

**INVESTIGATOR MANUAL**

Version: Oct 10, 2022

# Purpose

This Investigator Manual is designed as a guide through the IIT Institutional Review Board (IRB) policies and procedures for the review and oversight of human subject research conducted by IIT faculty, staff, undergraduates, graduate students, and post-doctoral researchers. Additionally, the Manual serves as a guide to prepare and submit materials in Cayuse for review by the IIT IRB.

The Manual is an ongoing work in progress as regulations periodically change, the IIT sponsored research portfolio expands, and an increasing number of undergraduates, graduate students and postdoctoral researchers explore opportunities in new topics to conduct research.

Research conducted through IIT must fall within IIT’s mission: “To provide distinctive and relevant education in an environment of scientific, technological, and professional knowledge creation and innovation.” In pursuit of knowledge creation and innovation IIT will not engage in advocacy. While individual IIT researchers may well be advocates for various causes, including those informed by their research, the aim of an academic research project must be to answer a research question objectively. Objectivity is lost if the aim of a research project is to produce a particular result or achieve a predetermined policy outcome.

The IIT IRB policies are based on the Federal regulations promulgated in [45 CFR 46 Federal Policy for the Protection of Human Subjects](https://www.ecfr.gov/on/2018-07-19/title-45/subtitle-A/subchapter-A/part-46). IIT commits to applying the Federal regulations and ethical standards to all human research regardless of funding.

[45 CFR 46 defines research](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102) as “a systematic investigation, including development, testing, and evaluation designed to develop or contribute to generalizable knowledge.”

[45 CFR 46 defines a human subject](https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46/subpart-A/section-46.102) as “a living individual about whom an investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens or (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.”

The Federal Policy 45 CFR 46 for the Protection of Human Subjects or the “Common Rule” was published in 1991 and updated in 2017. The Common Rule has been codified in separate regulations by [20 Federal departments and agencies](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html). The Department of Health and Human Services (DHHS) administers the [Federal Policy for the Protection of Human Subjects through the Office for Human Research Protections (OHRP)](https://www.hhs.gov/ohrp/index.html).

When IIT is engaged in human research that is conducted, funded, or otherwise subject to regulations by a Federal department or agency that is a signatory of the Common Rule, such as DOE, EPA, NIH, NSF, etc. IIT commits to apply the regulations of the specific agency relevant to the protection of human subjects.

**Policy on the Use of IIT Names, Logos and Insignias**

IIT has developed standards to regulate the use of the IIT name by schools, units, and individuals within the University, and their use by individuals and institutions outside IIT. The IIT IRB recommends using the IIT logo, and department/school logo if appropriate, at the top of informed consent documents and recruitment materials.

The IIT Investigator Manual was supplemented with information drawn from publically available sources at the Children’s Hospital of Philadelphia (CHOP), Harvard University, Lawrence Berkeley Laboratory, University of California, Berkeley, University of California, Los Angeles and the University of California, San Francisco.

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# Determining when IRB Review is Needed

The IIT IRB is responsible for the review and oversight of human subject research conducted by IIT faculty, staff and students. This oversight applies regardless of whether the research is conducted at IIT, another institution, internationally, and/or in collaboration with non-IIT affiliates. For research with non- IIT collaborators, see [Conducting Research with Non-IIT Collaborators](#NonIITCollaborators) for additional considerations.

**IIT Engaged or Not Engaged in Research**

IIT adheres to the Department of Health and Human Services (DHHS), Office for Human Research Protections (OHRP) Guidance on Engagement of Institutions in Human Subjects Research. The Guidance states “In general, an institution is considered engaged in a particular non- exempt human subjects research project when its employees or agents for the purposes of the research project are to obtain:

(1) data about the subjects of the research through intervention or interaction with them;

(2) identifiable private information about the subjects of the research; or

(3) the informed consent of human subjects for the research.”

Should an IIT agent (student, staff or faculty) not meet the above threshold for an institution engaging in research, the IIT IRB will not issue a research determination (notice of approval or exempt from review) which would indicate that the institution is engaged in research.

**Not Human Subjects Research Determination**

Some research activities do not require IRB review. Activities that do not meet the definition of “Human Subjects Research” are not subject to IRB oversight. 45 CFR 46 defines human subject as “A living individual about whom an investigator conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies or analyzes the information or biospecimens **or** (2) obtains, uses, studies, analyzes or generates identifiable private information or identifiable biospecimens.”

Before submitting research for IRB review, the Principal Investigator (PI) can first determine whether the proposed activities are non-human subjects research. Research that will only involve unidentifiable/de-identified or coded private information or biological specimens, the researchers will not have access to identifiers or keys to link coded data (even temporarily) is not human subjects research, and the research is not FDA-regulated. In cases where it is unclear whether or not an activity is human research, email the IRB at IRB@iit.eduB. An IIT investigator can request the IRB to make a formal “Not Human Subjects Research” determination.

**Not Considered Research**

Research is defined at 45 CFR 46 102(d): “A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” Generalizable is the intent to draw conclusions from research which will develop or contribute to a general body of knowledge (i.e., publish or present at conferences).

Quality Assurance and Quality Improvement activities are generally not considered to be research. If the information collected is intended to inform a broad field and not solely for application at the institution in which it is performed, then the research definition may apply.

The Common Rule has defined an additional 4 categories of activities that are not considered research and the FDA has 1 additional category.

1. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. The objective should not be to develop generalized knowledge. If the activity involves using the information for purposes of drawing general conclusions about the overall group, then the activity would be considered research for the purposes of the regulations.
2. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
3. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
4. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
5. (FDA) Taste and food quality evaluations and consumer acceptance studies (with conditions).

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**Research activities that typically do not need IRB review**

1. Data collection for internal departmental, school, or other University administrative purposes. Examples: teaching evaluations, customer service surveys, student residential life questionnaires, etc.
2. Service surveys issued or completed by IIT personnel for the intent and purposes of improving services and programs at IIT or for developing new services or programs for students, employees, or alumni, as long as the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and survey participation is voluntary. This would include surveys by professional societies or IIT consortia. Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge; IRB review may be required before the data could be released to the new project.
3. Information-gathering interviews where questions focus on things, products, or policies rather than people or their thoughts regarding themselves. Examples: canvassing librarians about their libraries’ inter-library loan policies or periodical purchases or interviews with company engineers or managers about how a product is made.
4. Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement, but are not intended for use outside of the classroom.
5. Biography research involving a living individual that is not generalizable beyond that individual.
6. Research involving cadavers, autopsy material or biospecimens from now deceased individuals. Note: Some research in this category, such as genetic studies providing private or medical information about live relatives, may need IRB review. Please contact the IRB for further information.
7. Quality improvement projects are generally not considered research unless there is a clear intent to contribute to generalizable knowledge and use the data derived from the project to improve or alter the quality of care or the efficiency of an institutional practice. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB.
8. Case history or Case Study which findings are published and/or presented at national or regional meetings are not considered research if the case is limited to a description of the clinical features and/or outcome of a three or fewer patients and do not contribute to generalizable knowledge.  Note: Investigators should contact the IRB if they are uncertain as to whether or not they are contributing to generalizable knowledge.
9. Publicly available data do not require IRB review. Examples: census data, labor statistics. Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as “publicly available.”
10. Coded private information or biological specimens that were not collected for the currently proposed projects do not need IRB review as long as the investigator cannot link the coded data/specimens back to individual subjects. If the data/specimen provider has access to the identity of the subjects (e.g. subjects’ names, addresses, etc.), the investigator must enter into an agreement with the data/specimen provider that states under no circumstances will the identity of the subjects be released to the investigator. Note: Investigators cannot independently make this determination. These projects require verification from the IRB Chair or their designee.
11. Some examples of Non-Engagement in Research include: when an institution’s employees or agents act as consultants on research but at no time obtain, receive, or possess identifiable private information, perform commercial services for the investigators, or inform prospective subjects about the availability of research. Note: the examples above are not an all inclusive listing.

### IRB Review Process

When a PI determines that his or her proposed research will need review by the IIT IRB an application is submitted in Cayuse. The Cayuse application will undergo a preliminary review by an IRB staff person. Following the preliminary review, the IRB staff may request clarifications, revisions, and/or additional information in a Cayuse communication to the PI. The Principal Investigator may “Submit Response” in Cayuse to resolve these requests. When resolved, the IRB staff will complete their review and issue a determination letter, refer the application for expedited review or assign the application to an IRB meeting for review. The expedited reviewer or convened IRB may request additional information following its review.

Once the review process is completed a determination letter will be issued in Cayuse. System notifications are sent from Cayuse throughout the review process to inform the PI when additional action is necessary. To check on the status of a submission, log in to Cayuse via [my.iit.edu](https://login.iit.edu/cas/login?service=https%3A%2F%2Fmy.iit.edu%2Fc%2Fportal%2Flogin). For questions or concerns, contact the [IIT IRB](mailto:%20irb@iit.edu).

### IRB Review and Approval Criteria

The criteria for IRB approval of non-exempt human research can be found in “[IRB Review Criteria](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\IRB%20Review%20Criteria.docx)”. Additional checklists may be applicable depending on the nature of the proposed human research, e.g., inclusion of prisoners, inclusion of children will often prompt the use of a checklist: “[Children](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Checklist%20children%20IIT.docx)”, “[Prisoners](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Checklist%20prisoners%20IIT.docx)”.

Worksheets and Checklists maybe used by IIT IRB reviewers at the time of initial review, continuing review, during the review of modifications to previously approved human research. Investigators are also encouraged to use these materials as a reference or guide when writing the Research Protocol in a way that addresses the criteria for approval.

# IRB Determinations and Modes of Review

### Exemption Determination

Certain categories of human research may be exempt from IIT IRB review regulations [(see below](#r2r73f)). Category 7 and category 8 have not been implemented at IIT at this time. The purpose of an exemption from IRB review is to minimize unnecessary oversight of research that may benefit the public and pose minimal risk to subjects. The PI must request an IRB exempt determination in Cayuse.

A limited IRB review may be required for Exempt Categories 2(iii) and 3(i)(c) when the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects. An IRB conducts a limited IRB review to make the determination required on whether there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

Most submissions determined as exempt will not require a modification if the submission does not change. A modification is needed for a change in PI or faulty sponsor, but is not needed for changes in other study personnel. If a significant change in research design is needed for an exempt protocol a new submission is required.

When conducting exempt human subject research internationally, the PI is required to comply with applicable local laws, legislation, regulations, and/or policies of the country. Additionally, if a local IRB/ethics review committee for an international site requires a review, it must be obtained before any human research activities are conducted in the country. For assistance with applicable international local requirements, contact the [IIT IRB](mailto:%20irb@iit.edu).

**Exemption Categories**

**Category 1:** Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

**Category 2:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.

(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)); that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

This category can include visual or auditory recording as research methods. Surveys cannot include collection of biospecimens or interventions, as those additional activities would disqualify the research from this category. Research involving children can only qualify for exemption under this category when it involves educational tests or the observation of public behavior without intervention. It does not allow surveys or interviews or the observer participating with children.

**Category 3:** (i) Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)); that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

(ii) For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

(iii) If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

Research using deception is not eligible for exemption in category 3 unless subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research. Exemption is permitted if the data are recorded in such a way that the identities of the subjects cannot be readily ascertained either directly or indirectly or if the identities can be ascertained, a disclosure of the subjects’ responses outside the research setting would not reasonably place the subjects at risk of harm.

Alternatively, if the subjects’ identities can readily be ascertained and if a disclosure of subjects’ responses has potential to harm subjects, the exemption is permitted if the IRB conducts a **limited IRB review** and determines that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

**Category 4**: Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

(i) The identifiable private information or identifiable biospecimens are publicly available;

(ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

(iii) The research involves only information collection and analysis involving the investigator’s use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); or

(iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities and if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501.

**Category 5:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

1. Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

**Category 6:** Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, or

(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**The IIT IRB has not implemented Exempt Category 7 and Category 8** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Category 7:** Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by [§46.111(a)(8)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111):

(i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of [§46.116(a)(1)-(4), (a)(6), and (d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111);

(ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with [§46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111); and

(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

**Category 8:** Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:

(i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with [§46.116(a)(1)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(1)) through [(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(4)), [(a)(6)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(a)(6)), and [(d)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116(d));

(ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with [§46.117](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.117);

(iii) An IRB conducts a limited IRB review and makes the determination required by [§46.111(a)(7)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.111(a)(7)) and makes the determination that the research to be conducted is within the scope of the broad consent referenced in paragraph [(d)(8)(i)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-a-46104/index.html#46.104(8)(i)) of this section; and

(iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.

A **Limited IRB review** requires the IRB to determine that there are adequate provisions for protecting privacy and confidentiality. The IRB considerations for privacy and confidentiality safeguards include the extent to which identifiable private information is or has been de-identified, the risk that such de-identified information can be re-identified, use of the information, the extent to which the information will be shared or transferred to a third party or otherwise disclosed or released, likely retention period or life of the information, security controls that are in place to protect the confidentiality and integrity of the information and potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the research parameters under the exemption.

**Expedited Review Procedure**

Certain categories of non-exempt human research may qualify for review using the expedited procedure. That is the proposed research may be approved by one or more designated reviewers, rather than by the convened IRB. Expedited review procedures are for certain categories of research that involve no more than minimal risk, and also for minor changes in approved research.

The categories of research that qualify for an expedited review are listed below. Protocols eligible for an expedited review are reviewed on a rolling basis.

**Expedited Review Categories**:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   1. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   2. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) 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.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   1. 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
   2. 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 non-disfiguring 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) uncannulated 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 age, weight, and health of the individual.

1. 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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. [45 CFR 46.101(b)(4)](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html). This listing refers only to research that is not exempt.)
2. Collection of data from voice, video, digital, or image recordings made for research purposes.
3. 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: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt.)
4. Continuing review of research previously approved by the convened IRB as follows:
   1. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or
   2. where no subjects have been enrolled and no additional risks have been identified; or
   3. where the remaining research activities are limited to data analysis.
5. 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.

The IRB may use the expedited review procedure to review minor changes in previously approved research during the period for which approval is authorized.

### Convened IRB Review (“Full Board”)

### Non-exempt human research that does not qualify for expedited review and/or is greater than minimal risk must be reviewed by the convened IRB. The IIT IRB meets monthly. The convened IRB meeting schedule and submission deadlines are available here: [Human Subjects [IRB]](https://research.iit.edu/orcpd/human-subjects-irb) Generally, when the convened IRB reviews a research application the Principal Investigator is in attendance to present a brief summary of the proposed research and to answer questions from IRB members. The PI will leave the meeting before the IRB members deliberate and vote on the application.

# IRB Decisions

The IRB has the authority to approve human research, require modifications to secure approval, or defer/disapprove human research. When the IRB cannot approve the research at a convened meeting for reasons unrelated to the research, such as loss of quorum, the review will be tabled. Under those circumstances, the research will be reviewed at the next meeting.

### Approval

Once the IIT IRB has approved the proposed human research, it may commence. For research reviewed by the convened IRB approval is granted for up to a year, which is noted in the approval notification letter and the Principal investigator is required to submit a renewal before the approval expiration date to continue the research. Research reviewed by expedited review will have approval granted for up to a year, but it is up to the Principal Investigator whether or not to submit a renewal after the approval expiration date. Research that was determined to be exempt from IRB review has no expiration date.

### Modifications Required to Secure Approval

If the IRB requires modification(s) to secure approval, the notification letter will outline specific revisions to the research and/or study materials, e.g., research protocol, consent form, study tools, etc. and the justification. Human subject research may not commence until the IRB grants final approval.

If the PI accepts the required modifications, he or she should submit the revised materials via Cayuse to the IRB within 45 calendar days. If all requested modifications are made, the IRB will issue a final approval notification letter after which time the human research can begin.

If the PI does not accept the IRB request for modifications, he or she should write a response detailing why such modifications are not appropriate and/or feasible and submit it to the IRB within 45 calendar days. If the Principal Investigator does not respond to the IRB within 45 calendar days, a decision to approve with the requested modifications will be withdrawn.

Typically, modifications submitted by a PI for minor revisions do not increase risk to subjects such as correcting recruitment materials, aligning information in the consent form with information in the application, changing personnel, etc. and are reviewed by IRB staff.

Modifications submitted by the PI for more substantive revisions such as changing incentives for participation, providing an adequate sample size for analysis, minor change in eligibility criteria, etc. are reviewed by one or two IRB members.

Modifications submitted by the PI for major revisions that involve increased risks to subjects, the design of the research, disclosure of identifiable data are reviewed by the convened IRB.

### Tabled

Made when the IRB cannot approve the research at a meeting for reasons unrelated to the research, such as loss of quorum. When taking this action, the IRB automatically schedules the research for review at the next meeting.

### Deferral

Made when the IRB determines that the convened board is unable to approve the proposed research and the IRB suggests modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision, describes modifications that might make the research approvable, and gives the investigator an opportunity to respond to the IRB in person or in writing. The deferral notification to the PI will also indicate whether the PI’s response is reviewed by the convened IRB or by the IRB Chair or designate.

### Disapproval

Made when the IRB determines that it is unable to approve research and the IRB cannot describe modifications that might make the research approvable. When making this motion, the IRB describes its reasons for this decision and gives the investigator an opportunity to respond to the IRB in person or in writing. Otherwise the PI can submit a new application.

