



Subject: Institutional Review Board Policies and Procedures		Department: Planning & Development
Date: 10.22.12 11.13.13 8.06.2015 10.14.2016	Prepared by: Saskia Shuman	Approved by: Board-11.09.2016
Pages: 13		

SECTION 1: PURPOSE & SCOPE

1. Purpose

The Institutional Review Board (IRB) policy is designed to protect the rights and privacy of human subjects participating in research activities for which the IRB has authority. The Institute's IRB is responsible for determining and ensuring that:

- The welfare and rights of human subjects are sufficiently protected and informed consent given, when necessary;
- Human subjects are not placed at unreasonable physical, mental, or emotional risk in the research process;
- The need and importance of the research outweighs potential risks to subjects; and,
- The principal investigator(s) (PI) are qualified to conduct research involving human subjects.

2. Scope

The Institute's Institutional Review Board has the authority to approve, disapprove, or request changes to all proposed research based on its responsibilities listed above. This authority applies to all research conducted by Institute staff, faculty and students, whether funded or unfunded, as well as all research involving Institute patients. The IRB prospectively reviews all planned research involving human subjects, approves research that meets the criteria for protection of human subjects, and monitors approved research to ensure that human subjects are protected. The IRB is chaired by Laura Fidler, MPH. The panel is comprised of members that include both Institute administrative and clinical staff and representatives from outside organizations. The IRB meets on a bi-monthly basis. In accordance with federal regulations, the Institute for Family Health requires that all research involving human subjects be reviewed in advance by its human subjects review committee, the Institutional Review Board (IRB). The legal authority for the IRB comes from the Federal Policy for the Protection of Human Subjects (described in 45 CFR Part 46). The Institute maintains on file with the Public Health Service a statement of assurance committing the Institute to compliance with the Federal policy. No research involving humans may be undertaken without prior review and approval by the IRB.

An Institute staff or faculty member must serve as principal investigator or co-principal investigator on research submitted for IRB review. Residents submitting IRB applications must have a faculty or staff member serve as a co-principal investigator on all research studies. For studies involving clinical interventions, the IFH medical director and chief nursing officer must approve research. Generally, proposed research projects must be presented to the Institute's research committee and approved prior to submitting an application for IRB review. All proposed investigators and key staff on research studies must complete human subject protection education prior to submitting an IRB application and must include documentation of this education along with their application(s).

SECTION 2: APPLICATION PROCESS

Specific steps must be taken by all Institute staff and students seeking IRB approval for their research.

1. Application Submission Process

1.1 Application: Potential researcher(s) must complete the Application for Approval to Use Human Subjects in Research, within the Mentor Axiom system, which may include a request for IRB exemption. Additional forms and documentation, such as an Informed Consent Forms and copies of surveys and questionnaires, may also be required.

1.2 Submission: After completing the required forms, the researcher(s) electronically signs and submits the application and all forms to the IRB administrator or designee. The Administrator conducts a pre-review to ensure that the application contains all pertinent materials. The IRB administrator may require researchers to make modifications or provide additional information prior to processing application for review by the IRB committee. Applications must be submitted at least two weeks prior to the scheduled IRB meeting date in order to ensure review at the next scheduled meeting.

1.3 Review Determination: Complete applications will be scheduled for IRB review. Depending upon research review category, studies will either: 1) be assigned to an IRB member or, 2) undergo a full board review. For exempt studies, the IRB Chair or her/his designee may make the determination. The IRB will be notified during meetings of any studies determined to be exempt.

1.4 Review Pathways:

1.4.a: Exempt Reviews: While the IRB is ultimately responsible for deciding if research qualifies for exemption, investigators are able to make an initial determination of as to whether their project meets the criteria set forth by the federal regulations. Although the regulations allow for several categories of research to meet the criteria for exemption, it is Institute's policy that only those protocols that meet the criteria below may be approved via this process:

- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens:
 - i. If these sources are publicly available; OR
 - ii. If the sources are not publicly available, but the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. **

**Example: A PI who receives restricted access data, but stores the data in a secure environment, may be eligible for exemption under this category if s/he is not recording identifiable private

information into her/his own research records, or is not merging datasets that may lead to identification of individuals.

