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**CONTENTS**

**SECTION 1: PURPOSE & SCOPE**

**SECTION 2: APPLICATION PROCESS**

**SECTION 3: PROTOCOL REVIEW**

**SECTION 4: IRB MEMBERS**

**SECTION 5: IRB ADMINISTRATIVE PROCESSES**

**SECTION 6: HIPAA**

**SECTION 7: SHARING RESEARCH DATA WITH EXTERNAL PARTNERS**

[**SECTION 1: PURPOSE & SCOPE**](#_top)

**1. Purpose**

The Institutional Review Board (IRB) policy is designed to protect the rights and privacy of human subjects participating in research activities at the Institute for Family Health.

All human subjects research involving the Institute for Family Health will be guided by the ethical principles documented in the [Belmont Report](https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html#xjust): Ethical Principles and Guidelines for the Protection of Human Subjects of Research. Primary/Principal investigators (PI) and staff (whether employees or agents of the Institute or employees or agents of another institution) involved in research in which the Institute is engaged will design and conduct research:

1. Demonstrating appropriate respect for the human subjects of the research.
2. Minimizing risks to the human subjects of the research.
3. Maximizing the possible benefits to the human subjects of research.
4. Ensuring the benefits of the research to the human subjects outweigh the risks of the research to the human subjects.
5. Ensuring the selection of the human research subjects is just, appropriately distributing any associated risks such that those who may bear the most risk are also most likely to receive the most benefit.

The Institute’s IRB and its administrative office will provide oversight (through primary review or through an agreement to rely on the review of another institution’s Institutional Review Board) over all human subjects research in which the Institute is engaged including:

1. Conducting IRB initial and continuing review of research as a convened board or using expedited review procedures, conducting limited or administrative IRB review of some exempt research, and reporting IRB findings to the primary investigator, responsible department employee and other institutional officials.
2. Conducting periodic IRB or administrative review(s) of research until study completion.
3. Ensuring prompt reporting to the IRB of proposed changes in a research activity, and for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval, except when necessary to eliminate apparent immediate hazards to research subjects.
4. Research covered by this policy that has been approved by the IRB or its administrative office may be subject to further appropriate review by other institutional officials. However, those officials may not permit the conduct of non-exempt human subjects research if it has not been approved by the IRB.

**2. Scope**

The Institute’s IRB has the authority to approve, disapprove, or request changes to all proposed research based on its responsibilities above. This authority applies to all research conducted by Institute staff, faculty and students, whether funded or unfunded, when the human subjects are Institute employees, or personnel. This authority also applies to all research involving Institute patients as participants.

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 members of the IRB Committee include both Institute administrative and clinical staff and representatives from outside/community-based organizations. The IRB meets once every two months. 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 human subjects may be undertaken without prior review and approval by the IRB.

An Institute staff or faculty member must serve as primary/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 appropriate senior nursing officer must approve research. 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 training education with their application(s).

**SECTION 2: APPLICATION PROCESS**

Specific steps must be taken by all Institute staff, residents and students who are seeking IRB approval for their research. All Institute PIs must seek and receive approval from the Institute’s Research Committee prior to formally submitting an application to the IRB.

**1. Application Submission Process**

1.1 Application: Potential researcher(s) must complete the Application for Approval to Use Human Subjects in Research (Application), within the Mentor Axiom system. Additional forms and documentation, such as Human Subjects Protection Certificate, Financial Conflict of Interest (FCOI), Good Clinical Practice Certificate, and informed consent files 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 to the IRB administrator or designee. The administrator conducts a pre-review to ensure that the application contains all necessary materials. The IRB administrator may require that researchers make modifications or provide additional information before the application can be processed for review by the IRB committee. Applications must be submitted at least two weeks prior to the scheduled IRB meeting date to ensure it is reviewed at the next scheduled meeting.