# Principal Investigator Eligibility

The basis for determining who is eligible to be a Principal Investigator (PI) is generally based on who may receive funds through a grant, contract, or other funding mechanism on behalf of IIT.

Those who may be named as PI on an IRB application in Cayuse follow these same guidelines, however, there is an alternative for those who are not PI eligible. Individuals not PI eligible may serve as a Co-PI on an IRB application if there is a PI eligible faculty or staff listed as PI/Sponsor. [See IIT PI Eligibility](https://research.iit.edu/sites/research/files/elements/OSRP/pdfs/PI-Eligibility-Policy-05-04-2020.pdf)

**Undergraduate Students, Graduate Students, and Post-Doctoral Researchers**

Undergraduate students, graduate students, and post-doctoral researchers affiliated with IIT, are permitted to Co-PI on an IRB Cayuse application however this designation is only valid if a PI eligible faculty sponsor is listed as PI on the IRB application. The Faculty Sponsor who is listed on the IRB application as PI will confirm that he or she will oversee the research and ensure that the Co-PI complies with all IRB requirements.

There may be times when the best person to oversee a student’s research is not considered PI eligible. For example, faculty classified as adjunct faculty, research associates or similar titles, may serve as advisors however they are ineligible to be named as a PI or faculty sponsor on a student project. An option for a PI ineligible individual to consider is to request approval from the Dean/Chair and the Vice Provost for Research for the non-PI eligible individual to serve as PI/Faculty Sponsor. The approval must be in place **prior** to the proposal preparation.

### Principal Investigator Responsibilities

For each application submitted to the IIT IRB, the Principal Investigator must acknowledge a “Principal Investigator Assurance Statement” in Cayuse. The PI must adhere to each requirement throughout the duration of the study (from initial submission to study closure). See [Principal Investigator Responsibilities and Assurance Statement](#PIresponsibilities).

# Human Subjects Protection Training

#### Human Subjects Protection Training

Any IIT faculty, staff, undergraduate, graduate student, postdoctoral researcher or non-affiliated researcher that will have direct interaction with research participants and/or access to identifiable information/specimens must complete human subjects protection training. Principal Investigators, Co- Investigators, and those meeting the definition of NIH “[Key Personnel](https://grants.nih.gov/grants/glossary.htm%23Senior/KeyPersonnel)” must complete human subject protection training regardless of whether or not they have direct interaction with participants and/or access to identifiable information/specimens.

The IIT human research training curriculum is offered through the [Collaborative Institutional](http://www.citiprogram.org/) [Training Initiative (CITI) Program (CITI).](http://www.citiprogram.org/) To access it, CITI Learnerscan register at the [CITI website](https://www.citiprogram.org/index.cfm?pageID=14) with “Illinois Institute of Technology '' and select the “Human Research (Protection of Human Subjects)” course. It is also possible to access CITI via [my.iit.edu](https://login.iit.edu/cas/login?service=https%3A%2F%2Fmy.iit.edu%2Fc%2Fportal%2Flogin). Once in my.iit.edu click on Research and a new tab opens, the CITI link is in the middle column.

Within the “Protection of Human Subjects” course, CITI Learners can select either the “Biomedical Research” or “Social & Behavioral Research” module. In addition to IIT CITI training, the IIT IRB will also accept another institution’s certificate of completion for CITI training or equivalent.

Human research protection training certification is valid for a three-year period from date of completion, regardless of which institution it was completed. When current training expires, a refresher course, or additional training, is required. Refresher training can be fulfilled by taking the IIT CITI refresher course, another institution’s CITI refresher course or equivalent course.

IIT IRB approval in Cayuse will not be granted for proposed human research where any staff member’s CITI human training remains incomplete. If a staff member does not complete CITI in a timely manner, the PI may remove that staff member from the Cayuse application.

#### NIH Good Clinical Practice Requirements

In effect since January 1, 2017, NIH's Good Clinical Practice (GCP) policy establishes the expectation that all NIH- funded investigators and staff who are involved in the conduct, oversight, or management of NIH clinical trials should be trained in Good Clinical Practice (GCP).

NIH's Office of Behavioral and Social Sciences Research has developed Good Clinical Practice (GCP) training modules specifically tailored to social and behavioral science researchers conducting clinical trials and are available through the Society of Behavioral Medicine (SBM), including for non-members of SBM. [Good Clinical Practice eCourse | SBM - Society of Behavioral Medicine](https://www.sbm.org/training/good-clinical-practice-for-social-and-behavioral-research-elearning-course)

# Reporting Financial Conflict of Interest

IIT’s policy on Financial Conflict of Interest (FCOI) requires that each Investigator disclose his or her "significant financial interests" to [IIT’s designated official](https://www.iit.edu/general-counsel/resources/conflict-interest) no later than the date of application for funds. A financial interest is "significant" if it exceeds the minimum threshold of $5,000 *and* "reasonably appears to be related to the Investigator's institutional responsibilities."

A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator’s spouse and dependent children) that reasonably appears to be related to the Investigator’s institutional responsibilities:

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (e.g., consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration (as defined in (1) above) received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when any equity interest (e.g., stock, stock option, or other ownership interest) is held; and

3. Intellectual property rights and interests (e.g., patents, copyrights) upon receipt of income related to such rights and interests that, when aggregated, exceed $5,000. Unlicensed, non-income generating intellectual property is excluded.

However, the following are *not* considered significant financial interests:

1. Salaries, royalties, or other remuneration paid if the Investigator is currently employed by the Institution.

2. Income from investment funds such as mutual funds or retirement accounts as long as the interests are not directly controlled by the Investigator.

3. Income from seminars, lectures, or teaching engagements from appropriate entities under 20 U.S.C. §1001(a).

4. Income from service on an advisory committee or review panel for an entity under 20 U.S.C. § 1001(a).

Pursuant to IIT’s Investigator Conflict of Interest and Conflict of Commitment Policy (the “Policy”), all Investigators are required, on an annual basis, to disclose certain significant financial interests. Further, all Investigators have an on-going obligation to submit an updated Disclosure Form within 30 days of discovering or acquiring (e.g., through purchase, marriage, inheritance) a new significant financial interest. Finally, by submitting this Disclosure Form, Investigators are acknowledging that they have read and understand the Policy and agree to abide by it. <https://www.iit.edu/general-counsel/resources/conflict-interest>

Because of federal regulatory requirements, IIT cannot submit any proposals on an Investigator’s behalf or allow an Investigator to expend any funds for funded research if he or she fails to fully and accurately complete and submit the [Disclosure Form](https://www.iit.edu/general-counsel/resources/conflict-interest) and comply with the Policy. For more information contact the Interim General Counsel at [whazlitt@iit.edu](mailto:whazlitt@iit.edu).

Under the Policy, the terms “Investigator” is defined as follow: Investigator means the project director or principal investigator and any other person, regardless of title or position, who is, or has been within the preceding 24 months, responsible for the design, conduct or reporting of funded research, or proposed for funding, which may include, without limitation, all full-time faculty members, collaborators, consultants and visiting and part-time faculty members with research privileges, but **excludes** visiting and part-time faculty members who only provide classroom instruction. Senior/key personnel, as such term is defined in the Policy, are deemed to be Investigators.

**Financial Conflict of Interest Training**

IIT FCOI Policy requires investigators to complete Financial Conflict of Interest (FCOI) training through CITI; regardless of research funding source. Investigator means the project director or principal investigator and any other person, regardless of title or position, who is, or has been within the preceding 24 months, responsible for the design, conduct or reporting of funded research, or proposed for funding, which may include, without limitation, full-time faculty members, collaborators, consultants and visiting and part-time faculty members with research privileges, but excludes visiting and part-time faculty members who only provide classroom instruction. Senior/key personnel are deemed “Investigator” for this policy. Typically these individuals have doctoral or professional degrees although individuals at the masters or baccalaureate level maybe considered Senior/Key Personnel.

# Individual Investigator Agreement (IIA) & IRB Authorization Agreement (IAA)

All IIT investigators engaged in human research must secure IRB review and approval. This applies when non-exempt human subject research is conducted at IIT, another institution, in another country, and/or in collaboration with non-IIT affiliates.

**Research with Non-IIT** **Collaborators**

Should an IIT PI plan to engage a non-IIT collaborator(s) in non-exempt human subject research the non-IIT collaborator(s) is expected to inquire at their home/affiliate institution to determine whether their IRB review and oversight is required or if their home/affiliate institution may consider entering into an *IRB Authorization Agreement* (IAA) to rely on the IIT IRB for the review.

An IRB Authorization Agreement allows one institution to serve as the Reviewing Institution/IRB (“single IRB” or “sIRB”) while the other serves as the Relying Institution/IRB (“participating site”) rather than each institution IRB conducting separate reviews and managing oversight for the same study. The Relying Institution must have a Federal-wide Assurance (FWA) to enter into a reliance agreement with IIT. Some institutions may use a [SmartIRB Online Reliance System](https://smartirb.org/reliance/).

When non-IIT collaborators do not have a home/affiliate institution, e.g., community member or independent contractor, they may be added to the IIT IRB-approved study as Individual Investigator(s)via an *Individual Investigator Agreement (IIA)*. An IIA is a formal written agreement between IIT and an individual investigator who is collaborating on the research, by which IIT agrees to extend its Federalwide Assurance (FWA) to the individual investigator who will agree to fulfill specified expectations and responsibilities. The individual investigator(s) are required to complete IIT CITI human subject research training or submit CITI certificate of completion form another institution.

An Individual Investigator Agreement (IIA) is not needed for research that the IIT IRB will determine is exempt from review. To include non-IIT collaborators on the IIT research protocol the collaborators must complete CITI and submit a Letter of Support to the IIT PI. The Letter of Support must be on the non-IIT collaborators institutional letterhead and describe his or her role for the IIT research.

**IRB Authorization Agreement (Designating a single IRB)**

A reliance agreement, IRB Authorization Agreement (IAA), or External IRB are all terms that refer to a situation where research is conducted at two (or more) institutions and one is designated to serve as the Reviewing Institution/IRB (“single IRB” or “sIRB”) while the other serves as the Relying Institution/IRB (“participating sites”).

Only non-exempt human research is eligible for such an Agreement, i.e., protocols reviewed on an expedited basis or by the convened IRB. Activities that are not human subjects research or are determined to be exempt are ineligible for a reliance agreement.

### IIT Accepting IRB Review Responsibilities for another Institution

The IIT IRB will accept reviewing responsibilities on a case-by-case basis, including but not limited to the following situations:

(i) When the primary work involving participants takes place on property under the jurisdiction of an Investigator from IIT, or

(ii) When the study involves a secondary institution or institution’s personnel but is initiated by an IIT Investigator, or

(iii )When one or more parts of the study are to be conducted at an institution or entity, or in a locale, that lacks a constituted IRB or other research ethics committee, but has a current FWA, or

(iiii)When IIT has been selected to be the Reviewing IRB according to the terms of an award for a Single IRB review.

In all situations where an IRB Authorization Agreement is in place, the relying institution must hold a current FWA.

### IIT Relying on the Review of another IRB

The IIT IRB may rely on the reviewing authority of another IRB under one or more of the following conditions, or for other reasons deemed appropriate:

* The IRBs are part of an established reliance network (e.g. Smart IRB) that has established contractual and SOP- level procedures to clarify the roles and responsibilities associated with IRB reliance and to establish mechanisms to ensure quality and consistency in the review process among institutions.
* The sIRB arrangement has been pre-determined by study sponsor or grant or established by prior arrangement.
* The IIT investigator is a collaborator on human research that is primarily conducted at the reviewing institution or organization and the IIT investigator’s role does not include interaction or intervention with subjects.
* IIT is engaged in human research solely because it is receiving federal funds. (Employees and agents of the institution do not interact or intervene with subjects, gather or possess private identifiable information about subjects, nor obtain the consent of subjects.) The role of the investigator at the reviewing institution includes interaction or intervention with subjects.

The IIT IRB will ordinarily not rely on the review of another IRB if any research activities conducted at IIT will require direct intervention or interactions with study participants unless the research activities at IIT are minimal risk and represent a small proportion of the study activities.

### Requesting IIT IRB as the IRB of Record

To request that the IIT IRB serve as the IRB of record, submit the [IRB of Record request form](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Request%20Form%20for%20IIT%20IRB%20Serve%20as%20IRB%20of%20Record.docx)[.](#_2zbgiuw)

When the Relying Request involves a SmartIRB [participating institution,](https://smartirb.org/participating-institutions/) an additional application is required through the SmartIRB Online Reliance System. Instructions on how to complete the SmartIRB reliance form are [available](https://smartirb.org/resources/) [online.](https://smartirb.org/resources/)

### IIT PI Obligations as the Overall Study PI for a Multi-site Study Reviewed by IIT as the sIRB

1. Coordinating with the IIT IRB to determine whether the IIT IRB can act as the single IRB for all or some institutions participating in the study or if an external IRB will assume oversight.
2. Identifying all sites that will be engaged in human research and requiring oversight by the IRB.
3. Ensure that all sites receive a request to rely on the reviewing IRB and that all institutional requirements are satisfied before a study is activated at a relying site.
4. Collaborate with the reviewing IRB to document roles and responsibilities for communicating and coordinating key information from study teams and the IRB or HRPP at relying sites.
5. Respond to questions or information requests from study teams or the IRB staff at relying sites.
6. Provide relying site investigators with the policies of the reviewing IRB.
7. Provide relying site investigators with the IRB-approved versions of all study documents.
8. Preparation and submission of IRB applications on behalf of all sites. This includes initial review, modifications, personnel updates, reportable new information and continuing review information for all sites.
9. Establishing a process for obtaining and collating information from all sites and submitting this information to the reviewing IRB. This includes site-specific variations in study conduct, such as the local consent process and language, subject identification and recruitment processes and local variations in study conduct.
10. Ensuring that consent forms used by relying sites follow the consent template approved by the reviewing IRB and include required language as specified by the relying sites.
11. Providing site investigators with all determinations and communications from the reviewing IRB.
12. Submitting reportable new information from relying sites to the reviewing IRB in accordance with the terms outlined in the authorization agreement or communication plan.
13. Reporting the absence of continuing review information from relying sites if they do not provide the required information prior to submission of the continuing review materials to the reviewing IRB. Notifying the relying site of their lapse in approval and applicable corrective actions.
14. Providing study records to the relying institution, reviewing IRB or regulatory agencies upon request.

### IIT PI Obligations as an Investigator for a Multi-site Study When IIT Relies on an External IRB (sIRB)

1. Check in with the IIT IRB prior to seeking review by another IRB.
2. Comply with determinations and requirements of the reviewing IRB.
3. Provide the reviewing IRB with requested information about local requirements or local research context issues relevant to the IRB’s determination prior to IRB review.
4. Notifying the reviewing IRB when local policies that impact IRB review are updated.
5. Cooperating in the reviewing IRB’s responsibility for initial and continuing review, record keeping and reporting and providing all information requested by the reviewing IRB in a timely manner.
6. Disclosing conflicts of interest as required by the reviewing IRB and complying with management plans that may result.
7. Promptly reporting to the reviewing IRB any proposed changes to the research and not implementing those changes to the research without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
8. When enrolling participants, obtain, document and maintain records of consent for each participant or each participant’s legally authorized representative.
9. Promptly reporting to the reviewing IRB any unanticipated problems involving risks to participants or others according to the requirements specified in the reliance agreement.
10. Proving the reviewing IRB with data safety monitoring reports in accordance with the reviewing IRB’s reporting policy.
11. Reporting non-compliance, participant complaints, protocol deviations or other events according to the requirements specified in the reliance agreement.
12. Specifying the contact person and providing contact information for researchers and research staff to obtain answers to questions, express concerns, and convey suggestions regarding the use of the reviewing IRB.

# Cayuse Record Access

### Principal Investigator

The Principal Investigator (PI) named in Cayuse has full access to the corresponding record. The PI has the ability to make edits, create modifications, add personnel, and submit continuing review applications. The PI will receive all notifications generated via Cayuse.

### Primary Contact

In addition to the PI, a Primary Contact can create submissions (on behalf of the PI) and receive copies of all study-related notifications generated in Cayuse. A PI may designate a Primary Contact by completing the “Assign Primary Contact” activity in Cayuse. There can only be one Primary Contact at a time.

### Other Personnel

Personnel named in Cayuse have access to the record. If others need access to the Cayuse record and submission documents, they can be added as a member of the guest list by completing the “Manage Guest List” activity in the main study workspace. This will allow any IIT-affiliated individual read-only access to the Cayuse record.

### Students, Postdoctoral Researchers and New Faculty

Undergraduates, graduate students, and new postdoctoral researchers must contact Deborah Richard in the Office of Research Integrity and Compliance at [drichard1@iit.edu](mailto:drichard1@iit.edu) to be added to an application in Cayuse. Ms. Richard will need full name, Hawk# (or A number), department, and IIT email address for registration.