All research projects involving human subjects must be reviewed by the Institute's IRB Committee, Committee Chair or designee to determine if they are truly "exempt" or if they must be reviewed by the IRB. All exempt category projects are then reported for disclosure purposes at the next convened IRB meeting. Exempt category projects do not need continuing IRB review and any annual reporting.

1.4b: Expedited Reviews: Other studies that are "[minimal risk](#)," but that do not meet the strict criteria for Exempt research. The regulations do allow, however, for these minimal-risk studies to be reviewed at an "expedited" level, in which only the IRB Chair, or an IRB member designated by the Chair, may review and approve the project.

The full criteria for protocols eligible to be reviewed under this expedited process can be found in section [§46.110 of the federal regulations](#).

All protocols reviewed via the expedited process are reported to the full IRB at their next convened meeting. However, because of the increased level of risk and complexity that might be involved with such projects, any IRB member, at any time, can ask that a protocol which was approved on an Expedited basis be brought back to the full IRB for further review and consideration at the next convened meeting.

1.4 c: Full Board Review: "When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects." Subparts A-D of the regulations outline the additional benchmarks for assessing risk in these vulnerable populations. Protocols that involve vulnerable populations may not be reviewed using the exempt or expedited pathway; these protocols require review by the full IRB Committee by convened session.

2. Principal investigator (PI) Requirements

2.1 All PIs and study personnel will maintain an up to date human subjects protection certificate. Human subjects protection certificates expire every three years. PI and study personnel are responsible for uploading up-to-date certificates into the Institute's Mentor system.

- The Institute for Family Health will recognize the required human subject protection certificates issued by the CITI training program, and the [NIH Office of Extramural Research](#).

2.2 Conflict of Interest & Financial Conflict of Interest (FCOI). PIs will follow and adhere to the Institute's Conflict of Interest policy:

All investigators engaged in research are required to comply with the policy. The protection of human subjects requires objectivity in communicating risks, selecting subjects, delivering informed consent, and gathering, analyzing and reporting data. Therefore, the IRB will consider conflict of interest issues in its deliberations of applications.

2.3 FCOI Reporting Requirements: In order to be in compliance with federal regulations for FCOI, investigators are required to complete the following actions:

- Investigators must complete required [Conflict of Interest Training](#). This training must be completed, with certificate uploaded to the Mentor system for documentation purposes, every four years.
- Investigators must complete the [Disclosure of Significant Financial Interests](#) form annually, and update within thirty days when there is a change.
- With any new (or renewal) IRB application, the Principal Investigator must also complete the conflict of interest questions on the application form. If the PI discloses a potential conflict, they will also be prompted to update their Disclosure of Significant Financial Interest form.

2.4 Conflict of Interest Review: The IRB will review conflict of interest disclosures and management plans to consider the effect of financial interests on participant protections. The IRB requires financial interests of principal investigators to be managed so that they do not adversely affect participant protections or the credibility of the human research protection program. Disclosure alone cannot be used to manage investigators' financial interests that might adversely affect participant protections. If a significant financial interest is disclosed, the IRB will alert the Institute's compliance officer. The compliance officer will have the final authority to decide whether the conflicting interests and management plans adequately protect participants and allow research to be approved. It is the responsibility of the compliance officer, in partnership with the IRB to ensure that all disclosures are made public and/or submitted for federal review.