1.3 Review Determination: Only fully completed applications will be scheduled for IRB review. Depending on their research review category, studies will either:

1) Be assigned to the IRB chair, an IRB member or designee for exempt/expedited review (“single reviewer”) or

2) Undergo a full review by the convened IRB (“full board/full committee review”). The IRB will be notified of any studies approved by a single reviewer between convened meetings.

1.4 Review Pathways:

1.4.a: Exempt Reviews (.104): While the IRB is ultimately responsible for deciding if research qualifies for exemption, investigators can make an initial determination as to whether their project meets the criteria set forth by the federal regulations. The final determination will be made by the Institute’s IRB Committee, Committee Chair or designee. All exempt category projects are reported at the next IRB meeting. Protocols approved via the exempt pathway do not need to meet the consent requirements outlined in Section .116, although the IRB Chair or designee will conduct a limited review to ascertain whether adequate provisions are in place for protecting privacy and maintaining confidentiality.

Formal Continuing Reviews (CRs) are no longer required for protocols originally approved via the exempt or expedited review processes, unless a reviewer explicitly justifies why the review would enhance protection of research subjects. This determination will be made on a case-by-case basis. The Institute will still require PIs to submit a modified administrative report on an annual basis, to address internal controls.

Although the regulations enable several categories to meet the criteria for exemption, it is the Institute’s policy to only review the following type of exempt protocols:

* .[104 (d)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101) Research, conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction..
* [.104 (d)(2)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101) Research in which interactions appertain only to educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if certain criteria is met.
* [.104(d)(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.101) Secondary research for which consent is not required if at least one of the criteria is met.

Research protocols that include the following Subpart categories may still eligible for exempt review, if certain conditions are met.

* Subpart B - Research involving pregnant women. All of the exemptions in .104 may be applied to research involving pregnant women, if the general conditions are met.
* Subpart C – Research involving prisoners. None of the exemption in .104 may be applied to research, except when it’s aimed at involving a broader subject population that only incidentally includes prisoners.
* Subpart D – Research involving children. Exempt research categories (d)(1) and (d)(4) may be applied to research that involves children. Exempt category (d)(2)(i) and (d)(2)(ii) may apply only to research activities that include educational tests or the observation of public behavior when the investigator(s) do not participate in the activities being observed. Research in category (d)(2)(iii) is not considered exempt when children are involved. More general information on research involving children can be found in Appendix D.

1.4b: Expedited Reviews: Studies that are “minimal risk” but that do not meet the strict criteria for exempt research may be reviewed under the expedited review process. Under an expedited review, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB. If a reviewer determines that a type of research listed on the HHS Secretary’s list of expedited research activities presents more than minimal risk, s/he must document this determination before moving it forward for review by the full IRB committee.

The full criteria for protocols eligible to be reviewed under this expedited process can be found in section §[46.110](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.110) of the federal regulations. The list of expeditable research activities developed by the HHS Secretary can also be found online.

An IRB may also use the expedited review procedure to review:

(ii) Minor changes in previously approved research during the period for which approval is authorized (e.g. amendment);

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.

Formal Continuing Reviews (CRs) will no longer required for protocols originally approved via the exempt or expedited review processes, unless a reviewer explicitly justifies why the review would enhance protection of research subjects. This determination will be made on a case-by-case basis. The Institute will still require PIs to submit a modified administrative report on an annual basis, to address internal controls.

1.4 c: Full Board Review: For protocols that present greater than minimal risk or the inclusion of vulnerable populations, a full board (full committee) review will be required.

Subparts B-D of the regulations outline the additional benchmarks for assessing risk in specific 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 at a convened session.

* Subpart B - Research involving pregnant women.
* Subpart C – Research involving prisoners.
* Subpart D – Research involving children.

1.4d: Other Reviews: Some clinical investigations are also subject to FDA investigation new drug (IND) or Investigational Device Exemption (IDE) regulations. The definition of a medical device in this context may be found [online](https://www.fda.gov/RegulatoryInformation/Guidances/ucm258946.htm), as can information about [drug/biologics](https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194516.htm). Please refer to [*Clinical Trials and Human Subjects Protection*](https://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm) for more information regarding these requirements.

