PITTSBURG STATE UNIVERSITY

POLICY ASSURANCE HANDBOOK

for

THE PROTECTION OF HUMAN RESEARCH SUBJECTS

Revised November 2023

Contents

List of Revisions

Nov 2023: ***Updated*** Exempt category 2 to reflect feedback from OHRP
Updated/Added Various material to reflect *Institutional Review Board Written Procedures: Guidance for Institutions and IRBs (2018)* (https://www.hhs.gov/ohrp/regulations-and-policy/guidance/institutional-issues/institutional-review-board-written-procedures/index.html)
Added Digital policies section
Added sIRB policy

Oct 2022: ***Added*** *Procedure for Protocol Amendment*
Updated *Procedure for Continuing Review of Exempt Applications*

Apr 2022: ***Added*** Procedure for recording of non-research activity communications, procedure for external review

Feb 2022: ***Updated*** Definitions of Research & Quality Improvement Project

Changes approved via email 02/2022

Feb 2021: ***Added*** Human Subjects Research and Quality Improvement Project descriptions, added revision cycle, added Incident Reporting and Suspension/Termination procedures, added Passive Consent Policy, added FERPA/PPRA policy.

Updated Exempt/Expedited/Full/Continued Review descriptions to match 2018 Common Rule, updated application form names

Changes approved at 04/13/21 full board meeting

Introduction

When an institution engages in research that involves human subjects, that institution has an obligation to protect the rights and welfare of the subjects involved. The federal government has provided guidance to institutions through the Code of Federal Regulations, Subpart A of 45 CFR Part 46: Basic HHS Policy for Protection of Human Subjects.

At Pittsburg State University, review of research involving human subjects is carried out by the Institutional Review Board (IRB), which is responsible to the Provost.

The IRB's responsibility is not to evaluate the quality of research being conducted, but rather to evaluate the adequacy of the protection of the rights and welfare of the human subjects potentially involved in the proposed research.

Administration of Research Ethics at Pittsburg State University

Pittsburg State University (PSU) has established the Institutional Review Board (IRB). The authorized institutional official for this IRB is the Provost of PSU, Pittsburg, Kansas. The University Compliance Officer/Research Integrity Officer is responsible for coordinating IRB activities. The Office of Research Administration and Compliance (ORAC) maintains all IRB records, including meeting agendas and minutes, policies, regulations, forms, reference materials, and protocols. Active IRB-approved individual protocols are maintained for the life of the project. When notification is received that a project has been completed, the files are electronically archived. Sponsored project guidelines shall be followed on record retention. ORAC is responsible for registering the IRB and maintaining IRB registration via the HHS internet-based registration system.

Jurisdiction and Purpose of the IRB

This IRB has been established to review proposed and ongoing research programs in order to comply with policies established by the Department of Health and Human Services Sub-Part A of *45 CFR Part 46* (also known as The Common Rule) and Pittsburg State University for the protection and safety of human subjects used in biomedical and behavioral research. The IRB has the authority to approve, modify, or reject any research activities in accordance with Sub-part A of *45 CFR Part 46*.

This document serves as Pittsburg State University's assurance of protection of human subjects and contains the policies and procedures to be followed by the Institutional Review Board, university departments, faculty, staff, and students when conducting research involving human subjects. Unless otherwise specified, all policies will refer to the Revised Common Rule which took effect January 21, 2019.

The IRB grants authority to individual Pittsburg State University department heads to determine during the initial application process whether the proposed activity requires review by the IRB according to the definitions of "research" and "human subjects" presented by *45 CFR 46.102(d)(f)*.. Regardless of funding source or support, the IRB is the final institutional authority in determining approval or rejection of all applicable research involving human subjects. No research involving human subjects covered by the PSU Federalwide Assurance (FWA) will be conducted until the IRB has reviewed and approved the research protocol and informed consent requirements *CFR 46.111, 46.116, and 46.117*; because of a need to document research activities involving Human Subjects, this includes research that is Exempt (policies for documenting Exempt research determination are discussed below). Further documentation of Informed Consent content and requirements are contained in the *Application for Review* and *Informed Consent Waiver or Alteration* forms.

All human subjects research conducted or supported by HHS involving pregnant women, human fetuses and neonates (covered in subpart B of *45 CFR 46*), prisoners (subpart C), and most research involving children (subpart D) must be approved by the IRB. Department heads are not authorized to exempt these types of research from review.

Governing Principles of the IRB

The IRB operates in accordance with both *45 CFR 46* and *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects and Research* (1979) regardless of whether the research being conducted is subject to Federal Regulations or with whom the source of support originated.

Pittsburg State University and its faculty, staff, and student body recognize the importance of their responsibility for protecting the rights and welfare of human subjects in research. No human subject involved in a research activity will be exposed to unreasonable risk to health or well-being.

Research involving minors (persons less than 18 years of age), others who may have limited ability to provide informed consent, or which involves greater than minimal risk must be approved by the IRB.

Minimal risk is defined as "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 or routine physical or psychological examinations or tests." (*45 CFR 46.102(i)*)

HHS-conducted or -supported research, research involving children, prisoners, pregnant women, human fetuses and neonates as defined in *45 CFR 46*, Subparts B, C, and D, must be approved by the IRB.

Except for research exempted (see *Review Criteria Form* for exemption criteria) *CFR 46.101(b)* or *46.101(i)*, informed consent will be:

(a) sought from each prospective subject or the subject's legally authorized representative, and to the extent required by 46.116;
(b) appropriately documented, to the extent required by 46.117.

Requests by any human research subject for withdrawal from a research activity will be honored promptly without penalty or loss of benefits to which the subject is otherwise entitled.

Revision Cycle for IRB Documents

As this is intended to be a living document, it should be reviewed by the Full Board at least once every other calendar year. Updates should be made to increase efficiency of the application process and to ensure that the most recent regulations are followed.

All application documents should be reviewed no less than once every other calendar year.

Procedures / Guidelines

Is Research Subject to Review?

The first issue that must be determined is whether the proposed research is subject to the IRB review. This decision can be determined by the following two questions:

1. Does this activity involve research?
2. Does this research involve human subjects?

Research is defined in *45 CFR 46.102(d)* as follows (1):

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

Human subjects are defined as

> *"living individual(s) about whom an investigator (whether professional or student) conducting research obtains*
>
> *a) data through intervention or interaction with the individual, or*
> *b) identifiable private information."*

If the responses to both of the above questions are "Yes," the proposed research is subject to the IRB review.

Additional Definitions

Many projects involve ***Quality or Continuous Improvement Activities*** which do not satisfy the definition of "research" under *45 CFR 46.102(d)*. It will be the responsibility of the IRB to determine whether or not a given project rises to the level of research by using the definition outlined in the Common Rule (described above). This means that a project or study will be considered research when any of the following factors occur:

- The information will contribute to a theoretical framework or an established body of knowledge
- The information will expand the knowledge base of a scientific discipline or scholarly field of study
- The primary beneficiaries of the study are other researchers, scholars, stakeholders, or practitioners in the field of study where the end product may inform daily practices, policy, research design, instruments, devices, data collection methods, or therapies
- Publication, presentation or other distribution of the results are intended to inform the field of study, such as but not limited to: oral presentation (e.g. lecture or conference talk), written presentation (e.g. research article or scholarly book), public display that is made available to persons beyond the University (e.g. conference poster).

- The findings are intended to be replicated in or transferable to other settings.
- The findings are intended to inform a larger study, the design of a device, drug, or biologic, or to aid in future planning of research activities
- Members of the public will likely make inferences from the data being collected.
- Results are intended to be used to develop/test/support theories or principles. This may include pilot work or feasibility studies.

In order to allow tracking and record-keeping of Human Subjects activities on campus, researchers collecting data and carrying out projects involving human subjects are required to submit an IRB application to their department reviewer even if their activities do not constitute research. Upon review of the activity by the department reviewer and acknowledgment of the activity by the IRB, the IRB will maintain a record of the application and the board's decision that a full IRB application was not required.

Identifiable private information includes "information about behavior that occurs in a context in which an individual can reasonably expect that no observation is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record)."

Application for Research Proposal Review Process

The forms used in the application for review process incorporate the requirements and criteria set forth in Federal Policy *45 CFR 46*. The intent of this format is to educate, train, and provide documentation for those involved in the application and review process each time this procedure is followed.

Approval of a study at any level will be based on the expertise of the relevant set or subset of the Board members. Members will consider expert opinion as required; this may be in the form of advice from outside experts, principal investigators, or other Board member expertise. Relevant discussion will be recorded in the form of meeting minutes, email correspondence, or as otherwise appropriate and stored as described later in this document.

Because no two studies are alike, details regarding study specifics will be evaluated on a case-by-case basis in light of relevant sections of HHS regulations, best practices in the field of study, and societal norms. Such details may include but are not limited to:

- Level of risk and mitigation of risk
- Benefits to subjects, selection of subjects, and appropriate level of compensation
- Use of Informed Consent and its application
- Data collection and storage practices

Findings and rationale will be provided with every study decision and may be appealed by the Principle Investigator (PI), which will require approval of the Board.

At any point during its life cycle, the IRB may conduct random audits of approved research to ensure that it is being conducted as outlined in the approved application materials.

Please refer to the following steps and associated flow diagrams from HHS.gov for submitting the research proposal for IRB review.