2.5 Penalties:

- If PI fails to comply with reporting requirements (See 2.2), the IRB has the authority to suspend all of the PI's active research protocols. All research protocols will remain suspended until PI submits required documentation.
- If a matter is referred to the compliance officer, and the compliance officer fails to take appropriate action, matter will be referred to President. If President fails to take appropriate action, matter will be brought to the Chair of the Board of Directors. Failing appropriate action by the Board Chair, the Office of Human Research Protection (OHRP), the Joint Commission, and/or the New York State Department of Health may be alerted. Any contact with these offices would be covered by the Institute's existing whistleblower protection policies.

SECTION 3: PROTOCOL REVIEW

1. IRB Review of Protocols

1.1 IRB Review: IRB applications will be assigned a primary (and in some cases secondary reviewer) committee member as the reviewer. For exempt or expedited studies, the reviewer will have the ultimate responsibility for approving or not approving the protocol. If assigned as the presenting review for an upcoming meeting, the committee member will lead the discussion of their designated applications. The IRB may approve, disapprove, or conditionally approve applications. All approved studies will be reviewed annually by the IRB, unless the IRB determines that the study involves an intervention that poses more than minimal risk to subject and/or researchers who have been noncompliant with IRB policy in the past. In these cases, more than annual review may be required.

1.2 Specific Review Criteria: The IRB will use the following criteria in determining whether to approve an application to include human subjects in research:

- Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- Risks to subjects are less than or reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks or benefits that fall within the purview of its responsibility.
- Selection of subjects is equitable. In making this assessment the IRB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons.
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by [§46.116](#).
- Informed consent will be appropriately documented, in accordance with, and to the extent required by [§46.117](#).
- When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.
- When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

1.3 Review Notification: The status of the IRB review, including the final IRB approval, will be indicated within the IRB's protocol management system, Mentor, and emailed to the applicant by IRB staff. This communication will remind researchers that they must complete a continuing review form within the specified timeframe, and that adverse events must be reported to the IRB within five days of the event.

1.4 Continuing Review: Within one year of approval or the timeframe established by the IRB, principal investigators are contacted by the IRB staff and asked to complete and submit a continuing review request within the Mentor system. Continuing review of research will follow the same procedure as the initial review.

1.5 Protocol Amendment: Prior to implementing any changes to the approved protocol, informed consent forms, or any other significant aspect, researchers are required to submit an amendment request to the IRB. Researchers complete the current IRB amendment form, which is reviewed by the IRB in the same manner as a newly proposed research.

1.6 Adverse Events: Research activities that result in unanticipated risks to study participants must be reported to the IRB Chair within 5 days of the event. An adverse event is defined as any experience or abnormal finding that has taken place during the course of a research project and was harmful to the subject participating in the research, or increased the risks of harm from the research, or had an unfavorable impact on the risk/benefit ratio.

- In the event of an adverse event: Please see **Adverse Events/Noncompliance/Conflict of Interest Determination Group (Section 6)**

SECTION 4: IRB MEMBER SELECTION

1. IRB Chair Information

1.1 IRB Chair: The IRB Chair is appointed by the president and CEO of the Institute for Family Health (or acting CEO/President) or designee, with the support and involvement of the Acting IRB Chair and IRB Administrator(s).

1.2 IRB Chair Selection Criteria: “In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas.” (38CFR16.107(a)).

The Institute has determined that IRB Chairs must meet the following criteria:

- At least 3 years direct research experience OR 2 years of service as an IRB board member;
- Ability to successfully manage a group;
- Willingness to commit to at least 2 years of service as the Chair

2. IRB Members

2.1 IRB Member Selection: IRB members are selected by the IRB Chair & IRB Administrator(s). Candidates are asked to submit a resume and cover letter, followed by an in-person interview.