1.4e NIH- Clinical Trials:

* Registration: All NIH-funded clinical trials are expected to register and submit results information to [Clinicaltrials.gov](https://clinicaltrials.gov/ct2/home), as per the "[NIH Policy on Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm)" for competing applications submitted on or after 1/18/2017. Information on registering your trial can be found [online.](https://grants.nih.gov/policy/clinical-trials/reporting/index.htm)
* Certificates of Confidentiality: Effective October 1, 2017, all ongoing or new research funded wholly or in part by NIH that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality (Certificate) as a term and condition of NIH grant awards. Identifiable, sensitive information is information about an individual, gathered or used during the course of biomedical, behavioral, clinical or other research, through which the individual is identified, or there is at least a very small risk that the identity of an individual could be identified.

Under the new Policy:

* Certificates will no longer be issued in a separate document. The Notice of Award and the NIH Grants Policy Statement will serve as documentation of the Certificate protection.
* Researchers are required to determine whether their research records generated with NIH funding are covered by a Certificate.
* The scope of research protected by Certificates extends beyond “human subjects research” and includes research:  1) in which identifiable, sensitive information is collected or used, 2) that collects or uses human biospecimens that are identifiable or that have a risk of being identifiable; 3) that involves the generation of individual level human genomic data; and 4) that involves any other information that might identify a person.
* Certificates will be issued to recipients for applicable research regardless of the country where the investigator or the protected information resides.  However, Certificates may not be effective for data held in foreign countries.
* Information protected by a Certificate and all copies are subject to the protections of the Certificate in perpetuity. Therefore, if a secondary researcher receives information protected by a Certificate the secondary researcher is required to uphold the protections of the Certificates.
* When a researcher is issued a Certificate and the researcher will be obtaining informed consent from participants, subjects must be told about the protections afforded by the Certificate and any exceptions to those protections. This information must be included in any written consent documents.

The NIH has provided useful FAQs and information about the new Policy at: <https://humansubjects.nih.gov/coc/NIH-funded>.

**Should you receive a subpoena or other legal process seeking disclosure of research records, please contact the** [SVP Administration](mailto:efried@institute.org) **immediately, and prior to disclosing any records or information.**

**2. Principal/Primary 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/or the certificate offered by the [Association of Clinical Research Professionals](https://acrpnet.org/courses/ethics-human-subject-protection/).

2.2 Conflict of Interest (COI) & 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 evaluations of applications. 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](http://ori.hhs.gov/education/products/u_minn/html/managers/mod1/objective.html). This training must be completed, with the certificate uploaded to the Mentor system for documentation purposes, every four years.
* Investigators must complete the [Disclosure of Significant Financial Interests](https://www.axiommentor.com/pages/irb/pop.cfm?osw=go&path=34,861&inline=1&id=112) form annually, and update it within thirty days when there is a change.
* With any new (or renewal) IRB application, the PI must also complete the conflict of interest questions on the application.  If the PI discloses a potential conflict, s/he will also be prompted to update their Disclosure of Significant Financial Interest form.

2.3 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 interfere with participant protections or affect the credibility of the human research protection program. Disclosure, however, does not suffice to manage investigators’ financial interests if these might adversely affect participant protections. If a significant financial interest is disclosed, the IRB will alert the Institute’s director of research compliance. The director of research compliance, in collaboration with the Institute’s compliance officer/management compliance committee 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 director of research compliance, in partnership with the IRB chair, to ensure that all disclosures are made public and/or submitted for federal review.

2.4 Good Clinical Practice: All PIs and study personnel will maintain an up-to-date Good Clinical Practice certificate, which expires every four 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 Good Clinical Practice certificates issued by the [National Institute of Allergy and Infectious Diseases](https://learningcenter.niaid.nih.gov/) and by CITI.

