing between unanticipated problems and adverse events can be difficult so the OHRP's guidelines should be utilized.²¹ Unanticipated problems can serve as adverse events and vice versa so gathering a solid understanding of the definitions is necessary as some of the reporting requirements extend beyond the PH IRB and institutional officials to OHRP itself. The Principal Investigator is responsible for the accurate documentation, investigation and follow-up of all possible study-related adverse events.



²⁰ See Reference Section for copy of form

²¹ See Reference Section for link to guidelines

The PH IRB has the authority to suspend or terminate approval of research that has been associated with unexpected serious harm to participants. When the PH IRB takes such action, a statement of reasons for the action will be provided and reports will be promptly made to the investigator, appropriate institutional officials, appropriate federal agency heads (e.g. NIH, OHRP), and if applicable, the FDA (if an investigational new drug or device is involved).

For studies that have a Data Safety Monitoring Board (DSMB), the investigator must forward summary reports to the PH IRB as soon as they are received. The PH IRB will communicate concerns to the DSMB or the institution sponsoring the study if it believes that the safety of study participants is in jeopardy.

Study Closure

Studies that are considered complete, meaning all enrollment, treatment, data collection, follow-up, and analysis have been done may be closed by the PH IRB. Researchers are asked to contact the PH IRB when such a scenario occurs so a Final Study Report/Closure Form can be submitted. Researchers may also notify the PH IRB Coordinator that the study no longer needs a continuing review at the time of its annual expiration, a Final Study Report/Closure Form will subsequently be sent their way. With the submission of this form, the PH IRB also must receive a summary of the study findings and any resulting publications or presentations.

A research project no longer involves human subjects and may be closed by the PH IRB, once the investigators have finished obtaining data through interaction or intervention with subjects or obtaining identifiable private information about the subjects, which includes the using, studying, or analyzing of identifiable private information. The Coordinator will send formal notice to the investigators and relevant program managers and data owners demonstrating that the study is now considered complete and the PH IRB has closed the file. All study records will be sent to State Archives.

NONCOMPLIANCE/COMPLAINTS

It is the duty of the PHD and MCHD to provide the highest level of protection to its human subject research participants. Reports of noncompliance will be directed to the PH IRB Coordinator and subsequently to the Board for investigation and corrective action.

All reports will be reviewed, however, each instance need not be subjected to the same level of scrutiny. In accordance with federal regulations, the PH IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements, or wherever there is evidence of serious or continuing noncompliance with FDA and DHHS regulations. The PH IRB is required to review allegations of investigator noncompliance with IRB-approved protocols as well as with federal regulations, state law, and institutional policy pertaining to human subject research. The PH IRB will also review allegations of misconduct that violate the rights of research subjects. Incidents of noncompliance will be reviewed by the PH IRB for corrective action appropriate to the incident. In all cases, the PH IRB's primary concern will be to protect the welfare of the research subjects.

The PH IRB will report to OHRP, and any other sponsoring Federal Department or Agency head:

- Any serious or continuing noncompliance with the regulations or requirements of the PH IRB; and
- Any injuries to human subjects or other unanticipated problems involving risks to subjects or others, and any suspension or termination of PH IRB approval for research to appropriate institutional officials.

For research misconduct, the Oregon Health Authority, Public Health Division, “Policy & Procedures for Responding to Allegations of Research Misconduct”²² will be consulted.

²² See Reference Section for copy of Policy

REFERENCES

(Press ctrl and click to follow the link)

1. Belmont Report
2. 45 CFR 46
3. Federalwide Assurance
4. Meeting Dates and Application Deadlines
5. Internal Data Request Process Map
6. External Data Request Process Map
7. FCOI Policy
8. Categories of Exemption
9. Expedited Review Categories
10. Continuing Review Questionnaire (CRQ)
11. CDC's Policy, "Distinguishing PH Research and PH Non-Research"
12. CSTE's "Public Health Practice vs. Research"
13. Initial Review Questionnaire (IRQ)
14. OHA PHD Pre-IRB Review Process for External Projects
15. PHD FCOI Disclosure Statement
16. HIPAA Questionnaires
17. Genetic Privacy Act and Administrative Rules
18. Project Revisions / Amendment Form
19. Protocol Deviations / Violations Form
20. Unanticipated Problem Report Form
21. OHRP Guidance on Unanticipated Problems
22. Policy & Procedures for Responding to Allegations of Research Misconduct

Additional policies

Children Participation in Research
Compensating Research Participants
Emergency Research – Exception to Informed Consent
Emergency Use of an Investigational Drug
Research Involving Investigational Medical Devices
Prisoner Participation in Research
Protocol Deviations and Noncompliance
Treatment Use of an Investigational New Drug
Reports of Unanticipated Problems and Adverse Events