2.2 IRB Member Composition: The IRB shall consist of at least 5 members with varying and diverse backgrounds to ensure an adequate review of research activities conducted or sponsored by the Institute. Every effort will be made to identify staff and employees representative of the Institute’s various departments and clinical domains. General membership criteria will include the following:

- At least one physician (M.D./D.O.), who has training and experience in a medical field sufficient to assess medical risks;
- At least one person with advanced training and experience in conducting scientific investigations;
- At least one person whose primary work is not in the area of scientific investigations;
- At least one person who is not, and whose immediate family is not, affiliated with the Institute.
- Institute staff, patients, and community members who meet these general criteria will be selected and interviewed. Previous IRB and/or research experience is not required, although it is preferred for all scientific members of the board.
- Considerations for IRB members include research, professional or administrative expertise, community experience, and availability to serve. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall also have the capability to discern the acceptability of proposed research in terms of department commitments and regulations, applicable laws, and standards of professional conduct and practice.
- The IRB Chair and Administrator(s) will interview and invite IRB board members to join for two-year terms.

Section 5: DUTIES OF IRB MEMBERS

Each IRB member's primary duty is the protection of the rights and welfare of the patients, community members, and staff who are serving as the research subjects. The IRB member must understand that s/he is not serving on the IRB to expedite the approval of research, but to be a gatekeeper between the Principal investigator (PI) and the research subjects. In order to fulfill their duties, IRB members are expected to be versed in regulations governing human subject protection, biomedical and behavioral research ethics, and the policies of the Institute germane to human subject protection.

1. Specific Member Duties

1.1 IRB Member Duties: IRB members must maintain the IRB's reputation for being fair and impartial, immune from pressure either by the institution's administration, the Investigators whose protocols are brought before it, or other professional and nonprofessional sources.

1.2 Unaffiliated members (community members): are expected to provide input regarding their knowledge about the local community and be willing to discuss issues and research from that perspective. Community members are tasked with representing the Institute's patient population and ensuring that a balanced perspective is afforded to each protocol.

1.3 Nonscientific members: are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. Nonscientific members should advise the IRB if additional expertise in a nonscientific area is required to assess if the research proposal adequately protects the rights and welfare of subjects.

1.4 Scientific members: are expected to contribute to the evaluation of a study on its scientific and statistical merits and standards of practice. These members should also be able to advise the IRB if additional expertise in a nonscientific area is required to assess if the research proposal adequately protects the rights and welfare of subjects.

1.5 All IRB members are required to attend scheduled meetings and actively participate in the discussions. All IRB members are also expected to periodically review those protocols assigned by the Chair or designee provided that the protocols meet previously specified criteria.

2. Duties of IRB Chair

2.1 In addition to the above responsibilities (germane to the member's capacity), the IRB Chair conducts meetings of the IRB. The IRB Chair or his/her designee also confirms exemption requests, and performs expedited review(s) when appropriate.

2.2 IRB Co-Chair or IRB Vice-Chair may assist or act on behalf of the IRB Chair in particular IRB matters and at IRB meetings, either as a general procedure, or on a case-by-case basis.

2.3 The IRB Chair also may delegate any of his/her responsibilities as appropriate to other qualified individual(s). Any such delegation of responsibility is documented in writing and maintained by the IRB Administrative Staff.

3. Training Requirements

3.1 Both regular IRB members and the IRB Chair(s) are expected to complete all trainings required to meet federal regulations and/or Institute policies. Proof of compliance must be submitted to the IRB administrators. Current training requirements include:

- NIH Protecting Human Research Participants training (re-certify every 3 years)
- NIH Financial Conflict of Interest Training (re-certify every 4 years)

SECTION 6: IRB ADMINISTRATIVE PROCESSES

Administrative Processes

1. Responsibilities of IRB Administrator(s)

1.1 General Responsibilities: Responsible for the oversight, administration, implementation, and management of all IRB business, including policies and procedures related to the protection of the rights and welfare of human subjects and the Institute's compliance with all federal regulations, state and local laws and institutional policies applicable to research involving human subjects in research.

2. Auditing: An IRB administrator may perform routine and for-cause audits using systematic methods to evaluate compliance with federal regulations, state and local laws, and Institute policies. The objective of a routine IRB audit is to ensure proper documentation, record keeping, data analysis, and adherence to Federal regulations and IRB policy in order to monitor, measure, and improve the effectiveness of the human research protection program. The audit assesses the study conduct procedure, identifies errors and omissions, and is a means to provide the investigator with recommendations for corrections and improvements in order to protect the rights and welfare of research participants.