Exempt Review

Exemption categories DO NOT APPLY when the research activities include any of the following:

- Prisoners, fetuses, pregnant women or human in vitro fertilization
- Survey or interview techniques which include minors (under 18 years of age) as subjects
  - This may be subject to limited review as described below
- Research involving the observation of the public behavior of minors (under 18 years of age)
  - This may be subject to limited review as described below
- The deception of subjects
- Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)

The following categories of human subjects research are Exempt from federal regulations, but still require application and tracking by the IRB. Exempt research categories will be reviewed and approved by the academic unit. For more details, see the *2018 Human Subject Regulations Decision Charts* provided by HHS (https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html) or the list provided on PSU's *Review Criteria Form*. Exemption criteria are met if ONE or MORE of the following applies:

Exempt 1. Research conducted in established or commonly accepted educational settings, involving normal educational practices.

Exempt 2(i). Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior and information obtained is recorded in such a manner that the identity of the human subjects cannot readily be ascertained.

- Research involving children can be classified as exempt under this category only if the research only involves educational tests, or observation of public behavior in which the investigator does not participate in the activities being observed.

Exempt 2(ii). Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior and disclosure of subjects' responses outside research would not reasonably place the subjects at risk.

- Research involving minors can be exempt under this category if it involves only educational tests, or observation of public behavior in which the investigator does not participate in the observed activities.

Exempt 2(iii). LIMITED IRB REVIEW REQUIRED. Research involving use of educational tests, survey procedures, interview procedures or observation of public behavior with information obtained recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained and disclosure of the responses outside the research could reasonably place the subjects at risk. This exemption cannot be applied to research with minors.

Exempt 3(i). Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and information obtained is

recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained.

Exempt 3(ii). Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and disclosure of subjects' responses outside research would not reasonably place the subjects at risk.

Exempt 3(iii). LIMITED IRB REVIEW REQUIRED. Research involving benign behavioral interventions in conjunction with the collection of information from adult subjects and information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained and disclosure of the responses outside the research could reasonably place the subjects at risk.

Exempt 4(i). Secondary research uses of publicly available identifiable private information or biospecimens.

Exempt 4(ii). Secondary research uses of identifiable private information or biospecimen information recorded in a manner that the identity of subjects cannot readily be ascertained.

Exempt 4(iii). Secondary research uses of HIPAA-regulated identifiable private information or biospecimens.

Exempt 4(iv). Secondary research uses of identifiable private information or biospecimens when the research was conducted by or on behalf of a federal department or agency using government-generated or government collected information obtained for non-research purposes that will be maintained according to certain federal privacy standards.

Exempt 5. Federal demonstration projects.

Exempt 6. Taste and food quality evaluation and consumer acceptance studies.

Exempt 7. LIMITED IRB REVIEW REQUIRED. Storage of identifiable information or biospecimens for secondary research use. Broad consent required.

Exempt 8. LIMITED IRB REVIEW REQUIRED. Secondary research use of identifiable information or biospecimens. Broad consent required.

Exempt Application Process:

1. When filling out the form, it is recommended to allow *at least* a week for signatures and review. See the IRB Page on www.pittstate.edu for the most recent documentation.
2. Refer to the *Review Criteria Form* to determine if exemption criteria apply.
3. Complete the *Application for Review* form.
4. Obtain the signature of the department chair or designee. Individuals who sign as reviewers should NOT be involved in the research (e.g. on the thesis committee for student research or co-investigator on faculty research).
5. Send an electronic copy to IRB@pittstate.edu
6. The IRB Chair or designee will assign a document number and will review the application for completeness.
    a. If necessary, the investigator may be asked to provide clarification or additional documentation to ensure a complete application.
    b. If there is disagreement about the Exempt status, a Full Board review may be convened.
7. The document number will be returned to the investigator, and the application will be stored in a central repository along with relevant correspondence.

Limited Review

The provision for limited IRB review allows certain research to be categorized as exempt, even when the identifiable information might be sensitive or potentially harmful if disclosed. In order to qualify for exemption, the study must meet the standards of the limited IRB review. If the information is both identifiable and sensitive or potentially harmful, the safeguards offered by the limited IRB review may allow an exemption determination to be made.

Limited IRB review is required in the following circumstances:

1. Exempt category 2(iii) (educational tests, surveys, interview or observations of public behavior): When the information is recorded by the investigator in an identifiable manner and disclosure of the subjects' responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.
2. Exempt category 3(iii) (benign behavioral interventions): When the information is recorded by the investigator in an identifiable manner and disclosure of the subjects' responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement or reputation.
3. Exempt categories 7 and 8 (broad consent): When investigators plan to store, maintain or use identifiable private information or identifiable specimens collected for non-research purposes and the information/specimens are obtained with a broad consent process.

Purpose of Limited IRB Review

When reviewing the exempt categories 2 and 3, the limited IRB review assures adequate protections for the privacy of subjects and adequate plans to maintain the confidentiality of the data.

When reviewing research involving broad consent under categories 7 and 8, the limited IRB review initially confirms that the elements of broad consent meet federal requirements, that the consent process will be appropriate, that consent is documented as required, and that privacy and confidentiality are protected. When research involving such data or specimens is proposed, the limited IRB review confirms that the proposed secondary use is within the scope of the broad consent.

Reviews Related to Privacy and Confidentiality

In order to assure appropriate protections, the limited IRB review may consider the following topics:

- The nature of the identifiers associated with the data
- The justification for requiring identifiers
- Characteristics of the study population
- The proposed use of the information
- The overall sensitivity of the data being collected
- Persons or groups who will have access to the study data
- The process used to share the data
- The likely retention period for identifiable data
- The security controls in place of physical safeguards for paper records
- Technical safeguards for electronic records
- Secure sharing or transfer of data outside the institution, if applicable

- The potential risk for harm that would occur if the security of the data was compromised.

Individuals Performing Limited IRB Review

Limited IRB review must be performed by the IRB Chair or by an experienced IRB member. The review can occur on an expedited basis and does not require consideration by a convened board. The reviewer may require modifications to the proposal prior to approval. A decision to deny the application can only be made by the convened board. If the limited IRB review does not result in approval under the exempt categories, then the IRB can evaluate whether or not approval is appropriate under the expedited categories. Expedited research must meet all the approval criteria under 45 CFR 46.111, including either informed consent or waiver of consent.

Limited Application Process:

1. When filling out the form, it is recommended to allow *at least* two weeks for review and return of the signed application; more time may be required for complicated applications. See the IRB Page on www.pittstate.edu for the most recent documentation.
2. Determine if Exemption criteria with Limited Review apply to the human subjects research by referring to *Review Criteria Form*.
3. Complete *Application for Review* form.
4. Obtain signature of the department chair or designee. Individuals who sign as reviewers should NOT be involved in the research (e.g. on the thesis committee for student research or co-Investigator on faculty research).
5. Send electronic copy to IRB@pittstate.edu
6. The IRB Chair or designee will assign a document number and reviewer(s)
7. A decision will be returned as soon as is practicable. A decision can be:
    a. Acceptance of proposal. A signed copy of application will be returned to the investigator and stored in a central repository with appropriate correspondence.
    b. Request for more information
    c. Recommendation for full board review

Expedited Review

Determine if criteria for expedited review apply to the human subjects research by referring to *Review Criteria Form* or the list below.

Expedited criteria DO NOT APPLY when the research activities include any of the following:

- Prisoners, fetuses, pregnant women or human in vitro fertilization
- Surveyor interview techniques which include minors (under 18 years of age) as subjects
- Research involving the observation of the public behavior of minors (under 18 years of age)
- The deception of subjects
- Techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life (the research activity presents more than minimal risk to human subjects)
- Identification of subjects/responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate

protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- Classified research involving human subjects.

Expedited criteria are met if ONE or MORE of the following applies (from HHS.gov):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   (a) Research on drugs for which an investigational new drug application is not required.
   (b) Research on FDA-regulated medical devices for which
      i. an investigational device exemption application is not required; or
      ii. the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling (for more information refer to Significant Risk and Nonsignificant Risk Medical Device Studies: Information Sheet (fda.gov)).
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or
   (b) from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   (a) hair and nail clippings in a nondisfiguring manner;
   (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   (c) permanent teeth if routine patient care indicates a need for extraction;
   (d) excreta and external secretions (including sweat);
   (e) un-cannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue;
   (f) placenta removed at delivery;
   (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
   (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   (j) sputum collected after saline mist nebulization.
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared

medical devices for new indications.) Examples:

(a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy;
(b) weighing or testing sensory acuity;
(c) magnetic resonance imaging;
(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). (NOTE: This listing refers only to research that is not exempt.)
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: This listing refers only to research that is not exempt.)
8. Continuing review of research previously approved by the convened IRB as follows:
   (a) the research is permanently closed to the enrollment of new subjects **AND** all subjects have completed all research-related interventions **AND** the research remains active only for long-term follow-up of subjects; **OR**
   (b) where no subjects have been enrolled and no additional risks have been identified; **OR**
   (c) where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Expedited Application Process:

1. When filling out the form, it is recommended to allow *at least* two weeks for review and return of the signed application; more time may be required for complicated applications. See IRB Page on PittState.edu for most recent documentation.
2. Determine if expedited criteria apply to the human subjects research by referring to the *Review Criteria Form*.
3. Complete the *Application for Review* form, which includes guidelines for Informed Consent.
4. Obtain signature of the department chair or designee. Individuals who sign as reviewers should NOT be involved in the research (e.g. on the thesis committee for student research or co-Investigator on faculty research).
5. Send electronic copy to IRB@pittstate.edu

6. The IRB Chair or designee will assign a document number and a minimum of 2 reviewers
7. A decision will be returned as soon as is practicable. A decision can be:
    a. Acceptance of proposal. A signed copy of application will be returned to the investigator and stored in a central repository with appropriate correspondence.
    b. Request for more information
    c. Recommendation for full board review

Full Review

Determine if full review criteria apply to the human subjects research by referring to the Review Criteria Form or the criteria listed below.