# Submitting an Initial Application in Cayuse

The IRB must review and approve all human research prior to the initiation of any activities. To create a new IRB application online using CAYUSE, [follow these instructions on the Cayuse Help Center](https://support.cayuse.com/hc/en-us/categories/115001977467-Human-Ethics)[.](http://estrsupport.fss.harvard.edu/creating-new-study)

If a separate sponsor’s protocol exists, submit it in addition to this document via the Supporting Documents page in Cayuse.

The Cayuse application is a series of SmartForms where information is entered and documents are attached.

The SmartForms may contain required information identified by a red asterisk (\*). You cannot proceed without providing this information.

Additional documents should be attached where appropriate, e.g. recruitment materials, consent forms, and study tools. Cayuse supports all common file formats (e.g. Word, PDF, Excel, Publisher, JPEG) however unsupported file formats (e.g. audio, video, mp4, mp3, wav, etc.) should be attached within a zip file. Zip files should only be used for this purpose and not used to consolidate supported file formats.

For each attachment, ensure that the name and version number/date of the document are accurate and reflective of the document content/purpose. It is recommended that the file name and version number/date also appear in either a header or footer within each document. When uploading a revised version of any document, click 'Update' in Cayuse rather than 'Delete' or 'Add.' Do not delete any documents from the Cayuse record unless instructed to by your IRB staff member.

Specific details about how to navigate the IRB online submission system and complete an application can be found on the [Cayuse Help Center website](https://support.cayuse.com/hc/en-us/categories/115001977467-Human-Ethics).

### Proposing Modification(s)

To change or update an active, IRB-approved human research protocol, a modification must be submitted in CAYUSE and approved by the IRB prior to implementation. If the activities were found not to constitute research with human subjects or determined to be exempt, changes do not require IRB review unless they might alter the IRB’s original determination. You will also want to take note of any institutional requirements that would require a modification. For example, use of the IIT Psychology Department Study Pool requires notation in the determination letter therefore requiring a modification. Contact the [IIT IRB](mailto:%20irb@iit.edu) [i](https://cuhs.harvard.edu/people)n cases where it is unclear whether a proposed modification might alter the IRB’s original determination or if institutional requirements might apply.

To request modifications, [follow these instructions from the Cayuse Help Center website](https://support.cayuse.com/hc/en-us/categories/115001977467-Human-Ethics). Attach all updated study documents including a copy of any revised study materials. When applicable, indicate how current or former participants will be notified of protocol modifications.

### Requesting Continuing Review / Renewal

Continuing review is required for most research that is reviewed by the convened IRB and certain expedited research in which the IRB expedited reviewer determined that continuing review or renewal is required.

To request continuing review or renewal, [follow these instructions from the Cayuse Help Center website](https://support.cayuse.com/hc/en-us/categories/115001977467-Human-Ethics). Attach any documents that contribute to the review of the submission (e.g. any progress reports, CITI refresher training). Do not attach any revised study documents (Research Protocol, consent forms, research tools, supporting documents, etc.). If modifications to the study need to be made at the time of continuing review, a Modification is required to submit these revisions for review and approval (see above section on “Proposing Modifications”). This should be done prior to creating a continuing review application so that revised study documents will be included in the approval for the upcoming approval period.

If continuing review or renewal is required, the protocol will already have an approval period of up to 12 months. If IRB approval of the human subject research expires, all human subjects activities must stop until approval is renewed. This includes recruitment, enrollment, interventions, interactions, and collection of private identifiable information. Continuing human research procedures during a lapse in approval for studies with an expiration date is a violation of federal regulations.

### Requesting Study Closure

Study closure is appropriate when (a) the research is permanently closed to enrollment; (b) all participants have completed all research-related interventions/interactions; (c) collection of private identifiable information is completed, and (d) analyses of private identifiable information is completed. After study closure, analyses of de- identified data/specimens and manuscript preparation can occur indefinitely.

To close a study it is necessary to complete a Study Closure submission in Cayuse. Open Cayuse to access the Study Details for the study. Click on New Submission, the blue box at the top right corner. In the drop-down menu, click on Closure. On the new Submission Details page, click Edit. Fill out the submission form and click Complete Submission. The study is marked closed once acknowledged by the IRB.

**Drafting a Research Protocol**

**General Requirements**

A research protocol is required for any human subject research application (this includes application for an Exempt Determination). A research protocol is not required when requesting a Not Human Subjects Research Determination.

The purpose of the Research Protocol is to provide members for a convened IRB, or expedited reviewers, with sufficient information to conduct a substantive review.

The sections below are general considerations to consider when preparing a research for IRB review before completing the Initial Application in Cayuse. The sections below was based on information from NIH, Office of Behavioral and Social Sciences Research.

**Study Introduction**

Provide a short description of the proposed research and a brief statement of the study hypothesis or rationale. This should only take a few sentences.

**Background**

Discussion of existing data and published research relevant to the proposed study; often a literature review. Include justification for the research. This is typically several paragraphs.

**Objectives**

An objective is the purpose for performing the study in terms of the scientific question to be answered. The primary objective is to address the main research question. Secondary objectives are other constructs of the study that could clarify findings from the primary objective.

Express each objective as a statement purpose (e.g., to assess, to determine, to compare, to evaluate) and include the general purpose (e.g., feasibility, acceptability, engagement of the study target, identifying, mediation, moderation, efficacy, effectiveness, dissemination, implementation).

**Study Design**

Provide an estimate of how much time will be needed to complete data collection for the research. If applicable, differentiate the number of subjects to screen to identify eligible subjects for the research. Is the research expected to last over the course of several years, months, etc.?

Describe the research procedures:

* + - * What is the timeline of all procedures being performed, including follow- up visits and procedures being performed to monitor participants for safety or minimize risks? Will participants be asked to participate in one session or multiple? How frequent are interactions with each subject and what is the duration of each interaction? How are participants re-contacted for follow-up?
      * What risks might participants incur during participation? Risks can vary in type and magnitude. People often think of physical risks as the main risk of research participation. However, other risks can include:
        + Emotional/mental, could procedures be upsetting?
        + Reputational, could procedures negatively impact a participant’s social standing in their community? At their job? Their academic standing?
        + Undue Influence, are there any factors that could make a participant feel compelled to participate?
        + Legal, could procedures have negative criminal or civil outcomes for participants?
      * In identifying the risks that may be associated with research procedures, also consider the procedures that can be taken to lessen the probability or magnitude of risks such collecting the minimally needed data and ensuring adequate data security, etc.
      * What data will be collected, including long-term follow-up data? What kinds of information will be obtained and kept? Will that data be identifiable, coded, de-identified? Will data be collected directly through an interaction or intervention with participants or received via a source?
      * Do study procedures include the use of incomplete disclosure or deception? Incomplete disclosure occurs when information is withheld from participants at the time of consent or during the course of study procedures. This information is often withheld in order to avoid introducing bias in to the study but can be used for many reasons. Deception occurs when participants are purposefully provided false information or are misled about procedure and the study purpose. Deception can be used as a tool to avoid introducing bias into a study or it can be used as part of the study design to ensure a particular outcome.
      * For both incomplete disclosure and deception, the rationale for their use should be considered. In addition to why, whether participants will be provided with the previously withheld information or told the correct information after participation should be considered. This is a process known as “debriefing”. Debriefing can be an important part of the risk mitigation process, ensuring participants feel comfortable with the outcome of their participation in the research. The debriefing process should include the opportunity for the participant to withdraw themselves, and all of their data, from the study.
        + When using incomplete disclosure or deception, the protection of research participants’ rights in the presence of these (tools) should be considered. Participants should still have sufficient information to make the decision to participate and procedures should still allow for the voluntariness of the research.

**Study Population**

Estimate the sample size, gender, age, demographic group, general health status, and geographic location as applicable. Ensure the proposed sample size is adequate for analysis to support the study’s objectives according to accepted quantitative or qualitative methodological standards.

**Inclusion/Exclusion Criteria**

Clearly define inclusion/exclusion criteria for enrolling subjects in the proposed study.

**Subject Recruitment**

Describe the source of prospective subjects and recruitment methods. If applicable describe any screening procedures for prospective subject eligibility. Include subject recruitment materials (e.g. ads, letters, recruitment invitation letters/emails, social media postings or scripts, etc.) as separate attachments.

**Risks**

Include a discussion of any potential risks already known or those cited in the literature. Typically the risks in social/behavioral research are minimal, that is the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life.

If research is greater than minimal risk describe immediate risks and long-term risks. If the risk is directly related to study procedures describe alternative procedures that have been considered and explain why the alternative procedures are not included with protocol. Also describe measures to minimize the risk.

Identify whether any of the information collected, if disclosed outside of the research, could reasonably place the participant at risk of criminal or civil liability or be damaging to the participant’s financial standing, employability, insurability, or reputation.

**Benefits**

Include a discussion of known benefits to participating individuals if any and to society that may be cited in the literature. There are not always direct benefits to the participating individuals (subject compensation is not a benefit), but there is the benefit of contributing to the advancement of science.

**Assessment of Potential Risks and Benefits**

Provide rationale for the necessity of exposing research subjects to the risks. Summarize how risks to subjects are minimized in the study design. Justify how the benefits or value of the information collected outweighs the risks to participants.

**Compensation**

Describe any plans for providing incentives or compensation to research subjects. If financially compensating subjects identify the information needed in order to pay the individuals. If payments participating in research made to a US citizen or permanent resident for participating in research total $600 or more in a given calendar year, the IRS requires that IIT report the total amount on a Form 1099. The IRS does not require reporting payments totaling less than $600 in a given calendar year; however, research subjects may still need to report such payments on their individual income tax returns.

**Confidentiality and Privacy**

Describe procedures for protecting confidentiality of research subjects’ data. Provide details about who will have access to the data. Describe whether identifiers will be attached to subject data or data are de-identified, or if data will be coded.

**Informed Consent Process**

Describe how the informed consent process is conducted. Not all research requires documenting informed consent or obtaining informed consent. Describe any requested waivers or alterations to the informed consent process. Describe any special circumstances regarding informed consent (vulnerable populations such as children, prisoners, individuals with impaired decision making capacity; non-English speakers), legally authorized representative (LAR) or assent for minors who are participants.

**HIPAA Privacy Protections**

Indicate if access is needed to research subjects’ Protected Health Information (PHI) for the proposed research. Describe whether subject authorization will be sought, or a HIPAA waiver will be requested from the IRB/Privacy Board. If relevant, describe the use of a Limited Data Set (LDS).

If protected health information (PHI) is derived from a covered entity, e.g. a hospital or community health center, plans to obtain patient authorization to access their protected health information will be needed. An alternative is to request a waiver of patient authorization for obtaining the information. If requesting the waiver, consider why it is not practical to obtain an authorization and why the research cannot be conducted without obtaining PHI.

The following three criteria must be satisfied for an IRB or Privacy Board to approve a waiver of authorization under the Privacy Rule:

1. The use or disclosure of protected health information 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 identifiers 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 protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

1. The research could not practicably be conducted without the waiver or alteration; and
2. The research could not practicably be conducted without access to and use of the protected health information.

**Vulnerable Populations**

Certain participant populations may require additional protections when included in research. The Federal regulations note that pregnant women, prisoners, and children should be considered vulnerable and additional regulations have been put into place to ensure protection during research participation. For research conducted with prisoners, there are conditions regarding the purpose of the research, recruitment procedures, and study procedures to ensure a voluntary research environment. Note that the IRB must make additional regulatory findings for the inclusion of pregnant women, neonates, fetuses; children, adults with impaired decision-making capacity, and prisoners. The checklists referenced below should not be submitted in Cayuse, but rather used as a guide to ensure sufficient information is provided in the Research Protocol.

* + - Adults with impaired decision-making capacity. If the proposed research involves adults who may be unable to consent, refer to: “Adults with Impaired Decision-Making Capacity” and consider the criteria.
    - Children. If the proposed research involves persons who have not attained the legal age for consent for procedures involved in the research, refer to [“Children involved in Research”](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Involving%20Children%20in%20Research.docx).
    - Pregnant Women: If the proposed research involves pregnant women, refer to [“Pregnant Women”](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Involving%20Pregnant%20Women%20in%20Research.docx).
    - Prisoners. If the proposed research involves prisoners, refer to: [“Prisoners ”](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Involving%20Prisoners%20in%20Research.docx).

While the regulations specifically cite these populations, there are other factors that may make a population vulnerable to undue influence, coercion, or increased risk. These factors can include the relationship of the participant to the researcher (e.g., student/professor), economic circumstances (e.g., under housed/homeless), among others.

Measures should be taken to mitigate any factors that could impact the voluntariness of the research and/or increase overall risk of participation as result of potential vulnerabilities. For example, in the case of a researcher who uses their own students as the participant population, someone other than the researcher could obtain consent of the students for participation. This would assist in students feeling free to decline participating. Inclusion of a sentence ensuring participation would not impact their grade or status in the course would also assist in mitigating the risk of students feeling compelled to participate because of their relationship with the researcher.

**Research Subject Privacy**

Maintaining research subject privacy is often a primary means of mitigating any risk to participants. The research team should consider the provisions that will be implemented to protect participants’ privacy during and after participation. Privacy is defined as a person having control over the extent, timing, and circumstances of sharing oneself (physically, behaviorally, or intellectually) with others. Privacy also refers to the right of individuals to limit access to/about themselves from/by others, especially information shared with researchers.

This includes identifiable information, HIPAA-defined protected health information, research data, photos, video recording, and information contained in biological specimens. It involves consideration of whether the participants will be comfortable with the research procedures. For example, conducting interviews in a private room or visiting a participants’ home in an unidentifiable manner, such as in an unmarked car, wearing plain street clothing. Identify the steps that will be taken to reduce any sense of intrusiveness that may be caused by study questions or procedures.

**Data Confidentiality**

Confidentiality pertains to the treatment of information that a participant has disclosed in a relationship of trust and with the expectation that it will not be divulged to others without permission.

If future open access is planned, this information should be included at the time of consent. If data is subject to NIH [Genomic Data Sharing policy](http://gds.nih.gov/) or data will be voluntarily submitted to an NIH-designated repository, additional information will be needed. This includes a description of all data fields to be submitted to the repository; a copy of the consent form(s) used to enroll participants and collect underlying data; a description of the PI’s plan for de-identifying datasets for transmission to the data repository, how the key linking the identity of each study participant will be maintained, and who will have access.

Data security plans developed to ensure data confidentiality must comply with protection requirements described in the IIT Research Data Security.

Per the [IIT Research Data Security](https://www.iit.edu/gridiit/policies) research data can be stored electronically, however there are data security level specific requirements and investigators must consult with OTS for data assigned level 3 or higher before beginning their research activities.

**Sharing Study Results**

If you will be sharing results with research participants, consider what impact, if any, this could have on the ability to maintain confidentiality. Could participants potentially be able to identify others based on the information shared? Identify the plan to share study results with individual participants and/or the participant group/community, if applicable (e.g., what contact information will be needed and how will it be stored)

**Cayuse Application Sections with Question Items**

**Sections**

1- Introduction 6- Study Design

2- Submission Information 7- Study Procedures

3- Sponsored Projects 8- Participant Protection

4- Study Information 9- Conflict of Interest

5- Study Selection 10- Attachments

**Required information in Cayuse is identified by a red asterisk (\*). You cannot proceed without providing this information.**

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**1- Introduction**

**About Cayuse IRB**

Cayuse IRB is an interactive web application. As you answer questions, new sections relevant to the type of research being conducted will appear on the left-hand side. Therefore not all numbered sections may appear. You do not have to finish the application in one sitting. All information can be saved.

**Additional information has been added throughout the form for guidance and clarity.** **That additional information can be found by clicking the question mark at the top-right corner of each section.**

For more information about the IRB submission Process, IRB Tracking, and Cayuse IRB Tasks, please refer to the [Cayuse IRB Procedures Manual](http://support.cayuse.com/)

**Getting Started**

Throughout the submission, you will be required to provide the following:

* Detailed Study Information
* Informed Consent Forms
* Study Recruitment Information

**Illinois Institute of Technology IRB**

* You cannot begin data collection until a formal approval letter from Cayuse of IRB approval has been received.
* The IRB meets as needed during the regular academic year.
* Principal Investigators (PIs) are responsible for timely submission of IRB administrative check-ins and renewals. Research activities may not be conducted without active IRB approval.
* For more information, please review the [website](https://research.iit.edu/orcpd/human-subjects-irb).

I have read the information above and I am ready to begin my submission.

* Yes

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**2- Submission Information**

Select the appropriate research activity for which you are requesting IRB approval.

* Research Study

Indicate which type of research (click the hyperlinks for definitions).

* + Exempt
  + Expedited
  + Full Committee
  + Unsure/do not know
  + Clinical Trial
  + Single Patient, Treatment Use, Continued Access Drug/Device Study
  + Emergency (or Compassionate) Use of Investigational Drug or Device
  + Activities Without a Plan to Conduct Research (Case Report or Quality Improvement project)

Is this a multi-institutional study?

* Yes
* No

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**3- Sponsored Projects**

Is this project supported by external funding?

All funded projects must have a Cayuse SP record.

* Yes
* No

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**4- Study Information**

Which option below best describes your affiliation with Illinois Institute of Technology?

* Faculty
* Student
* Staff
* Other

**Study Personnel**

Note: If you cannot find a person in the Find People tool, please contact [drichard1@iit.edu](mailto:drichard1@iit.edu) for assistance.