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 Institute’s 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**

**3. IRB Review of Protocols**

3.1 IRB Review: IRB applications will be assigned a primary (and in some cases secondary) committee member as the reviewer. For exempt or expedited studies, the reviewer will have the chief role in determining whether a protocol is approved. If the assigned reviewer is unable to approve a protocol, s/he will move the protocol to the full committee. If assigned as the presenting review for an upcoming meeting, the committee member will lead the discussion of his/her designated applications. The full IRB committee may approve, disapprove, or conditionally approve applications. All full board approved studies will be reviewed annually by the IRB, unless the IRB determines that the study involves more than minimal risk to subjects and/or researchers who have been noncompliant with IRB policy in the past. In these cases, more than annual review may be required.

3.2 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 children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Specific thought must be given to whether a participant may be particularly vulnerable to coercion and undue influence ((.111(a)(3) and.111(b)).
* 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](http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.116#46.116).See Appendix C for Consent Requirements.
* Vulnerable populations. The IRB should be particularly cognizant of the special problems of research that involves subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons. Additional protections or conditions may be required.

3.3 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 the IRB staff via Mentor. This communication will remind researchers that they must complete a continuing review form or annual administrative review form within the specified timeframe, and that adverse events must be reported to the IRB within 10 days of the event.

3.4 Continuing Review: Within one year of approval or the timeframe established by the IRB, PIs must complete and submit a continuing review request within the Mentor system. Continuing review of research will follow the same procedure as the initial review.

* Per .109(f)(1)(i), formal Continuing Reviews (CRs) are no longer required for protocols originally approved via the exempt or expedited review processes, unless a reviewer explicitly justifies why the review would enhance protection of research subjects. This determination will be made on a case-by-case basis. The Institute will still require a modified administrative review, to address internal controls.
* The Institute will still require PIs to submit a modified administrative report on an annual basis, to address internal controls.
* Continuing reviews may also be waived in favor of the modified administrative report for protocols, including those with greater than minimal risk, whereby the only ongoing study activities include 1) data analysis and/or 2) accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care;

It is the responsibility of the IRB and/or assigned IRB reviewer to document the rationale for conducting a full continuing review for a protocol that would not otherwise require this action.

3.5 Protocol Amendment: Prior to implementing any changes to the approved protocol, informed consent forms, or any overall protocol, 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. The IRB must approve any changes to the current study protocol before they are implemented, except when necessary to eliminate an apparent immediate hazard to subject(s).

The administrator will evaluate the proposed changes to determine if they are minor changes that could be approved by expedited review (see 45 CRF 46.111) or if they are more substantial changes that require full committee review and approval. Minor changes might include updates in informed consent language that help explain the information provided, changes that entail no further risk or impose no additional burden on the study subjects, changes that increase the potential or actual benefits to subjects without increasing the potential for undue influence, and certain administrative-only changes.

In cases that require full committee review, the administrator will determine if the research should be interrupted until the full committee can review and approve the changes. If the research is interrupted, the administrator and the IRB committee will make every effort to convene and promptly review the changes. In any case, the changes cannot be implemented without the written approval of the IRB. The IRB reserves the right to randomly audit projects to ensure that no protocols have been implemented without its prior review and approval.

3.6 Problems, Adverse Events, and Noncompliance: The IRB requires that problems, adverse events, and noncompliance be reported immediately (within 10 days) to the IRB, using the “adverse events” tab available in each protocol record in Mentor. PIs, study personnel, and others may also report any of these instances using the Institute’s anonymous reporting service, Lighthouse. The administrator will evaluate the reported problems to determine the gravity of the risk to human subjects or others and the steps that must be taken to address the situation. The administrator may need to act immediately without convening the IRB to protect human subjects or others. In such cases the administrator will notify the chair and the full committee about the problem, the immediate steps that were taken, and will alert the Institute’s Management Compliance Committee. In such cases, the Institute’s IRB chair may be asked to participate in the discussion. Please see **Adverse Events/Noncompliance/Conflict of Interest Determination Group (Section 5.4**) for further information.