Full review criteria are met if ONE or MORE of the following applies:

- Research in which more than minimal risks are involved (techniques which expose the subject to discomfort or harassment beyond levels encountered in daily life)
- Research in which identification of subjects/responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are not greater than minimal.
- Research involving prisoners, fetuses, pregnant women, or human in vitro fertilization
- Research involving survey or interview techniques which include minors (individuals under 18 years of age) as subjects
- Research involving the observation of the public behavior of minors (individuals under 18 years of age)
- Research involving the deception of the subjects
- Research which compromises informed consent
- Research which involves the use of information that is not publicly available such as student records or medical charts. Even if the researcher has routine access to such records, if individual identifiers are included in these records, they must be reviewed by full committee.
- Research involving vulnerable populations such as mentally disabled persons or economically or educationally disadvantaged persons

Full Review Application Process:

1. When filling out the form, it is recommended to allow *at least* 60 days for review and return of the signed application; more time may be required for complicated applications and the application could be delayed until future Full Board meetings are convened. See the IRB Page on www.pittstate.edu for most recent documentation.
2. Determine if Full Review Criteria apply to the human subjects research by referring to the *Review Criteria Form*.
3. Complete the *Application for Review* form, which includes guidelines for Informed Consent.
4. Obtain signature of the department chair or designee. Individuals who sign as reviewers should NOT be involved in the research (e.g. on the thesis committee for

student research or co-Investigator on faculty research).
5. Send electronic copy to IRB@pittstate.edu before the first Tuesday of the month during the Fall or Spring Semesters.
6. The IRB Chair or designee will assign a document number, and the review will be added to the next regular monthly meeting of the board during fall or spring semesters; check the IRB page at www.pittstate.edu for specifics); Full Boards will be convened over the summer on an ad-hoc basis. Meetings may be attended virtually as required.
7. The Principal Investigator is encouraged to attend the meeting of the board to provide necessary background or clarification.
8. A decision will be returned at the conclusion of the meeting. A decision can be:
    a. Acceptance of proposal. A signed copy of the application will be returned to the investigator and stored in a central repository with appropriate correspondence.
    b. Request for more information
    c. Denial of proposal with justification

Protocol Amendment

In the event that minor changes are required prior to the expiration of a study, the Investigators may fill out the *Protocol Amendment form* to describe the changes. This form may NOT substitute for a Continuing Review (discussed below), but may be used to modify study details such as a short extension to the expiration date, addition of research personnel, removal/addition of a research site, etc. Studies at any level of initial review (Exempt, Expedited, Full, etc.) may be amended; however, an amendment cannot override any requirements that necessitated a certain level of review. For example, a study that was initially reviewed by the Full Board cannot be subsequently reviewed as Exempt unless the criteria requiring the Full review have been removed.

Researchers may not initiate changes to research without prior IRB review and approval unless doing so would immediately prevent harm or hazards to subjects; in emergent cases such as this, the changes must be reported to the IRB as soon as practicable using any means appropriate (phone call, email, or other Incident Reporting procedures outlined in this document). IRB may – at its discretion – conduct random audits of approved protocols to ensure compliance.

In addition to the form, the original application materials must be submitted for review along with any new pertinent information. The Protocol Amendment form may be submitted to IRB@pittstate.edu at any time and may be reviewed on an *ad hoc* basis, but may require review by the Full Board at the next scheduled meeting.

Continuing Review

In conducting continuing review (at intervals appropriate to the degree of risk, but not less often than once a year), the IRB must ensure the same criteria used for approval during the initial review are satisfied for subsequent reviews. These criteria include risk to subjects, potential benefits to subjects and society, informed consent, and safeguards for human subjects. Continuing review constitutes review of the entire research protocol, not just changes in protocol. Continuing review may also apply to studies initially approved as Exempt if they are proceeding outside of their initially reviewed completion date, or as otherwise specified by the IRB. In the event that a complex project is up for continuing review, the IRB may enlist external source matter experts to confirm that no substantial changes have taken place and that the protocol is still representative of the research taking

place.

Federal regulations require that all research projects approved by IRB are monitored annually as a minimum (continuing review.) It is the principal investigator's responsibility to ensure continuing review is conducted by the project anniversary date. Continuing Review applications and instructions are located on the IRB website. Projects not reviewed by IRB annually will be designated as inactive and approval will be suspended.

Research projects which have been completed prior to the annual anniversary date do not need to go through the continuing review process. However, IRB must be notified that the research project has been completed.

In general, if research did not qualify for expedited review at the time of initial review, it does not qualify for expedited review at the time of continuing review. However, the expedited review process (assigning two IRB members for review versus the full committee) may be used for continuing review of research that was previously approved by the full IRB as follows:

Where:

- the research is permanently closed to the enrollment of new subjects;
- the subjects have completed all research-related interventions; and
- the research remains active only for long-term follow-up of subjects;

OR Where no subjects have been enrolled and no additional risks have been identified;

OR Where the remaining research activities are limited to data analysis.

Cooperative Research Involving PSU and Other Institutions

The revised Common Rule requires federally funded cooperative research to rely on a single Institutional Review Board (IRB) for study review and approval across all participating sites in the United States. Exceptions to this policy are allowed for:

- Cooperative research where more than one IRB review is required by law (including tribal laws passed by official governing bodies of American Indian or Alaska Native tribes).
- Research for which any federal department or agency supporting or conducting the research determines and documents that using a single IRB is not appropriate for the research context.

Definitions:

Reliance Agreement: A formal, written contract between two organizations outlining each party's authority and responsibilities in ensuring ethical oversight of human subjects research.

Relying Institution: The institution ceding responsibility for IRB oversight and approval to the reviewing IRB under the terms of the Reliance Agreement.

Reviewing Institution: The institution assuming responsibility for IRB oversight and approval under the terms of the Reliance Agreement.

Relying IRB: The IRB of the Relying Institution.

Reviewing IRB: The IRB of the Reviewing Institution.

Site Principal Investigator (Site PI): The lead investigator at each institution participating in multisite research.

Lead Principal Investigator (Lead PI): The study wide lead Principal Investigator with ultimate responsibility for the conduct and integrity of multisite research.
Reviewing IRB: The IRB which is responsible for conducting IRB review and approval as described in 45 CFR 46.109 for cooperative human subject research.

A single IRB is not required for:

- research determined to be Exempt by the IRB.
- research funded by non-federal entities or unfunded research.
- foreign sites that are participating in the same cooperative research as domestic sites.
- federally funded research meeting the exceptions provided by the revised Common Rule.

If exempt research is to be carried out at more than one site, a separate application should be submitted to each site's IRB by the local investigators involved in the project. However, a Reliance Agreement will be considered if it is deemed appropriate by the PSU IRB or is required by an external research site. Also, if the research project involves both exempt and non-exempt protocols, a Reliance Agreement will be necessary.

Procedures for non-exempt projects:

At least a month before the next scheduled meeting of the IRB, a PSU investigator who expects to enter a cooperative research project involving another institution(s) or who expects to submit a proposal for federal funding that involves human subjects research at more than one site must consult with the PSU IRB about the project. The consultation will be used to determine whether PSU is willing either to serve as the single IRB of record or cede IRB review to an external IRB. If PSU is requested to serve as the Reviewing Institution, it may not always be feasible, in which case a letter can be drafted ceding review to another institution, provided the external reviewing IRB appears capable of carrying out enforcement of the Common Rule.
Following the consultation, a *PSU External IRB Collaboration Form* must be submitted to the IRB providing the information in the following categories:

- Contact information for the site principal investigator.
- Contact information for the cooperating institution.
- Identity of the lead principal investigator.
- The nature of the relationship between institutions.
- Which institution should be designated as the reviewing institution.
- The roles of PSU investigators and investigators at the external institution(s).
- Ethics training and supervision of investigators at the external site.
- Special considerations.

If the PSU IRB agrees to be the Reviewing IRB:

- A separate collaboration form must be submitted for each relying institution.
- The *collaboration form(s)* must be accompanied by *an Application for Review* (or *Protocol Amendment* review for previously approved protocols) with supporting documentation.
- Each relying institution must agree to cede to the PSU IRB.
- All research conducted at relying institutions must adhere to PSU IRB policies as well as local policies, procedures, and local laws for the relying institution(s).

- Consent forms, information forms, and recruitment forms used at relying institutions must also meet PSU requirements.

If PSU will cede review to an external institution

- The collaboration form(s) must be accompanied by a copy of the approved protocol from the reviewing IRB.
- PSU investigators must meet all PSU ethics training requirements.
- The reviewing institution may charge each relying institution a review fee. The PSU investigator must have sufficient funding for this fee (if it is assessed).

After all materials are received and approved, a reliance agreement must be executed between the coordinating institutions.