**Principal Investigator/Faculty Sponsor**

Provide the name of the Principal Investigator (PI) of this study. NOTE: The PI for this study must be a faculty or staff member with IIT.

| **Name** | **Organization** | **Address** | **Phone** | **Email** | **Trainings** |
| --- | --- | --- | --- | --- | --- |

**Primary Contact**

Provide the name of the Primary Contact of this study.

| **Name** | **Organization** | **Address** | **Phone** | **Email** | **Trainings** |
| --- | --- | --- | --- | --- | --- |

**Co-Principal Investigator(s)**

Provide the name(s) of any Co-Investigator(s) for this study. Note: students leading research projects should be listed here.

| **Name** | **Organization** | **Address** | **Phone** | **Email** | **Trainings** |
| --- | --- | --- | --- | --- | --- |

**Other Personnel**

Provide the name(s) of other personnel for this study.

| **Name** | **Organization** | **Address** | **Phone** | **Email** | **Trainings** |
| --- | --- | --- | --- | --- | --- |

**Outside (non-IIT affiliated) Personnel**

Provide the name(s) of any research personnel not affiliated with IIT with their institutional affiliation (such as outside collaborators).

**Study Site**

Please select the location of the study.

* Illinois Institute of Technology

Please provide the names of the Illinois Institute of Technology locations.

Include specific buildings and lab locations on campus. E.g.: ERB 123.



* External Site (non Illinois Institute of Technology)
* Both (Illinois Institute of Technology and External Sites)

**Study Dates**

Please provide the study start and end dates.

**Start Date**



NOTE: study interventions with human subjects cannot proceed without IRB approval.

**End Date**



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**5- Study Selection**

|  |
| --- |
| Additional information and guidance can be found by clicking the question mark it the top-right corner of each section. |

|  |
| --- |
| **Subject Enrollment**  Enter the number of subjects that will be enrolled in this study. |

|  |
| --- |
| **Enrollment at IIT**  Please enter the number of subjects that will be enrolled at **Illinois Institute of Technology**. |

|  |
| --- |
| **Total Study Enrollment**  Please enter the total number of subjects to be enrolled at all study sites. |

|  |
| --- |
| **Ages**  Select the age range of subjects that will be enrolled in this study. Check all that apply.   * Fetus * Birth to less than 1 month * 1 month to less than 12 years old * 12 years old and less than 18 years old * 18 years and older |

|  |
| --- |
| **Vulnerable Populations**  Please check the population(s) that will be enrolled. Check all that apply.   * Fetuses * Pregnant Women * Minors with Parental Consent * Minors who can consent themselves * Prisoners * Cognitively Impaired Adult Subjects * Other  *Please describe.* * None of the Above   **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** |

**6-** **Study Design**

|  |
| --- |
| **Study Background**  Provide the background and rationale of the study. Do not include research jargon. |

|  |
| --- |
| **Hypothesis**  Provide the study hypothesis. |

|  |
| --- |
| **Objectives**  Provide the study objectives. |

|  |
| --- |
| **Outcome Measures**  Provide the main study outcome measures. |

|  |
| --- |
| **Inclusion Criteria**  List and describe the inclusion criteria. |

|  |
| --- |
| **Exclusion Criteria**  List and describe the exclusion criteria. |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**7- Study Procedures**

|  |
| --- |
| **Additional information and guidance can be found by clicking the question mark it the top-right corner of each section.** |

|  |
| --- |
| **Describe all study procedures and/or interventions.**  If this study involves data analysis, describe where the data will be obtained and what you will do with the data.  1. Procedures will begin after completing informed signed consent form. 2. Subject will be completing a brief survey 3. Through a finger prick, blood glucose concentration will be obtained 4.  A blood sample will be collected from subject's arm using a butterfly needle by a qualified health care professional. Approximately 14 mL of blood(less than 3 teaspoons) will be taken. This will be a small fraction of blood that you are allowed to donate (blood donation volume is 550 mL). |

|  |
| --- |
| **Describe the recruitment procedures and any material inducements given for participation** |

|  |
| --- |
| **Study Documents**  Attach any flyers or advertisements used to recruit participants. |

|  |
| --- |
| **Describe the duration of study participation, the length and number of study visits, and the timetable for study completion.** |

|  |
| --- |
| **Describe the information to be gathered and the means for collecting and recording data.**  If previously collected data is to be used, describe both the previous and proposed uses of these data. |

|  |
| --- |
| **Survey, Questionnaire, or Interview**  Will the study utilize surveys, questionnaires, or interviews? |

|  |  |
| --- | --- |
|  | * Yes |

|  |
| --- |
| Attach all copies of surveys, questionnaires, or interviews that will be administered to the subjects. |
| * No |

|  |
| --- |
| **Study Instruments**  Attach all instruments (i.e. personality scales, questionnaires, evaluation blanks, etc) to be used in the study. |

|  |
| --- |
| **Will the survey, questionnaire, or interview record any information that can identify the participants?** |

|  |  |
| --- | --- |
|  | * Yes |

|  |  |  |
| --- | --- | --- |
|  |  | * No |

|  |
| --- |
| **Genetic Testing**  Will this study involve genetic testing? |

|  |  |
| --- | --- |
|  | * Yes |

|  |  |
| --- | --- |
|  | * No |

|  |
| --- |
| **Drugs, Devices, Biologics**  Will the study involve administering any of the following? Check all that apply. |

|  |  |
| --- | --- |
|  | * Drug |

|  |  |
| --- | --- |
|  | * Biologic |

|  |  |
| --- | --- |
|  | * Device |

|  |  |
| --- | --- |
|  | * None of the above |

|  |
| --- |
| **Participant Data, Specimens, and Records**  Does this project involve the collection or use of materials (data or specimens) recorded in a manner that could identify the individuals who provided the materials, either directly or through identifiers linked to these individuals? Note: secondary use of de-identified materials already collected by an outside source does not apply. |

|  |  |
| --- | --- |
|  | * Yes |

|  |  |
| --- | --- |
|  | * No |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**8- Participant Protection**

|  |
| --- |
| **Additional information and guidance can be found by clicking the question mark it the top-right corner of each section.** |

|  |  |  |
| --- | --- | --- |
| **Do you anticipate study participants will be subject to any risks?** | | |
|  | * Yes |

|  |  |
| --- | --- |
|  | * No |

|  |
| --- |
| **Potential Risks** |
| Describe immediate risks, long-term risks, rationale for the necessity of such risks, alternatives that were or will be considered, and why alternatives may not be feasible.  *Describe any potential legal, financial, social, or personal affects on subjects of accidental data disclosure.* | |

|  |
| --- |
| **Expected Benefits**  Describe the expected benefits for subjects (if any) and/or society that will arise from this study. |

|  |
| --- |
| **Will deception be used as a method of data gathering?** |

|  |  |
| --- | --- |
|  | * Yes |

|  |  |
| --- | --- |
|  | * No |

|  |
| --- |
| **Safeguarding Subjects' Identity** |

|  |
| --- |
| **What uses will be made of the information obtained from the subjects?** |

|  |
| --- |
| **What precautions will be taken to safeguard identifiable records or individuals?** |

|  |
| --- |
| **Informed Consent**  Describe the procedures for obtaining informed consent. Identify all responsible research personnel whose primary responsibility includes handling informed consent procedures.  **Informed Consent Form**    Attach Consent Form |

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**9-** **Conflict of Interest**

|  |
| --- |
| **Do you or any investigator(s) participating in this study have a financial interest related to this research project?** |

* Yes
* No

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**10- Attachments**

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| --- |
| **Outside IRB of Record** |

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| --- |
| **Study Protocol**  Attach the protocol for this study that was reviewed by the Outside IRB. |

|  |  |
| --- | --- |
| **Outside IRB Approval Letter**  Attach the IRB Approval Letter from the Outside IRB. | |
| **Study Information** |

|  |  |
| --- | --- |
| **Letters of Support**  *Attach letters of support for all external collaborators.* | |
| **Study Procedures** |

|  |  |
| --- | --- |
| **Study Documents**  If applicable, this includes flyers used for recruitment. | |
| Attach recruitment |
|  |

|  |  |
| --- | --- |
| **Study Instruments**  Attach all instruments (i.e. personality scales, questionnaires, evaluation blanks, etc) to be used in the study. | |
| Attach Study Instruments |
|  |

|  |
| --- |
| **FDA Letter** |

|  |
| --- |
| **Participant Protection** |
| **Informed Consent Form**    Attach Consent Form | |

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**Informed Consent Considerations**

Consent is often thought of as a singular activity; however, consent is a process that begins with recruitment. It is the process by which participants are provided information about the research and what is expected of them. This information is what individuals will use to decide whether or not to participate.

When designing the research, the consent process must be considered a priority. Will consent be in a group setting or one-on-one in-person or online? Who will be responsible for obtaining consent? Will someone other than a research group member be obtaining consent? What method(s) will be used to obtain consent (online, electronically, verbally, in-person via a document)?

On occasion, some prospective subjects may have limited literacy capabilities and are unable to read and fully comprehend information in a consent form. If there is a possibility of limited literacy for the research sample population it is recommended that the researcher obtaining consent to read the consent form out-loud while the participant reads silently. Example: “I am required to read this consent out-loud as you follow along then you can ask me any questions you might have about the research.” Semi-literate individuals will typically not disclose their impairment.

As a process, consent can occur over multiple time points with information delivered across recruitment, prior to participation, and during participation or afterwards in the case of debriefing. The timeline for consent should be established whether taking place only once or over time. Take into consideration the setting of consent and the role between researcher and participant and any other factors that may influence the voluntariness of the research. If applicable, describe measures that will be taken to protect against the risk of undue influence on the participant to take part in the research.

When applicable, include a statement in the consent form or parental permission form that any suspected abuse or neglect of a child or adult age 60 or older must be reported to the Illinois Department of Children and Family Services (IDCFS) or Illinois Department on Aging (IDA).

**Other Consent Topics:**

* + - If prospective participants are screened for eligibility and found ineligible describe what will happen with any data or specimens that were collected and how the individuals are informed of ineligibility.
    - If new information about research procedures, risks, and benefits to participation becomes available, describe how participants will be informed.
    - If the research includes participants who speak a different language, consent information will need to be provided in their language in a consent form along with presentation by a researcher fluent in the language.
    - If there is not enough time to translate prior to the research, the short form consent is typically used when the prospective participant does not speak English. The English version of the approved consent document is orally translated into a language the prospective participant understands. Please see the section below on the Short Form Consent Process.
    - Consent documents should be prepared at a reading level that matches the literacy capacity of the study sample. The sample may include participants who have impaired decision making capacity that could affect their ability to consent. If the research involves any vulnerable population, describe the process to obtain an effective, legal consent, permission, or assent.
* If the research involves adults who may be unable to consent, describe the process to determine whether an individual is capable of consent and address the following, if applicable:

If permission of a legally authorized representative will be obtained:

Who are the individuals from whom permission will be obtained?

Which individuals are authorized under applicable law to consent on behalf of a prospective participant to their participation in the research procedure(s)? Contact the IRB to review the definition of “legally authorized representative” in 45 CFR 46.102(i) for this determination.

* Consent of the participant is typically documented via the signature line on the consent form. However, under certain circumstances, documentation of consent can be waived. If there are extenuating circumstances that make it impossible or inappropriate to meet this requirement, other options can be considered. For example, is obtaining someone’s signature for participation in the research culturally appropriate given the local context? If study procedures occur completely online, is it possible to obtain an electronic signature? In other cases, it may be that the primary risk of participation would be a breach of confidentiality and a signed consent document would be the record of participation placing the participant at risk.
* If the consent process will not be documented in writing, i.e., consent will be obtained, but the participant or representative will not sign a consent document, refer to [Waiver of Written Documentation of Consent](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Waiver%20to%20document%20consent.docx) and consider each of the criteria.
* If written documentation is waived under the criterion “That the only record linking the subject and the research would be the informed consent form and the principal risk would be the potential harm resulting from a breach of confidentiality”, the federal regulations require that, “each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern”. It is rare that the subject will request documentation that links him or her to the research.
* If the human subject research involves a waiver or alteration of the entire consent process (consent will not be obtained, required information will not be disclosed, or the research involves deception) review [General Waiver or Alteration of Consent](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\General%20Waiver%20or%20Alteration%20of%20Consent.docx) and consider each of the criteria.

**Creating a Consent for Exempt Human Subject Research**

Exempt human research does not require a long-form, signed consent form. However, the ethical principles outlined in The Belmont Report, namely, respect for persons, emphasizes the importance of ensuring that participants are fully informed. Therefore, a consent process is recommended when exempt research involves an interaction with human subjects. At a minimum, this process should disclose the following:

* That the activities involve research;
* The procedures to be performed;
* That participation is voluntary;
* The name and contact information for the investigator and the IIT IRB.

**Creating Consent Form for (non-exempt) Human Subject Research**

Consent documents must contain [all of the required and, as appropriate, additional elements of informed consent](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Elements%20of%20informed%20consent.docx). No informed consent (oral or written) should include exculpatory language whereby the participant or their representative is made to waive or appear to waive any of the participant’s legal rights or releases or appears to release the Investigator, the sponsor, the Institution or its agents from liability for negligence. For guidance on creating a consent form see: [Developing an Effective Consent Form](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Develop%20Informed%20Consent.docx)

* **Use of the first person** (e.g., "I understand that ...") could be interpreted as suggestive and can constitute coercive influence over a research subject. Use of the second person style is preferred (e.g., “You understand that …”). The use of scientific jargon such as “longitudinal”, “construct”, “aggregate”, etc. and legalese is not appropriate. Think of the document primarily as a teaching tool not as a legal instrument.
* **Description of the overall experience that will be encountered**. An explanation of the research activity for the subject. Informing the human subjects of the reasonably foreseeable risks, discomforts, and possible inconveniences that are associated with the research activity. If additional risks are identified during the course of the research, the consent process and documentation will require revisions to inform subjects as they are re-contacted or newly contacted.
* **Description of the benefits that subjects may reasonably expect to encounter**. There may be no direct benefit to the subject other than a sense of helping the public at large. PAYMENT IS NOT A BENEFIT. If payment is given to defray the incurred expense for participation, it must not be coercive in amount or method of distribution.
* **Description of any alternatives to participating in the research**. For example, in drug studies or behavioral clinical trials, the drug(s) or behavioral intervention may be available through their family doctor or clinic without the need to participate in the research activity. The alternative can often be to not participate in the research.
* **Subjects should be informed of the extent to which their personally identifiable private information will be held in confidence**. For example, some studies require the disclosure of information to other parties. In Illinois should a subject disclose abuse, neglect, or exploitation of a child, the investigator is mandated to report the disclosure to the Department of Child and Family Services (DCFS). The IRB will determine the level of adequate requirements for confidentiality in light of its mandate to ensure the minimization of risk and determination that the residual risks warrant involvement of subjects.
* **If a research-related injury (i.e. physical, psychological, social, financial, or otherwise) is possible in research that is more than minimal risk, an explanation must be given of whatever voluntary compensation and treatment will be provided**. Note that the regulations do not limit injury to "physical injury". This is a common misinterpretation.
* **The regulations prohibit waiving or appearing to waive any legal rights of subjects**. Therefore, for example, consent language must be carefully selected that deals with what the institution is voluntarily willing to do under circumstances, such as providing compensation in response to a research-related injury. For minimal-risk research, research-related injury is rare. In short, subjects should not be given the impression that they have agreed to and are without recourse to seek satisfaction beyond the institution's voluntarily chosen limits.
* **The regulations provide for the identification of contact persons who would be knowledgeable to answer questions subjects might have about the research, rights as a research subject, and research-related injuries. These three areas must be explicitly stated and addressed in the consent process and documentation.** Questions about the research are frequently best answered by the investigator(s). Questions about the rights of research subjects are best addressed by the IRB. Questions about research-related injuries (where applicable) may be referred to those on the research team or the IRB. Therefore, each consent document can be expected to have at least two names with local telephone numbers and email addresses for contacts to answer questions in these specified areas.
* **A statement regarding voluntary participation and the right of the subject to withdraw at any time**. Prospective subjects must be advised that participating in the research is voluntary. It is important to point out that no penalty or loss of benefits will occur as a result of either not participating or withdrawing from the research at any time. It is equally important to alert potential subjects to any foreseeable consequences, if any, to them should they unilaterally withdraw while participating in a clinical trial.

**Documenting Consent**

Use the signature block(s) approved by the IRB when obtaining informed consent. Ensure that all items in the signature block on the last page are complete, including dates and applicable checkboxes, e.g. audio or video recording, future use; specimen storage, etc.

The following elements are required for consent documents:

* The consent document used in the field is IRB approved. IRB-approval is evident by a reference to applicable version numbers/dates in IRB Notification letters.
* The participant or legally authorized representative signs and dates the consent document.
* When applicable, the individual who obtains consent signs and dates the consent document.
* Whenever required by the IRB, the participant or legally authorized representative signature is to be witnessed by an individual who signs and dates the consent document.
* For participants who cannot read and if required by the IRB or the sponsor, a witness to the oral presentation signs and dates the consent document.
* A copy of the signed and dated consent form is to be provided to the participant or legally authorized representative.
* A full copy of the signed and dated consent document is retained as part of the research documentation (usually contained within participant-specific files).