2.2 Protocol Audit Process: The IRB administrator or designee selects an Investigator or study for a routine audit based on criteria which includes, but is not limited to, the following:

- 1) Studies involving procedures that are greater than minimal risk to subjects,
- 2) Studies involving vulnerable populations,
- 3) Investigator-Initiated drug/device studies, and
- 4) Investigators conducting a large number of studies.

As part of the Institute's IRB audit process:

- The IRB administrator will conduct a thorough review of all files associated with the protocol, and contact the Principal Investigator (PI) if additional documentation is needed. The PI must make such documents available in a timely manner.
- After an audit, the Investigator is informed of the result of the review in a written report from the IRB administrator. The written report is also sent to the IRB Chair, and other Institutional Officials as appropriate.
- If the audit identifies problems or deficiencies, the IRB administrator includes appropriate corrective actions in the written report. The Investigator is expected to respond or comply with the corrective actions in a time frame determined by the IRB administrator. The IRB administrator follows up with the Investigator to ensure these corrective actions are completed.
- If the corrective actions are not completed, the IRB administrator may recommend to the convened IRB that a suspension be considered for the study that was audited or for the studies that an Investigator is conducting.
- If the audit identifies non-compliance, such as lack of oversight, deliberate falsification or omission, failure to comply with the requirements and determinations of the IRB, significant

protocol violations, or deviations or frequent occurrences of such, the IRB will follow the Adverse Events/Noncompliance/Conflict of Interest (Section 6, Subheading 3).

3. Adverse Events/Noncompliance/Research Misconduct/Conflict of Interest

3.1 If a PI identifies an adverse event or conflict of interest to the IRB Chair and IRB administrator(s), or if during a routine audit an issue of noncompliance or conflict of interest is discovered, it will be assigned to the IRB Unanticipated Problems Subcommittee for review and evaluation.

3.2 IRB Unanticipated Problems Subcommittee Membership: Standing membership for the subcommittee will include:

- Institute Compliance committee chair or designee
- IRB Chair
- IRB Administrator(s)
- Senior VP, Planning and Development

For a subcommittee meeting to be recognized, representatives from three of the four member categories listed above must be present.

3.3. IRB Unanticipated Problems Protocol: The IRB Unanticipated Problems Subcommittee may request clarifications, corrections, or revisions to the report from the PI if further information is needed to evaluate the event/noncompliant incident or conflict. The subcommittee will then evaluate the event by considering whether the problem is an unanticipated problem/conflict/issue of noncompliance involving risks to participants or others as defined by this policy. The convened committee will vote, and will record the rationale for any action in meeting minutes.

- If the subcommittee determines that the problem is not an unanticipated problem involving risks to participants or others as defined in this policy, the group will complete a checklist indicating the event is not considered to be an unanticipated event/issue of noncompliance or conflict involving risks to participants. No further action is taken.
- If the subcommittee determines that the problem might be an unanticipated problem/issue of noncompliance or conflict of interest involving risks to participants or others as defined by this policy, the members may consider any of the following actions, but is not limited to:
 - modification of the protocol;
 - modification of the information disclosed during the consent process provided by the investigator;
 - providing additional information to current participants (this must be done whenever the information may relate to the participant's willingness to continue participation);
 - providing additional information to past participants;
 - requiring current participants to re-consent to participation;
 - alteration of the frequency of continuing review;
 - observation of the research or the consent process;
 - requiring additional training of the investigator;
 - notification of investigators at other sites;
 - obtaining additional information;
 - administrative hold, termination or suspension of the research according to standard operating procedure.

In the event that the subcommittee determines that the event was an unanticipated problem/issue of noncompliance or risk involving risks to participants or others, the matter will be related to the full IRB, and to the IRB staff to handle according to Section 6, Policy 3.4 Reporting Procedures.