External Researchers Wishing to Conduct Research on the PSU Campus

If an external investigator or organization wishes to recruit participants from the PSU campus or conduct research on PSU campus, the research must either be sponsored by a PSU representative, or a PSU investigator must be participating in the research. The PSU representative must fill out the *External IRB Collaboration* form and include all relevant information including, but not limited to: An approved research protocol, ethics training records (e.g., CITI Training completion certificates) for research personnel, and contact information for the IRB at the partner institution (if available).

If the research is not otherwise approved, a completed PSU IRB application must be submitted along with the collaboration form, which will be approved prior to granting of the collaboration. If the study is not considered research (i.e., is a quality improvement project), documentation of that finding should be included or obtained.

If the PSU sponsor is NOT participating in the research, the requirement for ethics training may be waived; however, there must be someone on the project with appropriate ethics training, and if the PSU representative is participating in any way (e.g., handling the data, interacting with participants, etc.), the PSU representative must also have documented ethics training.
Upon receipt of a completed collaboration form, the Board will review the application on an ad hoc basis and a decision will be returned to the PSU representative. A decision can be:

a. A reliance agreement must be executed between the external researcher's organization and PSU.
b. Approval of the external researcher's protocol without a reliance agreement between the external researcher's organization and PSU.
c. Request for more information, possibly at a convened meeting.
d. Denial of proposal with justification.

If the external researcher's protocol is approved (along with a reliance agreement between PSU the cooperating institution(s), if required), An official letter from the Board will be returned to the investigator and all documentation will be stored in a central repository with appropriate correspondence.

Informed Consent

Investigators should refer to the Informed Consent guidelines included in the *Application for Review* document. This guidance includes a checklist derived from HHS regulations to help

ensure that all elements are accounted for. Such elements include but aren't limited to: process for collecting and maintaining consent/assent from subjects, waiver or alteration requirements, required statements and explanations, compensation, and contact information.

The regulations require that key information essential to decision making appear at the beginning of the consent document and that it be presented first in the consent discussion; this is intended to ensure that this information is perceived as a priority. The term "key information" is not defined, but examples of key information include:

- That consent is being sought for research.
- That participation is voluntary.
- The purposes of the research, the expected duration of participation, and the procedures to be followed.
- The reasonably foreseeable risks or discomforts.
- The benefits to the participant or to others that may reasonably be expected from the research.
- Appropriate alternative procedures or treatments that may be available to the prospective subject.

Since no two studies are alike, informed consent will be reviewed on a case-by-case basis by the Board based on the most recent guidance from HHS and will be conducted using the combined expertise of the entire Board at the level appropriate to the type of study (i.e. Full vs. Expedited). If applying for Continuing Review, informed consent will be reviewed in light of any relevant changes to the protocol as required; no revision may be necessary but will be considered on a case-by-case basis.

Research in Emergency Settings

Federal regulations allow expanded access or treatment use of certain research activities when more than minimal risk is involved to be conducted in emergency settings and include human subjects who are unable to consent for themselves, the purpose being to help facilitate potentially lifesaving and life-enhancing research while maintaining the rights and welfare of the subjects. It is important to note that the IRB "approval" is not given for use of an unapproved drug; however, regulations allow use of the drug without prior IRB review. The IRB requires that investigators provide prior notification of intent to use the drug/device/biologic, so it can review the proposed use.

Research in emergency settings will fall under either FDA regulations if it involves FDA regulated drugs (*21 CFR 56)*, biologics (*21 CFR 601*), devices (*21 CFR 812*), emergency use of a test article (*21 CFR 50*), or if it involves a Humanitarian Use Device (HUD, *21 CFR 814.100*), or OHRP requirements - almost identical to the FDA regulations - if it involves non-FDA regulated research (see *Informed Consent Requirements in Emergency Research (OPRR Letter, 1996)*, https://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html).

The IRB - with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation - may allow an investigation to proceed without requiring informed consent from all research subjects, provided that the each of the following is documented according to *21 CFR 50.24*:

1. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
2. Obtaining informed consent is not feasible because:
    a. The subjects will not be able to give their informed consent as a result of their medical condition;
    b. The intervention under investigation must be administered before consent from the subjects' legally authorized representatives is feasible; and
    c. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
3. Participation in the research holds out the prospect of direct benefit to the subjects because:
    a. Subjects are facing a life-threatening situation that necessitates intervention;
    b. Appropriate animal and other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects; and
    c. Risks associated with the investigation are reasonable in relation to what is known about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
4. The clinical investigation could not practically be carried out without the waiver.
5. The proposed investigational plan defines the length of the potential therapeutic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, to asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with § 50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is feasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (a)(7)(v) of this section.
7. Additional protections of the rights and welfare of the subjects will be provided, including, at least:
    a. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
    b. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;
    c. Public disclosure of sufficient information following completion of the clinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
    d. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and

e. If obtaining informed consent is not feasible and a legally authorized representative is not reasonably available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.

Furthermore, documentation should be provided of the procedures in place to inform the subject/legally authorized representative/family member of the subject's inclusion in the clinical investigation and any information that would have otherwise been outlined in the informed consent document. Such information includes, but isn't limited to:

A. that he or she may discontinue the subject's participation at any time without penalty or loss of benefits.
B. that if a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible.
C. that if a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.

Finally, the FDA requires that protocols such as this be performed under a separate investigational new drug (IND) application or investigational device exemption (IDE) and be clearly identified as such. The application must point out that the study may include subjects who are unable to consent. The submission of those separate IND/IDE protocols is required even if an IND/IDE for the same drug product or device already exists. Documentation of unique IND/IDE must be provided as part of the Application for Review.

If the IRB denies the application, the IRB will provide relevant feedback to the investigator promptly in writing; the investigator will then share it with the sponsor of the clinical investigation, the FDA, the sponsor's participating clinical investigators, and other IRBs involved in the research. All documentation will be retained by the IRB for at least 3 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by the FDA.

Suspension or Termination of IRB Approval of Research

The Full Board has the authority to terminate or suspend approval of research in the following situations:

- The research is not being conducted in accordance with regulations or PSU requirements (e.g. when discovered during a random audit)
- The research has been associated with unexpected serious harm to human subjects
- Suspension or termination has been initiated by an investigator or other outside entity

The IRB shall promptly report to the investigator any suspension or termination of approval of research for cause. The report shall include statement of the reason for the IRB's action, and shall be sent to the investigator, the appropriate supervisors and the Institutional Official,

and to the Office for Human Research Protection (OHRP) and other federal agencies as appropriate for federally funded research.

During the suspension of a research project, the current principal investigator may be permitted by the IRB to continue overseeing the participants until the suspension is lifted or until all participants have been safely withdrawn. However, if necessary, the IRB may mandate modifications to the oversight of the research project to ensure that the suspension or termination procedures are conducted in an orderly and compliant manner. The IRB has the authority to:

- Assign the responsibility of overseeing the remaining research activities to another investigator
- Demand independent monitoring for participants
- Transition participants to standard clinical care

Investigator Responsibilities:

The investigator will:

- suspend research activities as required in the notification until notified that the Full Board has approved resumption of the research activities, or in the case of termination, cease related research activities immediately.
- Provide notification to research subjects of the suspension or termination as described by the IRB.
- Report any adverse events or unanticipated problems involving risk to subjects or others that may occur while the research activities are suspended.
- Complete all corrective action(s) as required by the IRB.
- Consider additional actions that may be necessary to protect the rights and welfare of study subjects; for example, arranging for medical care outside of the study.

IRB Responsibilities:

The IRB will:

- Review any suspension or termination initiated by the sponsor or other outside entity.
- Notify the investigator that research activities have been suspended or terminated; the notification will include rationale for the decision.
- Direct the investigator to undertake corrective action as appropriate.
- Direct the investigator to provide notification to research subjects as appropriate.
- Review reports of unanticipated problems involving risks to subjects or others during the time in which research is suspended for cause.
- Report any actions to the Institutional Official and to regulatory agencies as appropriate. (Descriptions of actions taken are described below in *Incident Reporting.)*
- Consider actions to protect the rights and welfare of study subjects.

Unanticipated Problems and Adverse Events:

Any research that results in an unanticipated problem, an adverse event, or a complaint by a human subject or the subject's legally authorized representative must be promptly reported to

the IRB by the investigator. HHS.gov defines an ***Unanticipated Problem*** as [3]:

> *"…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 (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved 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."*

While an ***Adverse Event*** is defined as [3]:

"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."

Incident Reporting

Per 45 *CFR 46.103(a)* and *(b)(5)*, which require that institutions have written procedures to describe the reporting process for incidents that occur during research, this section lists the steps that will be taken.

Every application should include contact information for both the Principal Investigator and the IRB should the study participants wish to lodge a complaint, report problems or concerns about the study, or simply to ask additional questions about their rights as a research subject. Not all contacts with subjects will require Board review; however, events which require reporting include:

- Any unanticipated problems involving risks to subjects or others;
- Any serious or continuing noncompliance with this policy or the requirements or determinations of the IRB; and
- Any suspension or termination of IRB approval.

If the incident is witnessed by a member of the research team (e.g. principal investigator, graduate assistant, student worker, etc.), a study participant, or any member of the public, the event should immediately be reported to the IRB. Reports can be made to any member of the committee; however, for traceability and record-keeping purposes it is preferred to contact via the email IRB@pittstate.edu or by calling the director at the number on the PSU web page. The IRB will make all reasonable efforts to ensure that the reporting individual remains anonymous, except where required by federal regulation.