**SECTION 4: IRB MEMBERS**

**See Appendix A**

**SECTION 5: IRB ADMINISTRATIVE PROCESSES**

**Administrative Processes**

Responsibilities of IRB Administrator(s)

5.1. 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. The Administrator is also responsible for the Institute's compliance with all federal regulations, state and local laws and institutional policies that are applicable to research involving human subjects. Per section .108, IRBs must maintain an accurate list of IRB members, and each IRB shall have access to meeting space and sufficient staff to support the IRB’s review and recordkeeping duties.

5.2. 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 serves as a means of providing the investigator with recommendations for corrections and improvements in order to protect the rights and welfare of research participants.

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

1) Studies involving procedures that present 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 the files associated with the protocol, and contact the 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 within the time frame determined by the IRB administrator. The IRB administrator follows up with the Investigator to ensure that 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).

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

If a PI identifies an adverse event, instance or instance(s) of noncompliance, or conflict of interest to the IRB administrator(s) via Mentor, or if during a routine audit an issue of noncompliance or conflict of interest is discovered, it will be assigned to the Institute’s Management Compliance Committee for review and evaluation. It is also the responsibility of the Administrator to notify the IRB chair of any reports.

The Institute’s Management Compliance Committee 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 committee may request that the IRB Chair provide an assessment, analysis or recommendation prior to completing the final determination. The subcommittee will ultimately evaluate the event, make a determination of type (see below), and suggest an appropriate corrective action.

1. Type I

* Type IA: Adverse Event (AE).
* Type IB: Unanticipated problems involving risks to subjects or others (UP).
  + Often warrant substantive changes in the research protocol or informed consent process/documents; or
  + Other corrective actions in order to protect the safety, welfare, or rights of subjects or others.

1. Type II.

* Type IIA: Noncompliance (NC).
* Type IIB: Serious noncompliance (SNC).
* Type IIC: Continuing noncompliance (CNC).

3. Type III: Protocol deviation(s)

(Please see definition section for further information)

5.6 Determinations: If there is an unanticipated problem/conflict/issue of noncompliance *involving risks to participants or others* as defined by this policy, the convened Management Compliance Committee will vote and record the rationale for any corrective action in its meeting minutes. The committee will evaluate the unanticipated problem/adverse event or noncompliance and determine if the research should be immediately suspended or if suspension would result in more harm than allowing research to continue until the situation is resolved. The priority will be taking the immediate, necessary steps to protect the subjects. After this, the IRB administrator will gather evidence to evaluate responsibility and determine what actions are needed to ensure the risk is mitigated and to prevent further risk. If there is evidence to indicate responsibility for unanticipated risks, or serious or continuing noncompliance, the IRB can take a range of possible actions against the responsible parties, depending on the seriousness of the issue and the cooperation of the investigators. These actions range from working with the involved individuals in order to resolve the current situation to terminating the research and restricting participation in future human research activities that involves the department.

5.7 Possible penalties for misconduct include:

* + Suspension of all PI’s active research protocols. Duration etc. to be determined by the compliance officer;
  + Termination of all PI’s active research protocols;
  + Suspension of future research activities (and IRB approval) at the Institute.

If the compliance officer fails to take appropriate action, the matter will be referred to the President. If the President fails to take appropriate action, the matter will be brought to the Chair of the Board of Directors. If appropriate action is not taken 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.

5.8 Reporting: The IRB administrator is responsible for reporting:

1) Unanticipated problems involving risks to subjects or others and unexpected adverse events;

2) Serious or continuing noncompliance with 45 CFR 46, 21 CFR 50 and 21 CFR 56 or the requirements or determinations of the IRB, and/or

3) Any suspension or termination of IRB approval to the Institute’s Compliance Director, any supporting Agency or Department Heads, and OHRP, if federally funded.

[**SECTION 6: HIPAA**](#_top)

6.1 Privacy Rule and Research: The Institute’s IRB also serves as the Health Insurance Portability and Accountability Act (HIPAA) privacy board. As such, the IRB reviews requests for waivers of authorization to use protected health information (PHI) for research purposes. 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.