3.4 Adverse Events/Noncompliance/Conflict of Interest Reporting Procedures: It is the policy of the Institute to comply with all applicable local, state, and federal regulations in the conduct of research studies and to communicate certain actions to entities that may have an interest in the status of the research being conducted. The IRB will notify institutional officials, funding sources, regulatory agencies, as appropriate, once the IRB takes any of the following actions:

- Determines that an event represents an unanticipated problem involving risks to participants or others;
- Determines that non-compliance was serious or continuing;
- Suspends or terminates approval of research.

3.6 If at any point, the IRB becomes aware of potential misconduct, it is the responsibility of the IRB administrators to report to the incident reporting system (see below: CRM) and to the Institute's Compliance officer for review and evaluation.

- Examples of misconduct include but are not limited to: beginning a research protocol without prior approval by the research committee and IRB, accessing protected health information (PHI) for non-clinical or research related reasons without appropriate approval, publishing or presenting CQI/QI material to external sources, etc.

If at any point, a staff/provider/community member becomes aware of potential misconduct s/he may report without fear of reprisals using one of two systems:

- CRM system: This is the Institute's official incident reporting system. The CRM system is not confidential or anonymous, but all reports will be handled with the utmost discretion. CRM can be accessed via the Institute's Citrix system.
- Lighthouse: This is the Institute's confidential reporting system. If you are concerned about confidentiality, please use the Lighthouse system to report any potential misconduct concerns.

It is the responsibility of the compliance officer to determine if the misconduct requires additional action. It is also the responsibility of the compliance officer to alert the IRB Chair/Administrator(s) when a potential act of misconduct has been reported for review.

3.7 Potential Misconduct Review: It is the responsibility of the IRB Chair and administrators to alert the IRB board when a potential act of misconduct has been reported to the Compliance officer. The IRB Chair/administrators will keep the board apprised of any outcomes.

The Compliance officer will have the final authority to decide whether the act of potential misconduct requires additional action or remediation. It is the responsibility of the Compliance officer, in partnership with the IRB to ensure that any sanctions or actions deemed appropriate by the committee are implemented.

3.9 Outcomes and Penalties after review:

3.9 a. Regardless of outcome, it is the responsibility of the IRB administrator or designee to prepare a letter or formal written communication that contains the following information:

- The nature of the event/original complaint (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research);
- Name of the institution conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred;
- Name of the principal investigator on the protocol;
- Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);
- A detailed description of the problem including the findings of the IRB Unanticipated Problems Subcommittee and/or the Compliance Officer;
- Corrective actions and/or sanctions the institution is taking or plans to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.);
- Plans, if any, to send a follow-up or final report by a specific date or when an investigation has been completed or a corrective action plan has been implemented.

The IRB Chair will review the letter, after which the IRB administrator or designee sends a copy of the report to the following as applicable:

- Principal investigator;
- Sponsor, if the study is sponsored;
- Chairman or supervisor of the principal investigator and/or offending investigator;
- Office of Human Research Protections (OHRP), if the study is subject to the U.S. Department of Health and Human Services (DHHS) regulations or subject to a DHHS Federal Wide Assurance;
- Other federal agencies when the research is overseen by those agencies.

The IRB administrator or designee can provide copies to others as deemed appropriate by the Institutional Official or IRB chair. The IRB administrator or designee will ensure that all steps of this policy will be completed within 30 days of the initiating action. For more serious actions, the IRB administrator or designee will expedite reporting.

3.9 b. Possible penalties for misconduct include:

- Suspension of all PI's active research protocols. Duration etc. to be determined by Compliance officer;
- Termination of all PI's active research protocols;
- Suspension for future research activities (and IRB approval) at the Institute.