Once an incident is reported, or if the incident is observed by a member of the IRB, the board will contact the PI and instruct them to cease all research activities until further notice. The

incident will be discussed at the next Full Board meeting, which may be convened as a special meeting, depending on the severity of the incident. There is no defined time frame for reporting of incidents in the federal regulations other than to say "promptly" and that

> *"For a more serious incident, this may mean reporting to OHRP within days. For a less serious incident, a few weeks may be sufficient. It may be appropriate to send an initial report, and indicate that a follow-up or final report will follow by the earlier of:*
> - *a specific date; or*
> - *when an investigation has been completed or a corrective action plan has been implemented." [6]*

Some incidents do not rise to the level of necessary reporting, while others will require a report be filed with the Office of Human Research Protections or appropriate federal agency. At the meeting, the board will discuss the incident, considering all data and accounts, and strive to answer all the questions required as part of a full report to OHRS, even when a report may not be warranted. Data required as part of a full report includes, but not limited to:

- Name of the institution (e.g., university, hospital, foundation, school, etc.) conducting the research;
- Title of the research project and/or grant proposal in which the problem occurred or, for IRB or institutional noncompliance, the IRB or institution involved;
- 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; and
- Actions the institution is taking or plans to take to address the problem. For example:
    - revise the protocol or informed consent document
    - suspend subject enrollment
    - terminate the research
    - inform enrolled subjects
    - increase monitoring of subjects
    - educate the investigator, research staff, IRB or institutional official
    - develop or revise IRB written procedures
    - suspend the protocol or investigator
    - conduct random audits of the investigator or all investigators
    - require monitoring of the investigator or the research project

If the board determines that the incident does not require a report to OHRS (or other federal agency), the resolution may be to communicate the error to the PI along with a list of corrective actions required to resume the project. In any event, all relevant board minutes and supporting documentation will be sent to the Principal Investigator and Institutional Official, along with an official recommendation, and filed for future reference. Unless recommending termination or suspension of the research, the board will also advise the investigator if/when research may resume.

Reporting and Management of Researcher Conflicts of Interest

Pittsburg State University seeks to maintain objectivity, integrity, and credibility in research by preventing financial or non-financial interests from adversely affecting the ethical treatment of human research subjects. When an actual or perceived conflict of interest involving human

subject research exists, the IRB will determine whether and how the conflict should be disclosed to participants in accordance with guidelines. The IRB may require additional safeguards to address actual or perceived conflicts of interest.

Financial Conflicts of Interest

Investigators must disclose any significant financial interests that appear to be connected with their institutional responsibilities in accordance with Pittsburg State University's Conflict of Interest Policy. Investigators funded by the Public Health Service (PHS) and/or other agencies that abide by PHS conflict of interest regulations are subject to additional requirements as specified in PSU's policy. Investigators engaging or planning to engage in PHS funded research must complete FCOI training on investigator responsibilities prior to engaging in PHS-funded research and at least once every four (4) years.

Non-Financial Conflicts of Interest

Investigators must disclose non-financial interest that may compromise or may be perceived to compromise ethical treatment of human research subjects. A non-financial interest on the part of the researcher includes (but is not limited to): (1) having a personal relationship with an IRB member that would compromise, or have the appearance of compromising, the IRB member's professional judgment or objectivity in reviewing or evaluating proposed research; (2) having a relationship with the human research subjects of the proposed research that could compromise, or have the appearance of compromising, the ethical treatment of those subjects (such as an instructor/student relationship).

The IRB has the ultimate decision-making authority regarding management of all types of COIs (general or financial) in order to adequately protect human research participants. The IRB determines what information must be provided in the informed consent process, including details about funding sources, arrangements, and any financial interests held by parties involved in the research. If a perceived conflict is identified during initial review of a protocol, required actions to mitigate actual or perceived conflicts may vary based on the nature and severity of the potential conflict. Possible measures taken by the IRB might involve any combination of the following:

- Requiring disclosure of conflicts of interest in research materials like consent forms and recruiting advertisements.
- Modifying protocol procedures, roles within the project team, or data analysis methods to address potential conflicts of interest.
- Implementing independent safety monitoring and/or review of research data and analytical methods.
- Changing specific roles of project team members, reassigning responsibilities, or suspending or terminating their involvement in the project.

Conflicts of Interest at Relying Institutions

If the Pittsburg State University IRB is serving as the Reviewing IRB (sIRB) for another organization through a Reliance Agreement, the investigators will be subject to their organization's conflict of interest policies. Investigators at relying organizations are required to identify any conflict of interest that they have disclosed according to their organization's policies and provide the PSU IRB with any applicable conflict of interest determinations and managements plans conducted at the relying institution. The PSU IRB retains the authority to impose additional prohibitions or conflict of interest management requirements more stringent

or restrictive than proposed by the relying organization or institution, if necessary. However, the PSU IRB will not modify or change any management plan or mandate disclosure to participants without discussion with and an acceptance by the relying organization or institution.

Noncompliance

Examples of noncompliance include: (1) failure to disclose potential conflicts as required by PSU and IRB policy; (2) failure to comply with prescribed management plans. Noncompliance could result in investigations of the research, modification of protocols, reassignments of research personnel, suspension or termination of the research, and/or disciplinary actions in accordance with PSU policies.

IRB Review Meetings

The IRB is responsible for setting agendas and convening meetings as often as required to accomplish the business of the IRB. The meetings are open to the public except for those discussions which the Chair determines deal with private or confidential information. Full Board actions require the presence of a quorum of the voting members, defined as a majority of the membership (excluding the Chair who only votes in the event of a tie), including at least one member whose primary concerns are in nonscientific areas.

Principal Investigators (PIs) are expected to present new research proposals at the IRB meetings and to respond to questions from committee members. PIs are excused from the meeting prior to the vote of the IRB. PIs are not necessarily expected to be present for the continuing review of research activities, although their presence may be required by the Chair.

Committee meetings are conducted in accordance with Roberts Rules of Order. At a minimum, the Chair conducts the meeting, there is a predetermined agenda, the minutes from the prior meeting will consist of a list of proposals reviewed, the outcome, date of meeting and members in attendance.

The IRB may vote to approve, reject, or modify a research proposal. These actions require the vote of a majority of the members present at the meeting. The Chair does not vote, except to break a tie. If the vote is not unanimous, the minority opinion must be recorded in or attached to the minutes. A committee member may abstain from voting for any reason, without explanation. A member may change his/her vote until the time the vote is finally announced by the Chair. After that, a member's vote may be changed only by permission of the Committee which may be given by general consent.

The Expedited Research Review process requires only one IRB member to review a research proposal and this member may be the IRB Chair. The Expedited review process may also be used to review and approve minor changes in previously reviewed research during the period for which original approval is authorized. In both cases, the IRB Chair or designated representatives conducting the Expedited review must inform the full IRB of research which has been approved by this procedure by e-mail.

The IRB is authorized to modify, suspend, or terminate approval of research that has been associated with unexpected serious harm to subjects, or is not being conducted in accordance with *45 CFR 46 or* the Committee's decisions, conditions, or requirements.

By Federal Regulation, institutional officials may not approve research that has previously been disapproved by the IRB.

IRB Membership

Committee criteria include (but is not limited to):

a. Membership is greater than five individuals.
b. Member backgrounds vary to promote complete and adequate review of research.
c. Members are aware of and committed to compliance with PSU commitments and regulations related to research.
d. Members are aware of and committed to compliance with applicable law and federal regulations.
e. Members are aware of and committed to compliance with standards of professional conduct and practice.
f. At least one member is not a faculty member.
g. At least one member has primary concerns in scientific areas.
h. At least one member has primary concerns in nonscientific areas.
i. At least one member is not affiliated with PSU.
j. Member selection is not made on the basis of gender, but nondiscriminatory efforts are made to include both men and women.

According to guidance from HHS [7]:

> *"Members whose training, background, and occupation would incline them to view scientific activities from the standpoint of someone within a behavioral or biomedical research discipline should be considered a scientist, while members whose training, background, and occupation would incline them to view research activities from a standpoint outside of any biomedical or behavioral scientific discipline should be considered a nonscientist. In addition, the IRB must have members with sufficient knowledge of the specific scientific discipline(s) relevant to the research that it reviews."*
>
> *"… nurses, pharmacists and other biomedical health professionals should not be regarded to have "primary concerns in the non-scientific area." In the past, lawyers, clergy and ethicists have been cited as examples of persons whose primary concerns would be in non-scientific areas."*

Affiliation to the institution is understood to include an employee or representative of the university or a member of that person's immediate family. Possible affiliations include, but are not limited to, individuals who are:

- Full- or part-time employees
- Current students
- Members of any governing panel or board of the institution
- Paid or unpaid consultants
- Healthcare providers practicing at the student health center
- Volunteers working at the institution

Unaffiliated members may include people whose only association with the university is through service to the IRB or who are former students of the University.[8]

Membership includes (but is not limited to):

a. Chair, appointed by the committee
b. Two representatives from the College of Arts and Sciences
c. One representative from the Kelce College of Business
d. Two representatives from the College of Education
e. One representative from the College of Technology
f. One representative from Academic Affairs
g. One community representative

IRB members are appointed from within their individual Colleges and may be nominated by the unit head or may volunteer for service. A term for an IRB member is for one calendar year; however, in situations where an individual member is only appointed to a 9-month contract (i.e. does not teach over the summer), that member's term will end at the conclusion of the academic year.