According to the federal regulations, “informed consent shall be documented by the use of a written informed consent form approved by the IRB and signed by the subject or the subject's legally authorized representative. A written copy shall be given to the person signing the informed consent form.” While we are accustomed to thinking that documentation of consent is an in-person inked signature, there are many alternatives that satisfy these requirements.

**Guidelines to Document Informed Consent**

The regulations that govern human subjects research and other states, local, and institutional laws, policies, and guidance do not directly outline what is considered acceptable documentation of an informed consent form, however guidance is provided to ensure that the documentation is valid:

* There must be a mark or signature made by the research subject.
* The research group should have a reasonable way to verify the identity of the individual (“research subject”) signing the informed consent form.
* A copy of the informed consent form must be provided to the research subject.
* The research group will retain the signed consent document for their records.

**Mark Made by the Subject to Consent**

The default “mark” made by a study subject is their signature as noted by the federal regulations, “A person who speaks and understands English, but does not read and write, can be enrolled in a study by "making their mark" on the consent document, when consistent with applicable state law.” In this case, the mark may be an “X”, thumbprint, or other mark. If the study will be using an electronic signature capture method, know that there may be other requirements.

**Verifying Identity**

Some research groups have found that conducting the consent process virtually or by teleconference is an effective way to ensure not only study subject understanding but also a way to verify the identity of the person signing the form.

Examples of various methods that could be used include verification of state-issued identification or other identifying documents or use of personal questions, biometric methods, or visual methods. It may not always be possible to verify that the person signing the informed consent is the research subject and therefore encourages a risk-based approach to the consideration of subject identity. For example, if the consent form was mailed (either by postal mail, email, fax, etc.) directly to the individual, it may be sufficient verification if the signed informed consent form is sent back to the research group via the same method.

**Copy of Informed Consent Provided to Person Signing the Form**

According to the federal regulations, “…the person signing the informed consent (i.e., the subject or the subject’s LAR or the parents or guardians of subjects who are children) be given a copy of the written informed consent/permission form.

The various federal, state, local, and institutional laws, policies, and guidance do not specify the required medium of the form and indicate that the copy provided to the subject can be paper or electronic and may be provided on an electronic storage device or via email.

The Federal regulations further state that “If the copy provided includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion.”

**Retention of Electronically Signed Consent Document**

While HHS regulations do not specify a research records retention period, other federal regulations such as FDA and HIPAA do.

IIT policy states that, “Researchers have certain obligations to record, maintain and retain research records, and to make those records available for grant monitoring and auditing purposes, as well as to enable investigators and IIT to respond to questions of research integrity and stewardship.”

Additionally, all records associated with funded/sponsored projects must be retained for seven years after the final project account closing unless a longer period is specified by the granting agency. For non-sponsored projects at IIT, records must be retained six years after the research protocol is completed and closed.

**Short Form Consent Process**

Participants who have limited English proficiency may be enrolled in the research if the resources are available to communicate effectively with the prospective participant during the recruitment process while obtaining consent and for the duration of the research. The short form consent is typically used when the prospective participant does not speak English and there is not enough time to translate the English version of the approved consent document into a language the participant understands.

A short form consent document attests that the elements of informed consent, as required by DHHS, have been presented orally to either the participant or the participant's legally authorized representative. A short form consent may be used as described in [Short Form Consent Documentation](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/obtaining-and-documenting-infomed-consent-non-english-speakers/index.html#sample).

If the research plan is to enroll more than one participant with limited English proficiency or if the research is being conducted internationally, the IRB expects all research documents provided to participants will be translated into the appropriate language(s).

The investigator must provide the following to the IRB for review:

* A written summary of what is to be said to the participant or the participant's legally authorized representative. The summary must include all of the required and appropriate elements. The PI may use the English version of the IRB- approved informed consent document.
* The short form document that will be signed by the potential participant.
* Confirmation that:
  + The oral presentation will be conducted in a language understandable to the participant.
  + The person obtaining consent is authorized by the IRB.
  + There will be a witness to the oral presentation (this cannot be the same person who is obtaining consent). If the participant does not speak English, the witness should be fluent in both English and the language of the participant. If the person obtaining consent is assisted by a translator, the translator may serve as the witness.
  + The short form will be signed by the participant and the witness.
  + The written summary will be signed by the witness and the person actually obtaining consent.
  + A copy of the oral summary and the short form will be given to the participant.

The request to use the short form consent process is typically made because time is of the essence. As such, the IRB prioritizes the review of these requests to avoid denying a prospective participant an opportunity to participate in the research. However, once the participant is enrolled, the investigator is expected to adhere to the IRB's standard requirements for non-English speaking participants. If applicable, this includes providing the IRB with a plan for ensuring that ongoing communication with the participant is in a language understandable to the participant in a longitudinal study.

**Parent/Guardian Permission and Assent for Children and Adolescents**

Special regulations apply when research involves children. For children who have not attained the legal age (18 in most states, 19 in Alabama and Nebraska) to participate in research, the investigator will first need parental permission for the participation of their children. Children are considered inherently more vulnerable to coercion than adults. (See: [Research with Children and Adolescents](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html)) Emancipated youth can legally consent for themselves to participate in research.

To involve children in research requires the investigator to obtain permission from their parent(s) or guardian. Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research. ([See Parent Permission Signature Options](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Parental%20Permission%20with%20Child%20Assent%20form.docx)).

For minimal risk research, permission from one parent is adequate. For greater than minimal risk research permission is needed from both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. Parental permission can be obtained from individuals other than parents who are legally authorized to give permission such as a court-appointed guardian.

The investigator must also obtain assent from a child to participate in the research. Assent means a child's affirmative agreement to participate in research. Mere failure of the child or minor to object to participation should not, absent affirmative agreement, be construed as assent. Describe how and whether documented assent will be obtained from youth age 7 to 17. Children under the age of 7, should be provided a brief description of the research activities that they will engage in. (See [Assent Form Age 7 to 12](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Assent%20Form%207%20to%2012.doc)) (See [Assent Form Age 13 to 17](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Assent%20Form%2013%20to%2017.doc)).

If requested, the IRB can waive assent. If the capability of some or all of the children is so limited that they cannot reasonably be consulted to provide assent; if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research. (See: [Research with Children and Adolescents](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html))

Additionally, if the IRB finds that the research involves no more than minimal risk; the research could not practically be carried out without the requested waiver or alteration; and the waiver or alteration will not adversely affect the rights and welfare of the subjects.

Should a child or adolescent decline to participate in minimal risk research their decision is final despite the investigator having parent or guardian permission. There are two methods to document the parental permission and child’s assent.

One method is the parental/guardian permission form will have a signature line for the parent/guardian and a signature line for the assent of the youth. The second method is the parent/guardian permission form will have a signature line for the parent/guardian and a line for the name of the youth. A separate form is for the signature of the youth’s assent.

Depending on the design of the proposed research, the IRB will consider a request for a waiver of parental permission. If the IRB determines that a research protocol is designed to study conditions of children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the parental permission requirements. ([See guidance from Children’s Hospital of Philadelphia Waiver of Parental Permission](https://irb.research.chop.edu/waiver-parental-permission)).

An appropriate mechanism must be in place to protect the children and provided that the waiver of parental permission is not inconsistent with federal, state, or local law. The choice of an appropriate substitute mechanism (for example, appointing a child advocate or an assent monitor) for protecting children participating in the research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child’s age, maturity, status, and condition.

If children reach the age 18 in Illinois, during the research, the PI will need to describe the procedures that will be put in place to obtain consent from the participant who is now an adult. The procedures can be submit as an amendment to research already approved by the IRB or included in the initial submission for IRB review.

**Consent Process for Individuals with “Diminished Capacity”**

DHHS regulations require that the IRB ensure that “additional safeguards have been included in the research to protect the rights and welfare” of all subjects that are “likely to be vulnerable to coercion or undue influence.” See “[Adults with Impaired Decision-Making](file:///Z:\IRB\IRB%20Handbook%20and%20Forms\Adults%20with%20Impaired%20Decision-Making%20Ability.docx)”. Specifically, safeguards for subjects with impaired decision-making capacity, for example, as a result of trauma, cognitive impairment, some forms of mental illness, or dementia, whether temporary, progressive, or permanent.

In research involving adult subjects with mental illnesses or cognitive impairments, the IRB and investigator(s) must be knowledgeable about the condition and any level of impairment likely to be present in the subject population. The regulations do speak to the fact that the IRB must possess “the professional competence necessary to review specific research activities”.

This is achieved either by having members with the appropriate experience and expertise or inviting consultants with competence in the special area to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. Ensuring such expertise on the IRB improves its ability to make determinations about subject recruitment, enrollment, and informed consent requirements that best match the needs of the subjects.

In some research, such as longitudinal studies involving progressive disorders or aging populations, enrolled subjects may be competent to consent on their own behalf at the outset yet may experience the effects of progressive or intermittent disorders that lead to decisional impairment during the research.

In these situations, IRBs and investigators should consider the need to discuss with the prospective subjects whether they should designate someone to serve as a legally authorized representative at the outset of the study, consistent with all applicable laws. Even if a subject has consented on his or her own accord, a designated representative would be ready to step in as the legally authorized representative if the subject’s ability to assess his or her own needs and interests becomes compromised during the study.

**Consent Process for Illiterate English-Speaking Subjects**

A person who speaks and understands English, but does not read and write, can be enrolled in a study by either signing the consent document or marking an “X”.

A person who can understand and comprehend spoken English, but is physically unable to talk or write, can be entered into the research if they are competent and able to indicate approval or disapproval by other means.

If (1) the person retains the ability to understand the concepts of the study and evaluate the risk and benefit of being in the study when it is explained verbally and (2) is able to indicate approval or disapproval to study entry, they may be enrolled.

The consent form should document the method used for communication with the prospective subject and the specific means by which the prospective subject communicated agreement to participate in the study. The IRB may recommend that an impartial third party should witness the entire consent process and sign the consent document.

**Consent for Non-English Speaking Subjects**

The federal regulations require that the informed consent document be in language understandable to the subject (or authorized representative). When the study subject population includes non-English speaking people or the IRB anticipates that the consent process will be conducted in a language other than English, the IRB will require that the researcher have a translated consent document and assure that the translation is accurate. A copy of the consent document must be given to each subject. In the case of non-English speaking subjects, this would be the translated document. While a translator may be helpful in facilitating conversation with a non-English speaking subject, routine ad hoc translation of the consent document should not be substituted for a written translation.

**Re-Consent of Subjects**

While rare in social/behavioral research, the regulations require that researchers provide participants with significant new findings developed during the research when those findings may affect a participant's willingness to continue participation in the research. Significant new information could include revised risk information or information related to an unanticipated problem, such as a data breach. Significant new information about the research and the proposed modifications to inform participants must be submitted to the IRB as an amendment.

The provision of significant new information in the context of a given study will depend upon factors including the nature of the study, the nature and urgency of the new information, and the status of participants e.g., in the screening phase, receiving an intervention, long term-follow-up, etc. Providing the new information creates an explicit opportunity for participants to exercise their ongoing right to continue their participation or withdraw from the study.

Possible approaches to provide new information include:

* Repeating the informed consent process with the revised informed consent document(s).
* Present the new information using an addendum to the original informed consent document and either obtain documentation directly or describe the communication process in the participant’s research records.
* Orally communicate the new information and document the communication process in each participant’s research records.

Examples of Instances where changes to the study may affect a research participant’s willingness to continue and therefore should be disclosed to participants are, but not limited to, the following:

* Identification of new research-related risks
* Increase in the frequency or magnitude of previously described risks
* Unanticipated problem that exposes subjects to new risks, such as a data breach.
* Decrease in expected benefits to participation
* Change to the research that results in an increased burden/discomfort
* Significant changes in the research study design
* Change in the financial burden of participation
* Changes in the investigator’s financial conflict of interest

**Additional Consent Language Requirements Relating to Financial Conflict of Interest**

If required as part of the conflict of interest management plan, the following information may need to be disclosed in the consent form: sources of funding for the study, investigator conflicts of interest, and/or how to find out additional information. The following is recommended language to fulfill such requirements.

**Disclosing the Nature of any Financial or Proprietary Interests**

When required, create a new section in the consent template entitled “Researcher Financial Interests in this Study” to disclose the nature of any financial or proprietary interests. This section should identify the researchers or research staff by name and study role.

* + Example of language to indicate the interest in an entity or the product: Dr. Doe, a researcher in the research group, has a financial interest in [name of company], [the company paying for this study; the company that will manufacture the study drug or product; the company that will sell the drug or product, and/or the company conducting part of this study].
  + Example of language if the interest is other than a financial interest in an entity, e.g., in the product being tested: Dr. Smith, the PI for this study, has a financial interest in the [product, drug, device, name of company] being studied.
  + Example language for the inventor:
    - Dr. Chan invented the [product, drug, device] being studied and may benefit financially if it is marketed.
    - If possible, elaborate on the information provided. For example, “The consulting income Dr. Chan receives is in addition to the salary received from IIT.”

# Other Research Considerations

### Clinical Trial Research

IIT does not have a teaching hospital or the clinical research expertise to provide support for clinical trials of Investigational New Drugs (IND) or Significant Risk (SR) Investigational Device Exemptions (IDE). Clinical trial research for social/behavioral and nutrition/food safety, however, is supported at IIT.

### Data Security

In social and behavioral research, breach of confidentiality is a serious risk posed to participants. Rigorous data security is a key element of protecting subject data from an accidental or malicious breach. Increasingly important is the management of electronic data on desktops or servers as well as on mobile devices such as laptops and flash drives.

Data security must include a plan to manage the physical documentation associated with the project, such as paper surveys, signed consent forms or documents that contain contact information for subjects, to ensure that those materials are not lost or accessed inadvertently by an unauthorized person. Confidential paper records should be kept in locked file cabinets when not in use and physical access to any facility that contains confidential information should be restricted.

Access control measures should include smart card swipes, PIN keypads, and locked doors. Investigators should be aware of who has access to keys, and should consider this when storing data. Confidential information should not be left on copiers, fax machines, or other shared devices.

The level of security necessary is relative to the risk posed to the subject should personally identifiable information (PII) be inadvertently disclosed or released. In an effort to ensure best practice, it is always desirable to have a high level of security rather than to risk operating at a minimal standard. The IRB has the authority to decide if the proposed security plan to protect subjects’ confidentiality or anonymity is adequate.

All human subject research protocols must have in place a credible and documented procedure for the protection of identifiable and/or confidential information before the research will be approved, amended, granted continuing approval/renewal, or determined exempt from IRB review.

**Electronic Data Security**

Increasingly, the majority of research data is at some point collected, transmitted, or stored electronically. The PI is responsible for ensuring that research data is secure when it is electronically collected, stored, transmitted, or shared. All members of the research team should receive appropriate training about securing and safeguarding research data. Data security should be discussed regularly at research team meetings. Below are recommendations to securing and transmitting electronic data:

1. Secure passphrases should be used to protect electronic data files, including digital audio recordings.

2. When encrypting data, investigators should consult with IIT technology experts, when determining which encryption software to use.

3. In general, investigators should encrypt identifiable data before it is transferred over a network or over email. Consent forms should also be encrypted before being transferred over a network or over email when the forms themselves have the potential to reveal information that could place the subject at risk of criminal or civil liability or be damaging to the subject’s financial standing, employability, educational advancement, or reputation.

4. When using an online data collection site (e.g. Amazon Mechanical Turk, Qualtrics, etc.), investigators should carefully review the site’s data security policy. If the site stores identifiable information and/or links survey responses to individual participants, this must be made clear in the Cayuse application and in the corresponding informed consent document(s).

5. Generally, an electronic data file may be stored online (e.g., on a cloud storage system) only if the file does not contain identifiable information or has first been encrypted so that, should there be a security breach, the data cannot be linked back to individual participants. If considering storing data on a cloud, investigators should first consult technology experts to determine which cloud computing service to use. Important considerations include:

(1) data storage location;

(2) backup policy;

(3) deletion policy;

(4) rights that the cloud provider claims for the data;

(5) isolation guarantees that the provider offers. Investigators may wish to consider using local hosting options.

### International Research

Research conducted outside the United States may create additional challenges for the IIT researcher and the IIT IRB. Cultural, economic, or political conditions of the host country may alter the risk for participants compared to the same research conducted within the U.S. Other countries and institutions within those countries may have Institutional Review Boards, Ethics Committees or other research oversight bodies which require review of the research before it can be conducted in that country.

Conversely, some countries may have no mechanism for ethics review of social and behavioral research. The IIT IRB will consider alternatives to ensure that protections are in place for human subjects participating in the research.