If a matter is referred to the compliance officer, and the compliance officer fails to take appropriate action, matter will be referred to President. If President fails to take appropriate action, matter will be brought to the Chair of the Board of Directors. Failing appropriate action by the Board Chair, the Office of Human Research Protection (OHRP), the Joint Commission, and/or the New York State Department of Health may be alerted. Any contact with these offices would be covered by the Institute's existing whistleblower protection policies.

SECTION 7: HIPAA

7.1 Privacy Rule and Research: The Privacy Rule permits covered entities to use or disclose PHI for research purposes either with an individual's specific written permission, termed an "Authorization," or without it, if certain conditions are met.

As employees of a covered entity, it is the responsibility of Institute PIs to understand the specific scenarios in which they are permitted to use or disclose PHI for research purposes, including when:

- [Study team] obtains the **individual's Authorization** for the research use or disclosure of PHI as specified under *section 164.508* of the Privacy Rule, OR
- [Study team] obtains satisfactory documentation of an IRB's **waiver** of the Authorization requirement that satisfies *section 164.512(i)* of the Privacy Rule, OR
- [Study team] obtains satisfactory documentation of an IRB's **alteration** of the Authorization requirement as well as the altered Authorization from the individual; OR
- [Study team] produces a **limited data set** for a set recipient as specified under *section 164.514(e)* of the Privacy Rule.

7.2. PHI Authorization: PIs may use and disclose PHI for research purposes if they first obtain authorization from the human subjects. A valid 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 or recipients, as stated in the Authorization. An Authorization differs from an informed consent in that an Authorization focuses on privacy risks and states how, why, and to whom the PHI will be used and/or disclosed for research. An informed consent provides research subjects with a description of the study and of its anticipated risks and/or benefits, and a description of how the confidentiality of records will be protected, among other things. An Authorization can be combined with an informed consent document or other permission to participate in research. Whether combined with an informed consent or separate, an Authorization must contain specific core elements and required statements. A description of the core elements and required statements required for the Authorization can be found in the [Authorization Overview](#) document.

7.3 Limited data set: PIs may produce a limited data set, which includes some 'some identifiers,' for research purposes within the covered entity (CE). No Authorization or waiver or alteration of Authorization by the IRB is required for a covered entity to use or disclose a limited data set. This does not necessarily negate the need for a written consent form, but does remove any obligation on the part of the PI to include HIPAA Authorization language in the document.

7.4 Waiver or Alteration of Authorization: If it is not possible or practical for a PI to obtain authorization from each human subject participant, they are permitted to request a waiver from the IRB. In order for the IRB to issue a waiver, the following criteria must be met:

- The use or disclosure involves no more than a minimal risk to the privacy of individuals based on at least the presence of (1) an adequate plan presented to the IRB or Privacy Board to protect PHI identifiers from improper use and disclosure; (2) an adequate plan to destroy those identifiers at the earliest opportunity, consistent with the research, absent a health or research justification for retaining the identifiers or if retention is otherwise required by law; and (3) adequate written assurances that the PHI will not be reused or disclosed to any other person or entity except (a) as required by law, (b) for authorized oversight of the research study, or (c) for other research for which the use or disclosure of the PHI is permitted by the Privacy Rule; **AND**

- The research could not practicably be conducted without the requested waiver or alteration;
AND
- The research could not practicably be conducted without access to and use of the PHI.

7.5 De-identified data: The Privacy Rule permits covered entities to use and disclose data that have been de-identified without obtaining authorization from patients and without further restrictions on use or disclosure because de-identified data are not PHI and, therefore, are not subject to the Privacy Rule. This does not necessarily negate the need for a written consent form, but does remove any obligation on the part of the PI to include HIPAA Authorization language in the document.

7.6 Data use agreements: Regardless of Authorization, if a PI plans to share PHI or limited data set PHI outside of the CE (e.g. with researchers at an external or partner agency), they must first enact a data use agreement. For more information on enacting a data use agreement, PIs may contact the IRB Administrator, or the Institute's SVP Administration.