Aside for the requirement to maintain current CITI/other ethics training, no recurring review process is in place for members; however, if a member is found to be in violation of university policy, fails to attend multiple meetings (or respond to calls for action via email), or is otherwise deemed to be unfit to serve, the Full Board may vote to have the member removed. The removal process will be documented in the minutes of the meeting, and all decision actions will be forwarded to the member and their Unit supervisor. The decision may be appealed to the Board and/or the Provost.

The IRB Chair may be any faculty member of the Board in good standing and will be nominated and approved by the Board at the first meeting of the academic year. The chair should maintain currency in all relevant CITI/other ethics training, including but not limited to any relevant training pathways (e.g. Biomedical, Social-Behavioral-Educational), the same current Revised Common Rule module as the remainder of the Board, and at least one Chair-specific training module. The Chair serves for a term of one year (calendar or academic as outlined above); in the case where a Chair cannot serve over the summer, an interim Chair will be selected and voted on by members of the Board as needed. At any time, the Board may elect to remove the Chair from service for reasons similar to those outlined above.

IRB Members are individually responsible for understanding their own conflicts of interest (COI) and reporting any potential or perceived COI concerning protocols under review by the IRB. Members should follow the COI guidance outline above in the section titled "Reporting and Management of Researcher Conflicts of Interest." Members with actual or perceived COI should recuse themselves from reviewing the study in question; Board review may continue in the member's absence provided there is a quorum.

The IRB may, at its discretion, invite individuals (*ad hoc* members) with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the committee. *Ad hoc* members may not vote with the IRB to determine approval or rejection of IRB applications.

Full IRB actions require the presence of a quorum of the voting members, defined as a majority of the membership.

Current Membership

The current members of the IRB may be found at the following PSU web site https://www.pittstate.edu/office/grants/research/institutional-review-board.html or by searching "*IRB membership*" on the PSU website.

External Consultants for Protocol Review

Either before or during review of a protocol, the IRB chair/director or a reviewing board member may determine that an expert consultant is needed. Review must be suspended until an appropriate consultant is obtained.

Procedure for obtaining consultants:

- Expert consultants may be PSU faculty, employees, or experts outside of the PSU community.
- Recommendations for internal or external consultants may come from IRB members, PSU Department Chairs or Deans, or individuals outside of PSU with knowledge in the required area of expertise.
- The IRB Chair/Directors will contact the potential consultant to ascertain their willingness to serve.
- The consultant must provide a curriculum vitae and disclose any potential conflicts of interest that might compromise their objectivity.
- If the consultant is willing to serve, and they have no significant conflicts of interest with respect to the protocol under review, the IRB chair and members will review their credentials and add copies of their credentials to the IRB file.

Duties of the consultant

- Consultants will present their opinions in a written report to the IRB and may also attend the IRB meeting in person or virtually.
- After the consultant's review and/or presentation is complete, the consultant will return any materials relevant to the protocol under review.

The consultant may participate in the IRB's discussion of the protocol, but they may not vote, and their presence may not be counted toward quorum.

IRB and Department Training

The IRB chair, members, and unit heads receive a copy of the *Pittsburg State University Assurance Handbook*, a copy of *The Belmont Report*: *Ethical Principles and Guidelines for the Protection of Human Subjects and Research* (1979), and a copy of *45 CFR 46, Protection of Human Subjects*. Additional training will be required as prescribed by the IRB, and may include, but is not limited to:

- Biomedical CITI Training
- Social-Behavioral-Educational CITI Training
- Common Rule CITI Training
- IRB Member CITI Training

The University Handbook is designed, in conjunction with the forms utilized, to educate the principal investigator as well as the approving authority each time a research proposal is evaluated. Evaluation criteria are adapted directly from the appropriate sections of *45 CFR 46*. Since the IRB cedes partial control to each unit in determining the categorization and approval of research, it is critical that each unit head or designee is intimately familiar with the federal regulations and requirements; unit heads or designees will be expected to complete not only the CITI Training appropriate to their area, but will also need to be well-versed in the most recent Common Rule changes, so appropriate CITI Training will need to be documented. Approved ethics training (e.g. the CITI Training modules listed above) will also be provided to all department heads or designees, and investigators, and will be outlined on the appropriate University web page. Unless directly participating in review of applications, support staff will not be required to complete ethics training.

IRB Decision Actions

The Institutional Review Board (IRB) will decide on research proposals after appropriate discussion and voting by a majority of the quorum members present. The investigator will receive documentation of the decision in one of three formats:

1. Approval of Research as indicated with an e-mail and Application for Review signed by IRB Chair or designee
2. Rejection of Research as indicated with an e-mail from the IRB Chair or designee
3. Request for Modification of Research as indicated with a Modification e-mail by the IRB Chair or designee

Rejection of research by the IRB indicates that there are ethical or procedural conflicts in the project proposal which probably cannot be remedied without major revision. Research cannot be conducted by the principal investigator until IRB approval is received.

Requests for modification of research by the IRB indicate that the details and procedures involved with the research project are not fully complete, but the project is given conditional approval of the proposal. The IRB will indicate by e-mail the specific areas that need to be addressed, changed, or clarified by the principal investigator if she/he wishes to implement the proposal. These modifications must be re-submitted to the IRB for review at a later date. Research cannot be conducted by the principal investigator until final approval by the IRB.

IRB Criteria for Approving Research

When reviewing research proposals that include human subjects, the IRB must determine that all of the following requirements are satisfied prior to approval.

1. 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.
2. Risks to subjects are 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 should 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 should 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 that fall within the purview of its responsibility.

3. Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted (including any institutional requirements for sponsor-investigator studies) and should 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.
4. The investigator(s) and study staff have completed the CITI or equivalent training documents.
5. Informed consent will be sought from each prospective subject or the subject's legally authorized representative.
6. Informed consent will be appropriately documented
7. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects
8. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data
9. 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
10. The protocol conforms with applicable state law

IRB Documentation of Activities

Pittsburg State University's IRB utilizes this handbook and the forms and application materials referenced within as formats to document the following:

1. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects.
2. Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; and the basis for requiring changes in or rejecting research.
3. Records of continuing review activities.
4. Copies of all correspondence between the IRB and the investigators.
5. A list of IRB members in the same detail as described in *§46.103(b)(3).*
6. Written procedures for the IRB in the same detail as described in *§46.103(b)(4)* and *§46.103(b)(5).*
7. Statements of significant new findings provided to subjects, as required by *§46.116(b)(5).*
8. Copies of all training certifications, to include IRB members, researchers, and Reviewers.

The records required by this policy shall be retained electronically for at least 3 years by the Office of Research Administration and Compliance on behalf of the IRB, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research by either the responsible Department or the Principal Investigator. All records shall be accessible for inspection and copying by authorized representatives at reasonable times and

in a reasonable manner.

Research Involving Children

Subpart D, of *45 CFR 46* provides additional protection for children involved as subjects in research. Due to the sensitive nature of involving minors (under 18 years of age in the state of Kansas) in human subjects research, this guidance is included to provide further clarification to the Federal Regulations when including children in research. (Specifically, requirements are established for obtaining permission (not consent) by parent(s)/guardian(s) **AND** the assent of the child subject.)

Definitions

1. Children – persons who have not attained the legal age for consent to treatments or procedures involved in the research (under 18 years of age in the state of Kansas.)
2. Assent – a child's affirmative agreement to participate in research. Mere failure to object should not be construed as assent.
3. Permission – the agreement of parent(s) or guardian to the participation of their child or ward in research.

Categories of Research involving Children

1. Research not involving greater than minimal risk. There are no additional requirements of investigators or the IRB for activities involving this degree of risk other than those dealing with permission and assent.
2. Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Research which falls in this risk category may be conducted if the following provisions apply:
   a. The increased risk is felt to be justifiable by the anticipated benefit to the individual child subject.
   b. The relationship between the anticipated benefit and the risk involved in the research is at least as favorable as that involved in available alternative approaches to diagnosis and/or treatment of the child.
   c. Adequate provisions are made for obtaining assent of the child and permission of parent(s)/guardian.
3. Research involving greater than minimal risk and no prospect of direct benefit to individual subjects but likely to yield generalizable knowledge about the subject's disorder or condition. Research in this category may be conducted if the following provisions apply:
   a. The risk to the child subject is felt to represent a minor increase over minimal risk.
   b. The experience of the child undergoing the experimental intervention or procedure will be reasonably commensurate to that which he/she would experience in the course of his/her actual or expected medical, dental, psychological, social or educational situations.
   c. The research is expected to yield generalizable knowledge about the child subject's disorder or condition; and
   d. Adequate provisions are made for obtaining assent of the child and permission of parent(s)/guardian.
4. Research that does not fall into the above categories yet presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of

children. All activities involving children as subjects that do not fall into one of the above three categories (i.e., because they involve greater degrees of risk) require review by the Secretary of DHHS in consultation with a panel of experts in addition to review by the Committee. Request for review of such activities should be directed to the chairperson of the HSC.