In the review of proposed international research, the IIT IRB will consider the following information:

* Description of where the research will be conducted (including geographic location and specific performance sites, where applicable). Note: In some areas, government–issue research visas are required;
* Information about the local research context, including the current economic, cultural, political, or religious conditions of the area that may affect the conduct of the research, and a description of the researcher’s personal experience, if any, conducting research (or studying or residing) in the region;
* The language(s) in which consent will be sought from participants and the research will be conducted, as well as whether the researcher is fluent in this language or whether an interpreter will be required. If an interpreter will be used, it should be clear what limitations or risks, if any, this might present for participants, as well as how these potential problems will be overcome or minimized;
* A description of the informed consent process as appropriate for the culture;
* Any benefits to the local community that will remain in the community once the research is complete;
* If compensation is being offered, a description of its appropriateness for the setting;
* Procedures for data security and storage in the local setting and for transfer of data and/or specimens to IIT; and
* A copy of local IRB or equivalent ethics committee approval, where applicable. Depending on the location, this may take the form of a letter of approval from an IRB or research ethics committee, local university department sponsoring the research, institutional oversight committee, or an indigenous council. If the research is federally funded, check with the IRB for other regulatory requirements.

If the researcher is traveling to an international setting to conduct the research, submission of the IRB application is recommended well in advance of the planned travel date. This is particularly crucial for research that may involve more than minimal risk to participants and will require full board review.

**Risk to the Researcher**

When planning an international research project, consider the following:

* 1. Check the [US Department of State Travel Advisories](https://travel.state.gov/content/travel/en/traveladvisories/traveladvisories.html/) to determine if the region of interest is rated as high or elevated risk (Level 3 or 4).
     1. If the region of interest is rated as high-risk, undergraduate researchers should not conduct research there. The researcher must select another region for the study.
     2. If the region is rated as elevated-risk, the researcher should follow the steps described on the [IIT International Travel Policy](https://www.iit.edu/student-affairs/student-handbook/fine-print/student-travel-policy).
  2. When preparing the protocol, the researcher should describe the plan to protect his or her safety while working internationally. These plans could include checking in with the local U.S. embassy, working with local universities or non-governmental organizations (NGOs) to help navigate the cultural norms, and/or arranging safe meeting places when conducting interviews with research participants.
  3. Researchers should also provide details of their preparation for working in the area, including their fluency in the local language and any past travel or coursework that has helped them prepare for this project.

**Risk to Populations Involved**

When conducting research in an international location, the researcher should carefully consider the cultural and social norms in the region of interest. Research conducted with marginalized populations, or research projects that ask questions about socially-unacceptable or illegal behavior, could lead to negative consequences for the participants. In the research protocol, the researcher should explain how they will protect the participants, including plans to secure the data and to receive local IRB and/or community approvals in the region of interest.

Additionally, if the research will be conducted in any places of business or in educational facilities, etc., the researcher should provide a letter from the business owner or principal, etc., confirming that they have permission to conduct the project on the premises.

### Secondary Data Analysis Projects

Research that involves only the secondary analysis of data collected as part of a different research project does not require IRB review and approval if:

* + the data set is publicly available; or
  + the data set has already been de-identified, meaning that any data elements that could be used to identify an individual have been deleted and the investigator has no access to the code or link to re-identify.

If the IIT investigator is using coded private information or biological specimens, that is de-identified, the research may not require IRB oversight.The provider of the de-identified data should include a statement that the data are de-identified and the IIT investigator receiving the data will not have access to the code or link to re-identify.

Coded means that identifying information that would enable the researcher to readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); and a key (or crosswalk) to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Research using such a coded data set is not regulated by the IRB if the data were not collected for the proposed research and the IIT researcher does not have access to the code linking to the identifiable information. More information about coded private information or biological specimens can be found at: <http://www.hhs.gov/o/humansubjects/guidance/cdebiol.pdf.>

### Deception and Incomplete Disclosure Research

Deception is the intentional misleading of a subject about the nature of the study. Withholding full information is known as incomplete disclosure. Misleading or omitted information might include the purpose of the research, the role of the researcher, or what procedures in the study are actually experimental. Deception increases ethical concerns and should be used with discretion, because it interferes with the ability of the subject to give informed consent. The IRB recognizes that deception or incomplete disclosure may be necessary for certain types of behavioral research. Because people act differently depending on circumstances, full knowledge by the subject might bias the results in some cases.

**Waiver of Informed Consent for Deception or Incomplete Disclosure Research**

Because participants are not provided with all the details of the proposed research at the time consent is obtained, deception research must meet the criteria for waiver or alteration of informed consent including that the research poses no more than minimal risk to the subjects.

### Debriefing

In most circumstances, subjects have the right to full disclosure as soon as possible after participation in deception or incomplete disclosure research; a post-participation debriefing is usually required. The debriefing should disclose the full or true purpose of the research and allow the subject to indicate that their data not be used in the study.

In exceptional circumstances, the full or true purpose of the research may not be revealed to the subjects until the data collection is complete. In such cases, subjects should not be exposed to undue stress or embarrassment and should have the right to full disclosure of the purpose of the study as soon as possible after the data have been collected.

There may be circumstances when debriefing is not appropriate. This may be when disclosure of the information may cause more distress to subjects than if not disclosed or when disclosure may bias the scientific integrity of the study.

### Investigator Self-Experimentation

IIT does not prohibit Investigator self-experimentation. However, as it would with any proposed research, the IRB will review each protocol and determine the appropriateness of the research. The IRB will consider as part of its review the level of self-experimentation and the potential risks and benefits to the Investigator as a research participant.

One of the main concerns of the IRB is that the enthusiasm for a novel concept may outweigh the Investigator’s concern for his/her own welfare. For this reason, the IRB may require that a senior IIT official, Department Chair or an IRB member obtain informed consent from the Investigator. The IRB also may institute additional safeguards for the research project, such as shorter review periods and monthly progress reports.

# Additional Resources for Data Management

Early in the research project planning, investigators are encouraged to consider the lifecycle of their research data. In particular data management, data privacy and security, and using cloud services for storage. One resource of information for data management is the [IIT Galvin Library](https://guides.library.iit.edu/c.php?g=474679&p=3248483). Another is the [IIT Center for the Study of Ethics in the Professions (CSEP)](https://ethics.iit.edu/projects/data-management).

# Research Record Retention

Investigators must maintain human research records, including signed and dated consent documents, for at least six years after closing the study.

If the human research is sponsored, contact the sponsor before disposing of human subject research records as there may be specific policies related to record retention.

# Prompt Reporting Requirements

While harm to a subject participating in social/behavioral research is rare it does occur. Harm to a subject that is relatively minor and is anticipated by investigators such as a sore muscle after a physical intervention or a subject is unable to complete a timed research survey and is angry does not need to be reported to the IRB. Harm to a subject that is unanticipated and serious does need to be reported to the IRB such as a breach of sensitive confidential data.

Other issues that require reporting to the IRB are below:

1. Harm experienced by a participant or other individual, which in the opinion of the investigator is **unexpected** and at least **possibly related** to the research procedures.
   1. A harm is “**unexpected**” when its specificity or severity is inconsistent with risk information previously reviewed and approved by the IRB (via protocol, consent forms, etc.) in terms of nature, severity, frequency, and characteristics of the study population.
   2. A harm is at least “**possibly related**” to the research procedures if in the opinion of the investigator, the research procedures more likely than not caused the event/harm.
2. Non-compliance with the federal regulations governing human research or with the requirements or determinations of the IRB, or an allegation of such non-compliance.
3. Failure to follow the protocol due to the action or inaction of the investigator or research staff.
4. Breach of confidentiality.
   1. Per IIT Information Security policy, it is required that any researcher who experiences a security incident or breach involving research report the breach to the appropriate IIT personnel.
5. Change to the protocol without prior IRB review to eliminate an apparent immediate hazard to a participant.
6. Incarceration of a participant in a study not approved by the IRB to involve prisoners.
7. Complaint of a participant that cannot be resolved by the research group.
8. Premature suspension or termination of the protocol by the sponsor, investigator, or institution.

# Additional Requirements: Research with Children/Adolescents

Children are considered by the federal regulations as being vulnerable to coercion. To safeguard their welfare and protect them from harm, additional regulatory protections exist for research involving children. See “[45 CFR 46 Subpart D](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html)”.

**Assent**

Assent is a child’s affirmative agreement to participate in research. The child’s failure to object, absent affirmative agreement, should not be considered assent. When assent is required by the IRB, the decision of the child assenting is binding, provided parental or guardian permission, when applicable, has been obtained.

**C**[**hildren up to 7 years old**](https://irb.ucsf.edu/children-and-minors-research)

In most cases, children this young will not be able to participate in the assent process, and only a signed permission form from the parents or legal guardians will be needed. When appropriate, provide the child a brief description of the activities that he or she will engage in for the research such as counting games, reading, running, etc.

**Children 7 to 12 years old**

In most cases, children this age may be able to participate in the assent process, using a simplified assent form. A separate, more detailed permission form will be needed for the parents or guardians.

**Assent Notes:**

1. A very simple assent form is needed. If possible, the child should sign the form. If not, the form or study records must document that verbal assent was obtained.
2. The separate parental permission form should refer to the subject as "your child" throughout the form. On the permission form, preceding the parent name line, include a line for each child’s name that the parent(s) is giving permission to participate in the research. See “[Parental Permission](#ParentalPermission_ChildAssent)”

**Adolescents 13 to 17 years old**

In most cases, adolescents should be fully informed about a study and give assent to their own participation in the research. There are two ways to document their assent.

**Adolescent Consent Documentation-Option A**

Option A: One form is written for the adolescent subject and the parents or guardians.

**Assent Notes:**

1. This assent/consent form should use clear, straightforward language (eighth-grade reading level).
2. Refer to the adolescent subject throughout as “you.” Both the adolescent and the parents or guardians are asked to sign this form, with a signature line for the parent/guardian first. This preceded by the statement such as “By signing this you are giving permission for your child/ward to participate in this research.”
3. The signature line for adolescent should follow parent/guardian permission, preceded by the statement such as: “By signing this form, you are agreeing to participate in this research.”

**Adolescent Consent Documentation-Option B**

A simplified assent form is written for adolescents. A separate, more detailed permission form is written for parents/guardians.

Option B is reserved for studies where Option A is not feasible or appropriate such as a research setting when the adolescent and parent/guardian are approached at different times or in different settings. The adolescent can provide assent before parental permission is obtained, but cannot engage in the research activities until their parent/guardian has given formal permission.

**Assent Notes:**

1. This adolescent assent form should be simpler than the adult consent form for the same study. Refer to the subject throughout as “you.” Only the adolescent is asked to sign this form. (Note that assent forms written for 7-12 year olds are often too simple for adolescents, but can be expanded upon or adapted as appropriate).
2. The separate parental/guardian permission form should refer to the subject as "your child" throughout the form.
3. The signature line of parent’s or guardian’s form should precede a line to enter the adolescent’s name and an explanatory statement such as: “By signing this form, you are giving permission for your child/ward to participate in this research.”

**Number of Parent/Guardian Signatures Required**

* **Permission from one parent/guardian:** Generallysufficient for minimal risk research although the IRB may require permission from both parents/guardians in some circumstances.
* **Permission from both parents/guardians,** **unless one parent is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the child:** Required for greater than minimal risk research.

Signed parental permission forms must be retained with the research records.

**Document the assent of children who are deemed capable in one of several ways (upon approval by the IRB)**:

1. Assent form signed by child (e.g., see Adolescent Assent-Option B is retained with the study records).
2. Assent form signed by person conducting the assent discussion (PI or other study staff member) is retained with the study records.
3. Certification of discussion/assent signed by person conducting the assent discussion (PI or other study staff member) is appended to parental/guardian permission form; or retained separately with the study records.

**Waiving Assent**

In certain cases, the IRB may consider waiving the requirement to obtain children’s assent, for example:

* “The capability of some or all of the children is so limited that they cannot reasonably be consulted;” or
* “The research is greater than minimal risk, but holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research”. Here the parents’ right to make decisions for their child may come into conflict with the child’s right to give or withhold assent. In this situation, assent may be waived, though it always should be sought.

In such cases, the PI may propose a waiver of child’s assent in the IRB application. The IRB’s decision about waiver of assent will depend on the specifics of the study.

**Assent Notes:**

* If the child is considered capable of providing assent, always provide a simple verbal explanation of what will happen to him/her and the opportunity for questions and discussion.
* Even if the requirement for assent is waived, it is always preferable to seek the child’s assent, if possible.
* Document on the parental permission form or in the study records that the child was appropriately informed about the study.

**Waiving Parental Permission**

The IRB may also waive parental permission in some cases in which the study "is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children)." There must be “an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law.”

Examples where parental permission MAY be waived:

* Research on child abuse or neglect, or research that is reasonably likely to elicit information identifying child abuse or neglect, where there is serious doubt as to whether the parents’ interests reflect the child’s interests.
* Research on people under 18 who are in circumstances where they are clearly outside of parental influence or control. The IRB would evaluate each study carefully to determine whether parental permission is not a reasonable requirement to protect the subjects.

**Note**: Some people under age 18 who are living independently may be able to consent for themselves (see [UCSF guidance](https://irb.ucsf.edu/children-and-minors-research#exceptions)) without a waiver of parental permission. Investigators should address all such consent concerns for research with minors, including arguments for waiver of standard consent procedures in the IRB Application.

**Parents Disagree on Giving Permission**

If there are two parents available to give permission but they disagree about allowing their child to participate in the study, the child may not be enrolled unless that disagreement can be resolved. This restriction applies to all permissible categories; that is, when both parents are involved in the decision, they must agree for the child to be enrolled, even if only one parent’s signature is required.

**Emancipated Minors**

Emancipated minors — those who are either

* married or divorced, or
* on active duty in the U.S. armed forces, or
* emancipated by a court —

have the legal right to consent on their own behalf. They have rights to enter into legal and business arrangements, and can consent to participate in research (such as surveys or interviews).

**Consent:**With IRB approval, emancipated minors should provide consent and sign the consent form just as an adult would, unless the IRB approves a waiver of consent (see [UCSF guidance](https://irb.ucsf.edu/waiving-informed-consent)) or alteration of consent. The PI must ensure that any individual minor possesses the mental capacity (see [UCSF guidance](https://irb.ucsf.edu/enrolling-individuals-cognitive-impairments-and-assessing-decisional-capacity)) to consent or assent to the research.

**Recruitment & Compensation Issues**

It is important to minimize pressure children/minors to participate in research. When children are asked to do something by parents, doctors, teachers or other adult authorities, they often feel implicit pressure to agree. Similar issues with social or peer pressure (e.g., for studies in educational settings) may also arise in recruiting children to participate in research.

Describe the plan to minimize implicit pressure to participate in the "Recruitment" section of the Cayuse submission. As with all consent and assent forms, the freedom to decline participation should be made clear.

**Consider Special Arrangements for Participation**

In designing studies involving children, consider any special arrangements for participation, such as scheduling, parking and food, and discuss special arrangements with parents if appropriate. Though such information is not required, it could be helpful to parents in deciding about or planning for study participation.

Examples of special study arrangements to consider:

* If the subject is to receive a series of procedures or tests, can these be coordinated with school and/or work schedules?
* Are there siblings who will need childcare or other provisions made during the child’s participation?
* What about transportation and/or parking permits for the facility where the research is being conducted?
* Will subjects or their family members need snacks or meals during the study?

**Payment and Reimbursement**

Ethical considerations regarding payment of subjects who participate in studies become even more complex when the research involves children. The IRB neither encourages nor prohibits payment of children in research studies, but considers such proposals on a case-by-case basis.

When evaluating this issue, the IRB will look closely at certain factors such as age, health, socioeconomic and cultural backgrounds of the subjects to ensure that proposed payment does not constitute undue inducement to participate.

**Amounts and Recipients of Payment:** In most cases, the IRB recommends that payment for study participation be made directly to the subject or to both child and parent(s) at the same time, rather than to the parent(s) alone.

**Reimbursement:** The IRB considers reimbursement separately from payment, and recommends that study subjects or their families be reimbursed for expenses related to research (e.g., parking, travel, meals) whenever possible.

**Notes:**

* Types, amounts and schedules of payment or reimbursement should be described in the appropriate section of the consent form.
* If subjects need to keep receipts in order to be reimbursed, this should be clearly stated.
* The form should note whether subjects who begin but do not finish a study will be paid on a pro-rated basis.

**Discovery and Disclosure of Sensitive Information**

In the course of research with minors, especially adolescents, you may discover sensitive information about subjects that is not related to the study itself. Examples of such information include sexual activity, STDs, use of illegal substances, HIV status, and child abuse.

**Maintaining Confidentiality of Disclosure of Sensitive Information**

The IRB will consider the contingencies describe in the submission on how such situations are handled should they arise. The permission and/or assent form should describe plans for disclosure — or non-disclosure — of such information to parents/guardian, legal authorities and the subjects themselves. – In some cases, it may be appropriate for the PI to seek a NIH Certificate of Confidentiality.

**Child Abuse Reporting Requirements**

Ethical and legal obligations apply whenever child abuse is discovered. Be aware that, in most cases, the same reporting expectations pertain in research settings as in school or clinical settings.

* If the research is designed or likely to elicit information about sexual or physical abuse of a child, the application and consent/assent forms must indicate how discovery of such information will be handled.
* If such information is discovered unexpectedly (i.e., not anticipated given the research design or subject population), the PI will seek advice from his/her department chair or dean or from the IIT IRB who may refer the question to IIT Legal Counsel.

**Enrolling Children in Long-Term Studies**

Long-term research studies may involve subjects who are children at the time of enrollment, but reach the age of consenting for themselves (18 years old) while study procedures or follow-up are still ongoing. At age 18 a consent is required for such subjects to continue their participation.