Please see Appendix H-HIPAA Guidance for Institute Researchers

**SECTION 7: SHARING RESEARCH DATA WITH EXTERNAL PARTNERS**

7.1 Sharing Data with External Research Partners

If an Institute PI plans to share data with an external partner(s), s/he must utilize one of the approved pathways outlined below. The PI will request permission to share data via one of these options in the IRB application. Data shared without the appropriate documentation or secure method in place will be considered protocol noncompliance.

7.2 Approved pathways for sharing research data with external partners

* InstituteLink: allows external co-PIs to review patient charts in the Institute’s EHR through a web-based portal. This option will only approved in very limited circumstances, as it allows access to the patient record and requires significant oversight.
* Direct but limited access (CAG/Epic): allows external PIs to directly log into the Institute’s EHR. This option will only approved in very limited circumstances, as it allows access to the patient record and requires significant oversight.
* Secure File Transfer: No direct access to the EHR, but allows an Institute employee to safely and securely transmit research data (e.g. in an excel file) to an external partner through SFTP or other approved method. This is the most commonly used scenario, and the most likely to be approved.
* Device: If an Institute-owned device is available, external co-PIs may go through the full volunteer clearance process and as-needed, be granted access to Epic, Crytal reporting, Reporting workbench, and the share drive.

7.3 Business Associates Agreement (BAA) and Data use agreements (DUA): 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 BAA and/or a data use agreement (DUA). Templates for both the BAA and DUA are available in the Mentor system.

**DEFINITIONS**

**Adverse Event (AE**)—Any untoward or unfavorable occurrence including any abnormal sign symptom or disease, temporarily associated with participation in the research. This encompasses both physical and psychological harm. AEs sometimes necessitate changes to the protocol. They must also be reviewed so that a determination can be made as to whether the AE is **also** an UP. Most AEs, however, do not qualify as UPs. Adverse events that are not UPs do not need to be reported to OHRP.

**Children —** Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

**Clinical trial —** Defined by OHRP as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

**Continuing noncompliance (CNC) —** Indicates a pattern of noncompliance, compromises the integrity of the study data, and persists after the investigator knew or should have known about it.

**De-identified data set—**The following identifiers must be removed to create de-identified data:

1. Names

2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code if a) the geographical unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people or b) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such ages and elements may be aggregated into a single category of age 90 or older.

4. Telephone numbers

5. Fax numbers

6. E-mail addresses

7. Social security numbers

8. Medical record numbers

9. Health plan beneficiary numbers

10.  Account numbers

11. Certificate/license numbers

12. Vehicle identifiers and serial numbers, including license plates

13. Device identifiers and serial numbers

14. Web universal resource locators (URLs)

15. Internet protocol (IP) address numbers

16. Biometric identifiers, including fingerprints and voiceprints

17. Full-face photographic images and any comparable images

18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

**Documentation —** “Documentation” in 46.117 means obtaining the signature of subjects (or authorized representatives) on consent forms. Documentation in this context does not refer to a record of whether the consent process has taken place. This is a longstanding unique regulatory use of the word “documentation.”

**Exempt —** Research that is considered exempt from the federal regulations on the protection of human subjects; this type of research meets the definition of human subjects research but meets the criteria of one of the six exempt study designs.

**Generalizable Knowledge—** data or outcomes will result in universally or widely application information; results are expected to apply to a larger population beyond the site of data collection or population studied.

**Human subject—**living individual about whom an investigator obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information. A survey that only collects information about an institution or organization would not obtain information about a living individual. If any information about the individual (e.g. the respondent’s title, age, opinions, etc.) is also obtained, the research involves human subjects.

**Intervention**—means both physical procedures (e.g. collection of blood pressure, blood draw) by which data are gathered (for example, venipuncture) and manipulations of the subject or subject's environment (e.g. watching a movie, listening to music, playing a video game) that are performed for research purposes

**Interaction—**includes communication or interpersonal contact between investigator and subject, e.g. online surveys, telephone interviews, focus groups.