Requirements for Consent of Parent(s)/Guardian and for Assent of the Child Subject

1. Investigators must obtain the informed permission of parent(s) or guardian (except as noted below) to involve a child in a research activity. The elements of informed permission are basically the same as the elements of informed consent outlined in the *Application for Review*. The permission form should be worded in such a manner that it is clear to the person signing the form that these "elements" apply to the child subject. Particular attention should be paid in such documents to the questions of risk to the child, benefit (if any) to the individual child, the question of whether these benefits are only available to the child through his/her participation in the activity, the child's right (if applicable) to refuse to participate, and procedures to be followed if either parent or child wishes to withdraw. The requirement for parental/guardian permission may be waived if the activity is one in which such permission is not a reasonable requirement (e.g., studies on abused/neglected children). If the investigator feels that such a requirement should be waived for a particular research activity, the IRB will work with the investigator to establish an alternative mechanism for protecting the interests and rights of the child.
2. Children who are wards of the state can only be involved in research under special circumstances. Any investigator seeking to involve wards should contact the Committee for assistance in establishing mechanisms to deal with the stringent conditions under which such involvement can take place.
3. Investigators must also make adequate provision for soliciting the assent of the child subject.
    a. The concept of assent includes two basic elements:
        i. The child's awareness of his/her condition, the nature of his/her illness (if applicable), and of the activities involved in participating in the research project; and
        ii. The child's expression of willingness to participate in the proposed activity.
    b. As a general rule, children who are seven (7) years of age or older are capable of providing assent. The child's assent can be documented by having him/her sign a short, appropriately worded addendum to the parental permission form. This short paragraph should include a brief description of the nature of the proposed research activity and a statement that the child is willing to participate.
    c. The child subject should also be informed of his freedom to refuse to participate or to withdraw at any time when this is appropriate.
    d. If the child is less than seven (7) years old; or is felt to be incapable of providing assent; or if the anticipated direct benefits to the child are only available through participation in the proposed research activity, the assent requirement may be waived by the Committee.

Passive Parental Consent (Opt-Out Consent)

In certain cases, opt-out consent (sometimes referred to as a "passive consent") is allowable if the research meets the conditions for a waiver or alteration of informed consent outlined in *45*

CFR 46.116(f). This passive consent option may be used in school settings where the following conditions are met:

- The research involves no more than minimal risk to the subjects;
- The research could not practicably be carried out without passive consent;
- The research does not use identifiable private information;
- The research will not adversely affect the rights and welfare of the subjects;
- The parents/guardians will be provided with additional pertinent information after participation; and
- Subject selection is based on classroom membership and not exclusionary.

The investigator must describe the rationale for requiring the passive consent process and indicate on the *Application for Review* form that a Waiver or Alteration of Informed Consent is being requested in Section VI. The investigator must provide the parent(s) with a written document containing all the required elements of informed consent that gives parents the opportunity and sufficient time (no less than 14 calendar days) to opt their student out of the study. This document must be sent directly to the parents (i.e. NOT sent home with the student, rather mailed/emailed by the school or distributed at parent-teacher conferences). The application must include the written document and explain distribution methods for the document.

Because of differences between requirements of districts regarding active vs. passive parental consent, the researcher must check in with the participating school district(s) prior to the development of a passive consent process and must provide documentation of the district's policy or letter of support as part of the application.

Clinical Research with Adults or Emancipated Minors Incapable of Giving Consent

Kansas law (KSA 65-4974) applies to IRB-approved clinical research being conducted by a licensed physician having staff privileges at a medical care facility. If no legal guardian or attorney-in-fact exists to make health care decisions for the research subject, or the legal guardian or designated attorney cannot be contacted after due diligence, informed consent for the research protocol may be granted by a family member in the following order of priority:

1. The adult or emancipated minor's spouse, unless they are legally separated;
2. An adult child;
3. A parent; or
4. An adult relative by blood or marriage.

Handling of Digital Research Data

Digital Data Security

In an effort to ensure protection of Human Subjects data from digital loss or theft, the IRB requires that all study data be stored on an online file service (i.e., SharePoint, Teams, or OneDrive) that is administered by a single PSU employee who is not the PI, such as a Department/Unit/Program coordinator or administrative assistant. This will not only help relieve the burden of maintaining data for the federally mandated period, but it will also ensure that the data is stored in a way that meets minimum security requirements, eliminates the need to track a physical drive or computer, and allows access by ORAC in case of an audit.

Data files can be temporarily downloaded to a local computer for reasons such as statistical analysis, filtering, or transcription. The IRB recommends that all work be done using PSU-issued computers when possible (PSU lab computer, ITS-issued laptop, etc.). If it is not possible, and an investigator wishes to use a personal device for data analysis, investigators will be required to assure that they are following Minimum Recommendations for personal device security practices:

1. Ensure that the device is at least password protected with a strong password or strong PIN (for cell phones or mobile devices). Devices could also be protected with biometric features (fingerprint or face ID) or another multi-factor authentication (MFA) method. Passwords and PINs should be updated regularly.
2. Ensure that the device has an up-to-date OS, and that all browsers, software, and applications are updated.
3. Ensure that current anti-virus software is active
4. No data is stored on a personal/local hard drive. Whenever possible, try to utilize online editing tools (Microsoft 365) instead of local installations (MS Excel/Word/PowerPoint) so that the data doesn't "live" on a local machine.

When filling out an application for research, the Investigator will be required to affirm that they are using the minimum requirements above and provide information about who in their Department/Unit will maintain the data storage account (PSU's SharePoint, Teams, or OneDrive) and be able to access its contents should the PI leave the university. (Access might be required if the IRB, the federal Office of Human Research Protections, or another agency, were to initiate an audit due to adverse events, research ethics violations, participant complaints, and so on.) That individual should be someone other than the PI and should ideally be in a position that will continue to be staffed should the named individual leave PSU (e.g., the Department Administrative Assistant or Program Coordinator).

In addition to these PSU-specific policies, investigators must also abide by any local/state/federal regulations (e.g., HIPAA, FERPA), or any site-specific policies that may be in place (e.g., at a school district or hospital). Those PIs wishing/required to submit to an external repository (i.e., an open access policy required by some publications) should indicate this on their application and should include the relevant privacy policies; this submission will be IN ADDITION to the storage requirements outlined above.

When using an online tool (e.g., Survey Monkey, Qualtrics, Google Forms, etc.), investigators should provide links to the data policies of the tool, as well as a screen shot of the survey settings to ensure that the settings do not collect any identifiable data. Examples of data that could be collected include, but aren't limited to, email address, IP address, physical location. Some online tools collect these data points by default and it is up to the Investigator to determine if they are required and justify their collection, or to turn off the collection within the survey.

Social Media in Research

Due to the unsecure nature of the platforms (Facebook, Twitter/X, Instagram, Snapchat, etc.) and their terms of use, which favor the parent company at the expense of user privacy, collecting data using social media is not a permitted form of research for PSU representative. It is allowable to conduct recruitment for research using social media; however, when using social media to recruit subjects, it is required that researchers doing investigations on behalf of PSU

(either as their own research or part of a course of study) use accounts maintained by PSU personnel, and accounts should be maintained at the Department/Unit/Program level. This has multiple benefits:

- It gives participants the assurance that the request is coming from PSU, not a private citizen or fraudulent account
- It allows the University to have fewer points at which the information can be compromised and ensures a minimum level of information security on the account
- It makes it easier for the University and the Department/Unit to track who is doing what research
- It gives the researcher peace of mind that they won't be liable if their personal account gets hacked and loses protected research data

When filling out an IRB application for such research, the Investigator will be required to provide information about who in their Department/Unit/Program controls the account; this can be a named individual, but should ideally be a position (e.g. the Department Administrative Assistant or the Program Coordinator). Investigators must also provide copies of all study-related material (e.g. recruitment information, survey questions, images) that will be posted to the account prior to approval.

Health Data for Research (HIPAA)

The Health Insurance Portability and Accountability Act of 1996 (otherwise known as "HIPAA" or the "Privacy Rule") outlines specific standards and obligations regarding the privacy of certain protected health information (PHI). Since the primary function of Pittsburg State University as a state educational institution of Kansas is not to provide health care, the University recognizes itself as a "hybrid entity." Pittsburg State University voluntarily complies with PHI standards.

PHI consists of information created or received by a health care provider, health plan or health care clearing house that relates to past, present, or future physical or mental health of an individual. It may also include information about health care services or payment for health care services. The Privacy Rule governs PHI in any form: oral, written, or electronic.

If a researcher obtains PHI information from a covered entity (either within or outside of Pittsburg State University,) the subject of the information must have granted permission via a written authorization form, or one of the following criteria must be met:

1. The information is "De-Identified"
2. The information is compiled into a limited data set and a data use agreement is executed
3. The activity qualifies as preparatory to research
4. A waiver of the individual authorization requirement is obtained from the IRB
5. The researcher is accessing information solely on decedents

De-Identification

Health information which has been de-identified may be disclosed and used for research purposes. To qualify as being de-identified under HIPAA, the following data elements about

the individual and the individual's relatives, employers, or household members must be removed:

- Names;
- All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geographic codes, except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
  - The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and
  - The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000;
- 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 age, except that such ages and elements may be aggregated into a single category of age 90 or older;
- Telephone numbers;
- Fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers;
- Health plan beneficiary numbers;
- Account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web Universal Resource Locators(URLs);
- Internet Protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints;
- Full face photographic images and any comparable images; and
- Any other unique identifying number, characteristic, or code, except a covered entity may assign a code or other means of record identification to allow information de-identified under this section to be re- identified by the covered entity, provided that:
  - The code or other means of record identification is not derived from or related to information about the individual and is not otherwise capable of being translated so as to identify the individual; and
  - The covered entity does not use or disclose the code or other means of record identification for any other purpose, and does not disclose the mechanism for re-identification.