* If there is continued interaction with subjects who were first enrolled as children, “re-consenting” when a subject’s legal status changes will usually be required.
* If relevant, address the above issue in the initial IRB submission and include a consent form for the subject that will turn age 18.

# Additional Requirements: Research in Schools

Research conducted in K through 12 schools, as well as in colleges and universities, receiving U.S. Department of Education funds may be subject to additional federal regulation. Schools that grant access to researchers may also have requirements, such as district approvals or informed consent processes that would not be required by the IRB.

When planning studies involving children in educational settings, consider the following issues:

First, it is best to obtain support from the educational community of their target school/subject group. This may include contacting school district officials, the local PTA, and/or the principal of a particular school. School officials and/or teachers may approve recruitment for a study, but they do not have authority to give permission for participation of individual children in research — only a parent or guardian, with the child’s assent, can do so.

Active consent is usually required vs. implied consent. The IRB is unlikely to approve use of “implied consent” — e.g., a child brings home information about participating in a study at school, and absence of parental response is considered agreement. In most cases, obtaining “active consent” via permission and assent procedures appropriate for the subject group(s) is required.

Offer alternative activities. If the study will be conducted during school hours, an equivalent alternative activity should be offered for students who do not wish to participate or a parent/guardian did not give permission for their child to participate.

In regard to access to student health records, the HIPAA Privacy Rule does not apply to elementary or secondary schools because a school is either: (1) not a HIPAA covered entity or (2) is a HIPAA covered entity but maintains health information only on students in records that are by definition “education records” under FERPA and so not subject to the HIPAA Privacy Rule.

**School Approval**

IIT investigators should obtain letters of permission or authorization from each elementary, middle, or high school at which human subjects research will be conducted, even if the school is not engaged in the research. A letter of permission or authorization should be on school letterhead, and be signed by the school principal or alternate school official who can speak on behalf of the school and provide permission or authorization for the conduct of the research at their site. The school in which the research is being conducted should have policies regarding the physical examinations or screenings that researchers may administer to students.

**School District Acknowledgement**

IIT researchers must consult the school district for any proposed research which will be conducted in one or more school(s) in the district and document district comments.

**School Approval**

IIT researchers should obtain letters of permission or authorization from each elementary, middle, or high school at which human subjects research will be conducted, even if the school is not engaged in the research. A letter of permission or authorization should be on school letterhead, and be signed by the school principal or alternate school official who can speak on behalf of the school and provide permission or authorization for the conduct of the research at their site. If all the schools for the research are in a single district a letter from the School District authorizing the research for all the schools is sufficient.

**Family Educational Rights and Privacy Act (FERPA)**

<http://www.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

IIT Researchers are responsible for complying with FERPA laws when accessing student education records for research purposes. The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education.

Schools may disclose, without parent/guardian permission, "directory" information such as a student's name, address, telephone number, date and place of birth, honors and awards, and dates of attendance. Unless the parent/guardian has notified the school not to release directory information.

FERPA regulates the disclosure of student information from education records in all schools, school districts, education agencies, state education agencies, and any public or private agency or institution that has funding from ED. The purpose of FERPA is to protect student and parent information maintained in an Education Record. Access to identifiable student records, aside from directory information, requires written permission from the parent/guardian (for minors) or from the adult student unless the research is being conducted by the researcher for or on behalf of the school.

**The Protection of Pupils Rights Amendment (PPRA)**:

<https://studentprivacy.ed.gov/faq/what-protection-pupil-rights-amendment-ppra>

The Protection of Pupil Rights Amendment (PPRA) applies to the programs and activities of a state education agency (SEA), local education agency (LEA), or other recipient of funds under any program funded by the U.S. Department of Education. Investigators will obtain parental permission before administering the survey to students that includes any items of the eight protected areas listed below. The investigator will make the survey available for parent(s) to review before administration. PPRA governs the administration to students of a survey, analysis, or evaluation that concerns one or more of the following eight protected areas:

* + - 1. Political affiliations or beliefs of the student or student’s parent;
      2. Mental or psychological problems of the 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 respondents have close family relationships;
      6. Legally recognized privileged relationships, such as with lawyers, doctors, or ministers;
      7. Religious practices, affiliations, or beliefs of the student or parents; or
      8. Income, other than as required by law to determine program eligibility.

IIT investigators will communicate with the school(s) where the research will be conducted to ensure that the school(s) has developed PPRA-compliant policies regarding parental review of surveys; privacy for protected information surveys; physical examinations or screenings; and collection, disclosure, or use of personal information.

PPRA also concerns marketing surveys and other areas of student privacy, parental access to information, and the administration of certain physical examinations to minors. The rights under PPRA transfer from the parents to a student who is 18 years old or an emancipated minor under state law.

# Additional Requirements: NIH Funded Research, including Certificates of Confidentiality

As part of the NIH initiative to improve the quality and transparency of NIH supported research, a suite of initiatives have been launched. These initiatives include [dedicated funding opportunity announcements](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-147.html) for clinical trials, [Good Clinical Practice training](https://grants.nih.gov/policy/clinical-trials/good-clinical-training.htm)[,](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html) enhanced [registration and results reporting](https://s3.amazonaws.com/public-inspection.federalregister.gov/2016-22129.pdf) on [ClinicalTrials.gov,](http://www.clinicaltrials.gov/) and required use of [single](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html) [IRBs for multi-site studies.](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html)

#### Definition of “Clinical Trial”

Determining whether these initiatives apply to your research largely depends on whether your research meets the NIH definition of a clinical trial. [The NIH definition of a clinical trial i](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html)s “a research study in which one or more human subjects are prospectively assigned to one or more [interventions](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html) (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes”.

The NIH has annotated this definition to four basic questions:

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

If the answer to all four questions is yes, then NIH considers the research a clinical trial.

#### Good Clinical Practice (GCP) Training

All NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials can learn about the requirement to be trained in Good Clinical Practice (GCP).

Effective date: January 1, 2017***.***

The principles of Good Clinical Practice (GCP) help assure the safety, integrity, and quality of clinical trials by addressing elements related to the design, conduct, and reporting of clinical trials. GCP training describes the responsibilities of investigators, sponsors, monitors, and IRBs in the conduct of clinical trials.

GCP training aims to ensure that:

* the rights, safety, and well-being of human subjects are protected
* clinical trials are conducted in accordance with approved plans with rigor and integrity
* data derived from clinical trials are reliable

Training in GCP may be achieved through the CITI online training module: GCP or the NIH online training module for social behavioral researchers.

#### Single IRB (sIRB) Policy for Multi-Site Research

Historically, in many multi-site studies, each site has its own IRB which conducts an independent review of studies involving human research participants. After January 18, 2017 NIH required all multi-site research undergo review by a single IRB (sIRB). The use of a sIRB of record for multi-site studies that are conducting the same protocol helps streamline the IRB review process by eliminating the unnecessary repetition of those reviews across sites so that research can proceed as quickly as possible without compromising ethical principles and protections for human research participants.

This policy applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research. It does not apply to career development, research training or fellowship awards. The IIT IRB recommends a sIRB review for non-NIH funded multi-site research.

#### Requirements for Registering & Reporting NIH-funded Clinical Trials in ClinicalTrials.gov

All NIH-funded clinical trials are expected to register and submit results information to [Clinicaltrials.gov,](https://clinicaltrials.gov/ct2/home) as per the "[NIH Policy on Dissemination of NIH-Funded Clinical Trial Information](https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm)" This *ClinicalTrials.gov* website provides resources for understanding and complying with this NIH requirement.

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#### Policy for Issuing Certificates of Confidentiality

Certificates of Confidentiality (CoC) protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations.

The [NIH Policy on CoCs](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html) applies to *“…all biomedical, behavioral, clinical, or other research funded wholly or in part by the NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information”* that was commenced or ongoing after December 13, 2016.

NIH funded researchers whose institutions determine that their research involves collecting or using identifiable, sensitive information are automatically deemed to be issued a CoC through their award. Several Department of Health and Human Services (HHS) agencies (CDC, FDA, HRSA, IHS, SAMSHA) issue CoCs for research they fund or are subject to FDA jurisdiction. Researchers can request a CoC from NIH for health-related studies that are not funded by NIH or another HHS agency that issues CoCs. Appropriate issuance of a CoC is determined by NIH.

CoCs are automatically granted, and the requirements of such must be complied with, whenever a NIH- funded activity falls within the scope of the policy. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the policy.

NIH policy expands upon 42 U.S.C. 241(d) by explaining that NIH considers research in which identifiable, sensitive information is collected or used, to include:

* + Human subjects research as defined in 45 CFR 46, including research determined to be exempt (except for exempt research when the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects);
  + Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
  + Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, **regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained;** or
  + Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

### CoC Protections and Requirements

When a CoC is issued, whether automatically or under an approved application, the person(s) engaged in the research must not disclose or provide the name of a subject or any information, document, or biospecimen that contains identifiable, sensitive information about the subject and that was compiled for the purposes of the research:

* 1. In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, unless the disclosure is made with the consent of the individual to whom the information, document, or biospecimen pertains; or to any other person not connected with the research, unless:
     1. Required by Federal, State, or local laws (e.g., adverse event reporting to the FDA, transmissible disease reporting required under State law), but excluding proceedings as described in “1” above;
     2. Necessary for the medical treatment of the subject to whom the information, document, or biospecimen pertains and made with the consent of the subject;
     3. Made with the consent of the individual to whom the information, document, or biospecimens pertains; or
     4. Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects research.

### The CoC coverage includes:

1. Identifiable, sensitive information protected under a CoC, and all copies thereof, are immune from the legal process, and shall not, without the consent of the of the individual to whom the information pertains, be admissible as evidence or used in any action, suit, or other judicial, legislative, or administrative proceeding.
2. Identifiable, sensitive information that has been collected under a CoC, and all copies thereof, are protected for perpetuity.
3. Nothing in the rule (42 U.S.C. 241(d)) may be construed to limit the access of a subject to information about himself or herself collected during the research.
4. When consent is obtained, the consent should inform subjects that a CoC is in place and describe the protections and limitations.

### NIH CoC Policy Determination

IIT IRB staff and IIT Office of Sponsored Research and Programs (OSRP) staff will, in consultation with the principal investigator(s) (or Program or Project Director, if applicable), determine if the NIH policy applies to any NIH-funded activity. The questions outlined in the NIH policy will be used to guide the analysis. When it has been determined that the NIH policy doesn’t apply, investigators (or Program or Project Directors, if applicable) are responsible for consulting with the IIT IRB and OSRP staff whenever they are proposing changes to the NIH- funded activity that may impact or change the analysis.

### CoC Application Procedures for non-NIH Research

Any person engaged in human subjects research that collects or uses identifiable, sensitive information may apply for a CoC. For most human subjects research, CoCs are obtained from NIH. An investigator may apply for a CoC through the NIH Institute or Center funding research in a scientific area similar to the project. CoCs may also be issued by other Federal agencies and departments, such as CDC, SAMSHA, or HRSA. For more information, see the [NIH CoC Website.](https://humansubjects.nih.gov/coc/index)

### IRB Review for Certificate of Confidentiality (CoC)

Investigators are responsible for clearly representing in the IRB submission that a CoC is in place (e.g. as terms and conditions of an NIH award), or that an application for CoC has been submitted. When the CoC application is in process or pending, the IRB may condition final approval upon its receipt.

For studies that are already underway, investigators must submit a Modification Request to the IRB, along with updated consent language (if applicable), when a CoC is applied for, or when automatically issued under the NIH policy. This includes NIH funded studies that were approved by the IRB prior to December 13, 2016 and for which a CoC was issued retroactively.

When reviewing research under a CoC, the IIT IRB will evaluate whether the research protocol is consistent with the obligations to protect information and specimens under a CoC and whether the consent language, if applicable, discloses the CoC and appropriately describes the associated protections and limitations. The informed consent language referencing a CoC (see “[Children’s Hospital Philadelphia guidance](https://irb.research.chop.edu/certificates-confidentiality)”):

When non-NIH research is not under a CoC, the IRB may require an investigator to apply for a CoC if the research includes identifiable, sensitive information and the IRB determines that a CoC is necessary to minimize risks and adequately protect subjects’ privacy and the confidentiality of subjects’ information or specimens

# Additional Requirements for Clinical Studies Sponsored by NIH or

# a Common Rule Agency – ClinicalTrials.gov

If an IIT research project is a clinical study or trial and supported by NIH or a Common Rule agency, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms (see [Posting Clinical Trial Informed Consent Forms](https://grants.nih.gov/policy/clinical-trials/informedconsent.htm)).

The form must be posted after recruitment closes, and no later than 60 days after the last study visit. The consent form must have been used in enrolling participants in order to satisfy this provision. For an IIT research project that is a clinical study or trial not supported by a Common Rule agency the consent form posting is optional.

Currently, there are two publicly available Federal websites that will satisfy the consent form posting requirement, as required by the revised Common Rule:

* [ClinicalTrials.gov](https://www.clinicaltrials.gov/ct2/manage-recs/register)
* [Docket Folder on Regulations.gov (Docket ID: HHS-OPHS-2018-0021).](https://www.hhs.gov/ohrp/regulations-and-policy/informed-consent-posting/uploading-informed-consent-documents/index.html)

Consent forms for NIH sponsored clinical studies/trials can only be posted on ClinicalTrials.gov. ClinicalTrials.gov is a web-based resource that provides research subjects, health care professionals, researchers, and the public with easy access to information on publicly and privately supported clinical studies on a wide range of diseases and conditions.

The ClinicalTrials.gov website is maintained by the National Library of Medicine (NLM) at the National Institutes of Health (NIH). Information on ClinicalTrials.gov is provided and updated by the sponsor or principal investigator of the clinical study. Studies are generally submitted to the Web site (that is, registered) when they begin, and the information on the site is updated throughout the study.

The ClinicalTrials.gov site offers more information about the study than the Docket Folder on Regulations.gov.

To post a consent form on ClinicalTrials.gov

<https://prsinfo.clinicaltrials.gov/tutorial/content/index.html#/lessons/ZaiGS0D0DYHroTB-jJh6oLQlGYpvRiq1>

# Additional Requirements: DHHS-Regulated Research

### When a study subject withdraws from a study

1. When a participant chooses to withdraw from a clinical trial or longitudinal study, the investigator conducting the trial or study should ask the participants to clarify whether he or she wishes to withdraw from all components of the trial or only from the primary interventional component. If the latter, research activities involving other components of the clinical trial, such as follow-up data collection activities, for which the participant previously gave consent may continue. The investigator should explain to the participant who wishes to withdraw the importance of obtaining follow-up data about the participant.
2. Investigators are allowed to retain and analyze already collected data relating to any participant who chooses to withdraw from a clinical trial or longitudinal research study or whose participation is terminated by an investigator without regard to the participant’s consent, provided such analysis falls within the scope of the analysis described in the IRB-approved protocol. This is the case even if that data includes identifiable private information about the participant.
3. When seeking the informed consent of participants, investigators should explain whether already collected data about the participant will be retained and analyzed even if the participant chooses to withdraw from the research.

# Additional Requirements: Department of Defense (DOD) Research

The Department of Defense research agencies that fund extramural research: Army Research Office (ARO), Army Medical Research and Materiel Command (AMRMC), Air Force Office of Scientific Research (AFOSR), Office of Naval Research (ONR, Defense Advanced Research Projects Agency (DARPA), Intelligence Advanced Research Projects Agency (IARPA), and Homeland Security Advanced Research Projects Agency (HSARPA)

For classified research DoD may require a PI and the research personnel receive clearance for proposed research and/or the PI and research personnel must be U.S. citizens.

Other considerations for DoD research:

1. When appropriate, research protocols must be reviewed and approved by the IIT IRB prior to the Department of Defense approval. Consult with the Department of Defense funding component to see whether this is a requirement.
2. Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
3. Employees of the Department of Defense (including temporary, part-time, and intermittent appointments) may not be able to legally accept payments to participate in research and should check with their supervisor before accepting such payments. Employees of the Department of Defense cannot be paid for conducting research while on active duty.
4. Service members must follow their command policies regarding the requirement to obtain command permission to participate in research involving human subjects while on-duty or off-duty.
5. Components of the Department of Defense have stricter requirements for research-related injury than the DHHS regulations.
6. There may be specific educational requirements or certification required of non-DoD investigators.
7. When assessing whether to support or collaborate with IIT for research involving human subjects, the Department of Defense may evaluate IIT’s education and training policies to ensure the IIT research personnel are qualified to perform the research.
8. When research involves U.S. military personnel, DoD policies and procedures require limitations on dual compensation:
   1. Prohibit an individual from receiving pay of compensation for research during duty hours.
   2. An individual may be compensated for research if the participant is involved in the research when not on duty.
   3. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to $50 for each blood draw.
   4. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
9. When research involves large scale genomic data (LSGD) collected on DOD-affiliated personnel, additional protections are required:
   1. Additional administrative, technical, and physical safeguards to prevent disclosure of DoD- affiliated personnel’s genomic data commensurate with risk (including secondary use or sharing of de-identified data or specimens)
   2. Research will have a NIH Certificate of Confidentiality
10. DoD Component will conduct a security review
11. When conducting multi-site research, a formal agreement between institutions is required to specify the roles and responsibilities of each party.