**Limited Data Set**—For data sharing purposes, limited-data sets are considered PHI by the Institute. The following identified must be removed in order to meet the criteria:

1. Names

2.  Postal address information, other than town or city, State, and zip code

3.  Telephone numbers

4.  Fax numbers

5.  E-mail addresses

6.  Social security numbers

7.  Medical record numbers

8.  Health plan beneficiary numbers

9.  Account numbers

10.Certificate/license plate numbers

11. Vehicle identifiers and serial numbers

12. Device identifiers and serial numbers

13. Web URLs

14.  Internet Protocol (IP) address numbers

15. Biometric identifiers, including fingerprints and voiceprints

16.  Full-face photographic images and any comparable images

**Minimal risk—** Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

**Noncompliance (NC)—**Failure to comply with the research plan, regulations, or institutional policies and procedures. Any deviation from the IRB-approved protocol is considered NC. An outcome or event is often considered noncompliance if/when the deviation occurred due to any action or non-action on the part of the study team.

**Protected health information (PHI) —** For these purposes, PHI includes all individually identifiable health information. Individually identifiable health information” is information, including demographic data, that relates to: 1) the individual’s past, present or future physical or mental health or condition, 2) the provision of health care to the individual, or 3) the past, present, or future payment for the provision of health care to the individual, and that *identifies the individual or for which there is a reasonable basis to believe it can be used to identify the individual.* Individually identifiable health information includes many common identifiers (e.g., name, address/zip code, birth date, Social Security Number). For a list of all of the identifiers, please refer to the [NIH's privacy page.](https://privacyruleandresearch.nih.gov/pr_08.asp)

Principal Investigator (PI) **—** The lead scientist for a particular research project. In general, the principal investigator is the person who takes direct responsibility for the design and conduct of the research, and the individual with the greatest responsibility for the protection of human subjects involved in research.

**Protocol deviation (PD)—** Any change, divergence, or departure from the study design or procedures of a research protocol that is under the investigator control that has not been approved by the IRB and does not impact subject safety, compromise the integrity of study data and/or affect subject willingness to participate in the study. *In certain scenarios, a PD may need to be reported to IRB, but may not be considered noncompliance, if the deviation occurred due to the actions of someone outside of the study team (e.g. lab tech forgot to complete a required test, but lab tech is not study personnel).*

**Serious noncompliance (SNC**)—Increases risk to subjects, decreases potential benefits, has a substantive effect of value of data collected, OR results from willful misconduct of the study team. Generally, OHRP considers the following incidences to be serious:

* Non-exempt human subjects research conducted without IRB review and approval, particularly when greater than minimal risk;
* Human subjects research conducted without appropriate informed consent, when consent could not be waived;
* Substantive changes to IRB-approved research without IRB approval;
* Incidences determined to be serious by the IRB.

**Systematic Investigation**—Activity that 1) attempts to answer a pre-set research question; 2) is methodologically driven (e.g. collects data or information in an organized and consistent way); 3) data or information is be analyzed; 4) conclusions are drawn from the results.

**Unanticipated problems** **involving risks to subjects or others (UP)** **—** Unanticipated problems often require changes to the protocol, consent, or procedures. They may also require increased monitoring of subjects, and sometimes lead to suspension in IRB approval. UPs must be reported to OHRP (and FDA, if relevant) if the project is receiving federal funds. OHRP considers UPs to include incidents that meet all of the following three criteria:

1. Unexpected: problems are unexpected in terms of nature, severity or frequency given the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB) approved research protocol and informed consent document and the characteristics of the subject population being studied. Also, an event that occurs and is not consistent with either:
   1. Known or foreseeable risks described in study documents; OR
   2. Unexpected natural progression of underlying condition and subject’s risk factor profile.
2. Related: Must be at least partially caused by (or possibly caused by) the research procedures; **AND**
3. Risk: Suggests that the research places subjects or others at greater risk of harm than was previously known, whether the harm is:
   1. Physical
   2. Psychological
   3. Economic
   4. Social