A de-identified data set might include age, gender, ethnicity, marital status and relevant medical information, provided there are no identifying links to the source data. De-identified data is not subject to HIPAA's Privacy Rule. Thus, if a researcher receives only de-identified data or samples from an entity covered by HIPAA, the Privacy Rule's additional requirements do not apply.

If a researcher him/herself views records containing identifiable health information and from those records extracts a de-identified data set, one of the other exceptions to the individual authorization requirement must be met. Alternatively, in some cases, the covered entity may be able to enter into a business associate agreement with the researcher to create a de-identified data set. HIPAA's requirements for business associate agreements must be met.

Limited Data Set and Data Use Agreement

HIPAA permits research using a Limited Data Set, i.e. a data set in which direct identifiers have been removed but certain potential identifiers remain. To qualify as a Limited Data Set, the following direct identifiers of the individual or of relatives, employers, or household members of the individual must be removed:

- Names;
- Street address/postal address information, other than town or city, state, and zip code;
- Telephone and fax numbers;
- Electronic mail addresses;
- Social security numbers;
- Medical record numbers, health plan beneficiary numbers or other account numbers;
- Certificate/license numbers;
- Vehicle identifiers and serial numbers, including license plate numbers;
- Device identifiers and serial numbers;
- Web universal resource locators (URLs) or Internet protocol (IP) address numbers;
- Biometric identifiers, including finger and voice prints; and
- Full face photographic images and any comparable images.

A Limited Data Set is still considered to be PHI under the HIPAA. Prior to disclosing the Limited Data Set, the entity releasing the Limited Data Set and the researcher must execute a Data Use Agreement. The agreement must contain the following elements:

a) The permitted uses and disclosures by the recipient
b) The approved users and recipients of the data
c) Agreement by the recipient not to re-identify the data or contact the individuals
d) Assurances that the recipient will use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as permitted by the Data Use Agreement
e) Agreement that the researcher will report to the covered entity any uses or disclosures of the Limited Data Set which were not specifically allowed
f) Agreement to require that any agents and subcontractors adhere to the same safeguards

Activity Preparatory to Research

HIPAA also permits a researcher to access PHI from a covered entity if he/she attests in writing that:

- The information is being sought solely to prepare a research protocol or for similar purposes preparatory to research;
- No PHI is to be removed from the covered entity by the researcher; and
- The information being sought is necessary for research purposes

Waiver of Individual Authorization

Researchers may apply for a waiver of the privacy authorization requirements under HIPAA if the research meets the following criteria.

- The use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements;
  - An adequate plan to protect the identifiers from improper use and disclosure;
  - An adequate plan to destroy the identifier at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
  - Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA;
- The research could not practicably be conducted without the alteration or waiver; and
- The research could not practicably be conducted without access to and use of the PHI.

Research on Decedents

In order to access medical records on decedents, HIPAA requires a researcher to provide a covered entity with written assurances that the information is being sought solely for research on decedents and is necessary for research purposes. The covered entity has a right to require documentation of the death of the individuals.

Student Data for Research (FERPA & PPRA)

FERPA

The Family Educational Rights and Privacy Act (FERPA) is a federal law that concerns disclosure of personally identifiable information from student education records and is based on *34 CFR 99* [4]. "Personally identifiable information" (PII) is defined as:

a) The student's name
b) The name of the student's parent or other family members
c) The address of the student or student's family
d) A personal identifier, such as the student's social security number, student number, or biometric record
e) Other indirect identifiers, such as the student's date of birth, place of birth, and mother's maiden name
f) Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty; or
g) Information requested by a person whom the educational agency or institution reasonably believes knows the identity of the student to whom the education record relates.

FERPA applies to all educational institutions that receive funds under programs administered by the U.S. Department of Education, which can include public or private elementary, intermediate, high school, or college institutions. Since FERPA states that an educational institution has the authority to determine what information may be accessed from an education record, the IRB cannot overrule the decision if an institution denies an investigator access to information in an education record,

Until a child reaches the age of majority (18 in Kansas) or becomes a student of a post-secondary educational institution (i.e. takes a class at PSU), FERPA gives certain rights to the parents or legal guardian with respect to their children's education records, including:

- the right to consent to any disclosure of personally identifiable information from the education records
- the right to review the records
- the right to request an amendment in the records.

Once a student when the student reaches the age of majority or attends an educational institution beyond the high school level (at which point they are referred to as "eligible students") these rights transfer to the student.

In most circumstances, signed and dated written consent from a parent or eligible student is required to disclose personally identifiable information from a student's education record. The consent must be specific about what records may be disclosed, the purpose of the disclosure, and identify the individual(s) to whom the records will be disclosed. With few exceptions, FERPA defines "education records" as records that are: "*(1) Directly related to a student; and (2) Maintained by an educational agency or institution or by a party acting for the agency or institution."* [4]

Exceptions to the Requirement of Prior Written Consent

Directory Information.

Educational institutions may disclose without prior consent information that is designated by the educational institution as "directory information." The educational institution must give appropriate prior notice of the information designated as directory information. FERPA requires that eligible students or parents be given the opportunity to "opt out," which is to file a request to prevent disclosure of directory information. An educational institution may not release any directory information of anyone who has "opted out," even after they have left the institution.

Directory information includes, but is not limited to:

- the student's name
- address
- telephone listing
- electronic mail address
- photograph
- date and place of birth
- major field of study
- grade level
- dates of attendance
- enrollment status (e.g., undergraduate or graduate, full-time or part-time)
- participation in officially recognized activities and sports
- weight and height of members of athletic teams
- degrees, honors and awards received
- and the most recent educational agency or institution attended.

Researchers should contact each educational institution from which student record access is required and be prepared to follow that institution's FERPA policy. A description of these activities and the appropriate documented approval should be included as part of the IRB application.

De-identified Information.

Institutions may disclose information from student education records without prior consent if reasonable efforts have been made to remove personally identifiable information from the records, to confirm that a student's identity would not be personally identifiable through single or multiple releases and ensure that other reasonably available information is taken into account. The IRB may require confirmation that the educational institution from which the researcher is seeking records has made this determination before approving the protocol because it is the institution that holds the student records that has to make this determination.

An educational institution can release of student data from records for the purpose of education research once it has been de-identified by attaching a code to each record. This code may allow the researcher to match additional information received from the same institution, provided that:

- the educational institution does not disclose any information about how it generated and assigned the code, or that would allow the recipient to identify a student based on a code
- the code is not used for any purpose other than identifying a de-identified record for purposes of education research and cannot be used to ascertain personally identifiable information about a student
- the code is not based on a student's social security number or other personal information.

Research Conducted for or on Behalf of Educational Institutions

PII from student records may be disclosed to researchers when the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:

- develop, validate, or administer predictive tests, OR
- administer student aid programs, OR
- improve instruction.

The study must be performed in such a way that it does not permit identification of parents or students by anyone other than representatives of the organization with legitimate interests in the information. The information must be destroyed when no longer needed for the study for which it was originally intended. If PII from records will be disclosed using this exception, the researcher must provide proof of a written agreement with the educational institution that contains specific descriptions of data confidentiality; this document must be provided to the IRB as part of the application.

PPRA

The Protection of Pupil Rights Amendment (PPRA) also known as "Student Rights in Research, Experimental Programs, and Testing," along with the No Child Left Behind Act of 2001, give parents rights with regard to surveys that ask questions of a personal nature, the surveying of minor students, the collection of information from students for marketing purposes, and certain non-emergency medical examinations. [5]

The PPRA applies to any an elementary school, secondary school, school district, or local board of education that receives funding from the U.S. Department of Education, otherwise known as a "local educational agency." It also applies to research funded by the U.S. Department of Education.

Protected PPRA Information

PPRA lists eight categories of protected information for survey responses:

1. Political affiliations of student or student's parent
2. Mental or psychological problems of student or student's family
3. Sex behavior or attitudes
4. Illegal, anti-social, self-incriminating, or demeaning behavior
5. Critical appraisals of others with whom students have close family relationships
6. Legally recognized privileged or analogous relationships
7. Religious practices, affiliations or beliefs of student or student's parent
8. Income, other than as required by law to determine eligibility for participation in a program or for receiving financial assistance under such program

There are two sets of requirements for surveys set by PPRA

1. Requirements that apply to “protected information” surveys that are funded in whole or in part by the U.S. Department of Education.
2. Requirements that apply to "protected information" surveys that are funded by sources other than the U.S. Department of Education and that are administered or distributed by education institutions that receive funds from the U.S. Department of Education (i.e. public elementary and secondary schools and some private schools).

Documentation of these requirements, and how they will be addressed by the investigator should be provided as part of the IRB application.

References

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[2] HHS.gov "Quality Improvement Activities FAQs" (2021) Retrieved 02/12/21 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html

[3] HHS.gov "Unanticipated Problems Involving Risks & Adverse Events Guidance (2007)" Retrieved 03/09/21 https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html

[4] Ed.gov "*Personally Identifiable Information for Education Records*" Retrieved 03/10/21 https://studentprivacy.ed.gov/content/personally-identifiable-information-education-records

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