# Additional Requirements: Department of Energy (DOE) Research

The U.S. Department of Energy (DOE) Office of Science (SC) looks to the private sector to assist in the accomplishment of its mission and program objectives. Organizations and individuals are encouraged to submit proposals which are relevant to the DOE’s research and development mission either in response to formal DOE solicitations and opportunity announcements or through self-generated unsolicited proposals. Human research protection considerations:

1. Research that involves one or more of the following must be submitted to the appropriate IRB for human subjects research review and determination:
   1. Study of humans in a systematically modified environment. These studies include but are not limited to intentional modification of the human environment:
      1. Study of human environments that use tracer chemicals, particles or other materials to characterize airflow.
      2. Study in occupied homes or offices that:
         1. Manipulate the environment to achieve research aims.
         2. Test new materials.
         3. Involve collecting information on occupants’ views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
   2. Use of social media data.
   3. Human Terrain Mapping (HTM).
   4. All exempt HSR determinations must be made by the appropriate IRB and/or IRB office.
2. Personally identifiable information (PII) collected and/or used during HSR projects must be protected in accordance with the requirements of [DOE Order 206.1, Department of Energy Privacy Program](https://www.directives.doe.gov/directives-documents/200-series/0206.1-BOrder-chg1-minchg/@@images/file).
3. Requirements for human participant protections for classified research apply to all classified research conducted or supported by the DOE and its national laboratories, including contracts, and including Human Terrain Mapping research.
4. Researchers conducting human subjects research in any other country or on citizens or other individuals residing in that country must be cognizant of country-specific human subjects research requirements and consult the IRB regarding applicability of such requirements.
5. No human subjects research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research, may be initiated without both a Federalwide Assurance (FWA) or comparable assurance (e.g., Department of Defense assurance) of compliance and approval by the cognizant Institutional Review Board (IRB).

Human subjects research involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, or if authorized by the DOE and/or NNSA HSP Program Manager, other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization responsible for IRB review.

1. Human subjects research that involves DOE federal and/or contractor employees must first be reviewed and approved by the appropriate DOE IRB (the DOE site IRB or one of the Central DOE IRBs), or if deemed more fitting by the federally assured DOE site or Headquarters, other appropriate IRB of record, in accordance with an IAA or MOU negotiated between the DOE site or Headquarters and the organization responsible for IRB review.

## Additional Requirements for DOJ Research Funded by National Institute of Justice

## The National Institute of Justice (NIJ) is the research, development and evaluation agency of the U.S. Department of Justice. NIJ awards grants and cooperative agreements for various research, development, and evaluation projects; and fellowship programs through competitive solicitations.

1. If IRB approval is required for a project, applicants must submit a copy of the IRB's approval as well as supporting documentation concerning the IRB's institutional affiliation, necessary assurances, etc., to NIJ prior to the initiation of any research activities that are not exempt from review.
2. The funded project must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer. [NIJ Privacy Certificate Guidelines](https://nij.ojp.gov/funding/privacy-certificate-guidance)
3. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator.
4. The confidentiality statement on the consent document must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
5. Under a privacy certificate, investigators and research staff do not have to report child abuse unless the subject signs another consent document to allow child abuse reporting.
6. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.
   1. At least once a year, the researcher shall provide the Chief, Office of Research and Evaluation, with a report of the progress of the research.
   2. At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
   3. In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
   4. The research shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
   5. Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

**Additional Requirements: Environmental Protection Agency (EPA) Research**

Research funded through EPA’s Science to Achieve Results (STAR) grants provides invaluable engagement between the agency and scientific community, fostering a collaboration and knowledge-sharing platform. These grants not only engage top scientists throughout the U.S., resulting in a strong scientific foundation to support EPA in meeting its mission, but the funded research provides the underlying scientific and engineering knowledge needed to address environmental and human health issues and to improve decision-making, problem detection, and problem-solving.

1. Research conducted, supported, or intended to be submitted to EPA is subject to Environmental Protection Agency Regulations.
2. Intentional exposure of pregnant women or children to any substance is prohibited. Research involving intentional exposure of human subjects means a study of a substance in which the exposure to the substance experienced by a human subject in the study would not have occurred but for the subject’s participation in the study.
3. Observational research involving pregnant women and fetuses are subject to additional DHHS requirements for research involving pregnant women (45 CFR **§**46 Subpart B) and additional DHHS requirements for research involving children (45 CFR **§**46 Subpart D.)

# Additional Requirements: General Data Protection Requirements (GDPR)

1. Human subject research involving personal data about individuals located in (but not necessarily citizens of) European Union member states, Norway, Iceland, Liechtenstein, and Switzerland is subject to EU General Data Protection Regulations.
2. For all prospective human research subject to EU GDPR, contact the IIT IRB that will consult with IIT General Counsel to ensure that the following elements of the research are consistent with institutional policies and interpretations of EU GDPR:
   1. Any applicable study design elements related to data security measures.
   2. Any applicable procedures related to the rights to access, rectification, and erasure of data.
   3. Procedures related to broad/unspecified future use consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.
3. Where FDA or DHHS regulations apply in addition to EU GDPR regulations, ensure that procedures related to withdrawal from the research, as well as procedures for managing data and biospecimens associated with the research remain consistent with items 1 and 2 above.

# Additional Requirements: Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required Congress to adopt a health information privacy law (the “Privacy Rule”), which was enacted in August 2002 and effective on April 14, 2003. The Privacy Rule is intended to protect the privacy of an individual's health care information when that information is held or handled, used or disclosed, by an entity covered by HIPAA, which generally includes health care and social service providers, hospitals, nursing homes, insurance companies, managed care plans, and Medicare/Medicaid authorities, among others.

Generally, the HIPAA Privacy Rule does not apply to elementary or secondary schools because a school is either: (1) not a HIPAA covered entity or (2) is a HIPAA covered entity but maintains health information only on students in records that are by definition “education records” under FERPA and, therefore, is not subject to the HIPAA Privacy Rule.

#### Effects of HIPAA on Research

HIPAA’s definition of research is identical to that of the Common Rule: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." Under HIPAA, “covered entities” must manage what is called “protected health information,” or “PHI,” in accordance with the Privacy Rule. IIT is a hybrid entity, meaning that only certain divisions (including the University Health Services and the Bureau of Study Counsel) must follow the HIPAA regulations. Thus, any research conducted by IIT faculty and students and taking place at a "covered entity" and involving PHI, or drawing PHI from a “covered entity,” must comply with the Privacy Rule.

#### Complying with HIPAA for IIT Research

The HIPAA Privacy Rule’s requirements must be respected by investigators in research protocols that involve handling PHI within, or drawing PHI from, an entity covered by HIPAA. In order for an investigator to handle PHI within, or draw Protected Health Information from, an entity covered by HIPAA, the investigator must do so under one of the following categories:

* a HIPAA authorization signed by the subject
* a waiver of authorization granted by a Privacy Board, which may include, but is not limited to, the IRB of cognizant jurisdiction
* review preparatory to research, during which the investigator reviews PHI solely to assess the feasibility of a potential research protocol, but does not retain any Protected Health Information from that review
* research on decedents’ health information
* a Limited Data Set

**De-Identified Information**

The Privacy Rule does not apply to de-identified health information. Researchers therefore may access, use and disclose de-identified information without any special permission or authorization under the HIPAA Privacy Rule.

De-identified information consists of information in one of two categories:

1. A qualified statistician or expert has determined that the risk of re-identification is "very small" and must document the methods used to reach that conclusion; or
2. Eighteen identifiers have been removed (similar to identifiers removed to create a limited data set), and the covered entity does not have actual knowledge that the remaining information could be used to identify an individual. The eighteen identifiers of the individual, and of relatives, employers, or household members of the individual, that must be removed include:
   1. Names;
   2. All geographic subdivisions smaller than a State, including street address, city, county, precinct,

zip code, and their equivalent geocodes, except for the initial three digits of a zip code in certain situations;

* 1. All elements of date (except year) for dates directly related to an individual, including birth 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;
  2. Telephone numbers;
  3. Fax numbers;
  4. Electronic mail addresses;
  5. Social security numbers;
  6. Medical record numbers;
  7. Health plan beneficiary numbers;
  8. Account numbers;
  9. Certificate/license numbers;
  10. Vehicle identifiers and serial numbers, including license plate numbers;
  11. Device identifiers and serial numbers;
  12. Web Universal Resource Locators (URLs);
  13. Internet Protocol (IP) address numbers;
  14. Biometric identifiers, including finger and voice prints;
  15. Full face photographic images and any comparable images; and
  16. Any other unique identifying number, characteristic, or code.

**Using PHI in Human Subjects Research: Complying with HIPAA**

When planning or reviewing a research protocol that involves identifiable information relating to an individual’s health or mental health condition, or payment for treatment of that condition by a third party (“protected health information,” or “PHI”), an investigator, IRB staff, or IRB member must consider whether any entity from which such information is drawn or in which it is handled is covered under the HIPAA Privacy Rule.

If such an entity is covered by the HIPAA Privacy Rule, then the investigator may only handle PHI within the entity, or draw PHI from the entity, under (1) appropriate, signed subject authorizations; (2) a Limited Data Set; or (3) waiver of authorization granted by a Privacy Board.

The research protocol must include, either as part of the informed consent form, or as a separate document to be signed by each subject, a HIPAA authorization, setting forth a description of the information to be used or disclosed, the parties to whom the information is to be disclosed and by whom it will be used, the purpose of the disclosure, the time period within which the authorization will be effective, which may be the duration of the research study itself, and the subject’s right to revoke the authorization. See [Documenting](#_4du1wux) [HIPAA Authorization](#_4du1wux) for additional considerations.

**Limited Data Sets**

Without obtaining subject authorizations, the investigator may gain access to and use for research purposes a limited category of PHI, known as a Limited Data Set, from which all "direct" identifiers listed above must have been removed, except for dates and geographic information without street address.

In order to obtain access to a Limited Data Set, the investigator must assure that a Data Use Agreement (DUA) be agreed to between the investigator’s institution(s) and the HIPAA-covered entity. A DUA describes the permitted uses and disclosures of the information received and prohibits any attempt to re-identify or contact the individuals.

A DUA must be reviewed and approved by the IRB, as part of the research protocol, the School Security Officer, and the Sponsored Programs Administrator of cognizant jurisdiction, before the DUA may be accepted and signed by the Office of Sponsored Programs. No researcher may enter into or accept a DUA without such review and approval of his or her cognizant sponsored programs office.

**Waiver by IRB or Privacy Board of HIPAA Authorization Requirement**

Without obtaining subject authorizations or using a Limited Data Set, the investigator may gain access to and use for research purposes PHI by obtaining from a Privacy Board a waiver or alteration of the authorization requirement. The IIT IRB may serve as a Privacy Board.

In order for the IRB to alter or waive authorization, the HIPAA Privacy Rule requires that the IRB find that:

1. Disclosure of the PHI involves no more than minimal risk.
2. The waiver will not adversely affect the privacy rights or welfare of the subject.
3. The research could not practically be carried out without the waiver.
4. The research could not practically be carried out without access to the PHI.
5. The privacy risks are reasonable in relation to the information to be gained.
6. There is an adequate plan to protect the identifiers from improper use and disclosure.
7. There is an adequate plan to destroy the identifiers at the earliest opportunity.
8. There is written assurance that the PHI will not be further disclosed, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of PHI would be permitted by the HIPAA Privacy Rule.

**Compliance by IIT Investigators with the Privacy Policies of Research Sites and Collaborating Institutions**

Each IIT Investigator is required to comply with all applicable privacy and security policies of the HIPAA-covered entity in which that Investigator, as part of a research protocol, is handling PHI or from which the investigator is drawing PHI. It is the responsibility of each investigator who is conducting research within, collaborating with, or seeking cooperation from, a HIPAA-covered entity to know and to comply with the privacy policies of those entities. In general, investigators should ask about privacy policies and compliance rules when dealing with health care providers, social service agencies, mental health and substance abuse treatment facilities, counseling services, health insurers, managed care providers and government benefits offices, including those administering Medicare and Medicaid.

#### Illinois Law

#### (410 ILCS 50/3.1) (from Ch. 111 1/2, par. 5403.1) Sec. 3.1. (a) Any patient who is the subject of a research program or an experimental procedure, as defined under the rules and regulations of the Hospital Licensing Act, shall have, at a minimum, the right to receive an explanation of the nature and possible consequences of such research or experiment before the research or experiment is conducted, and to consent to or reject it. (b) No physician may conduct any research program or experimental procedure on a patient without the prior informed consent of the patient or, if the patient is unable to consent, the patient's guardian, spouse, parent, or authorized agent. (c) This Section shall not apply to any research program or medical experimental procedure for patients subject to a life-threatening emergency that is conducted in accordance with Part 50 of Title 21 of, and Part 46 of Title 45 of, the Code of Federal Regulations. (Source: P.A. 90-36, eff. 6-27-97.)

#### While any person may make a report if they have reasonable cause to believe that a child or elder was abused or neglected, Illinois Public Act Code mandates that personnel of higher education institutions who suspect child or elder abuse or neglect report this to the Illinois Department of Children and Family Services (DCFS) or the Illinois Department on Aging (IDA), as appropriate.

#### To make a report concerning a reasonable cause to believe that a child is being abused or neglected immediately call the IDCFS Child Abuse Hotline at 1-800-25-2283. Hotline staff are social workers with special training in determining what constitutes child abuse and neglect.

#### To make a report concerning suspected abuse, neglect, or financial exploitation of adults age 60 or older and people with disabilities age 18-59 call the IDA 24-hour Adult Protective Services Hotline: 1-866-800-1409.

#### As a matter of IIT policy, if a report is made to IDCFS of IDA, a supervisor or manage of the individual reporting the incident must be promptly notified that a report was made, as well as the underlying circumstances for the report. The supervisor or manager will notify the department chair, director, dean, vice president, or provost as appropriate.

#### Child Abuse Reporting/Mandated Reporter – Parental Permission and Child Assent

Research proposals involving children must include a plan for reporting suspected abuse or neglect of children to IDCFA. Additionally, parental permission forms for parent(s) and assent forms for children should include a statement that suspected child abuse or neglect may be reported to IDCFA.

**Emancipation of Minors Act.**

 (750 ILCS 30/2) (from Ch. 40, par. 2202)

Sec. 2. The purpose of this Act is to provide a means by which a mature minor who has demonstrated the ability and capacity to manage his own affairs and to live wholly or partially independent of his parents or guardian, may obtain the legal status of an emancipated person with power to enter into valid legal contracts.

**Illinois Definition of Guardian**

(750 ILCS 30/3-4) (from Ch. 40, par. 2203-4)   
Sec. 3-4. Guardian. "Guardian" means any person, association or agency appointed guardian of the person of the minor under the Juvenile Court Act, the Juvenile Court Act of 1987, the "Probate Act of 1975", or any other statute or court order.

**Illinois Definition of Parent**

(750 ILCS 30/3-3) (from Ch. 40, par. 2203-3)   
Sec. 3-3. Parents. "Parent" means the father or mother of a lawful child of the parties or a child born out of wedlock, and includes any adoptive parent. It does not include a parent whose rights in respect to the minor have been terminated in any manner provided by law.

**Illinois Definition of Surrogate Decision Maker**

(755 ICLS 40/) (from Ch. 110 1/2, par. 851-10)

Sec. 10. Surrogate Decision Maker. “Surrogate Decision Maker” means an adult individual or individuals who (i) have decisional capacity, (ii) are available upon reasonable inquiry, (iii) are willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity, and (iv) are identified by the attending physician in accordance with the provisions of this Act as the person or persons who are to make those decisions in accordance with the provisions of this Act.

# Principal Investigator Responsibilities and Cayuse Assurance Statement

For the IRB to initiate the review of the research application in Cayuse the PImust certify the following criteria:

1. I will not start human research activities until I have obtained all applicable institutional approvals, including local ethics committee review for international sites; and approvals of departments or divisions that require approval prior to commencing research that involves their resources.
2. I will ensure that there are adequate resources to carry out the research safely, e.g. sufficient investigator time, equipment, and spacing.
3. I will ensure that Research Staff are qualified (e.g., including but not limited to appropriate training (CITI), education, expertise, credentials, protocol requirements) to perform procedures and duties assigned to them during the study.
4. I will update the IRB with any changes to the list of study personnel.
5. I will personally conduct or supervise the human subject research.
   1. Conduct the human subject research in accordance with the relevant current protocol as approved by the IRB.
   2. When required by the IRB ensure that consent and/or permission is obtained in accordance with the protocol as approved by the IRB.
   3. Not modify the research without prior IRB review and approval (when required) unless necessary to eliminate apparent immediate hazards to participants.
   4. Protect the rights, safety, and welfare of participants involved in the research.
6. I will submit to the IRB in a timely manner:
   1. Proposed modifications to the previously-approved human research, when applicable.
   2. A continuing review application (to avoid a lapse in approval), when applicable.
   3. A continuing review application when the research study is closed, when applicable.
7. I will submit to the IRB any reportable new information within five business days.
8. I will personally submit and ensure that Research Staff submit an updated Financial Interest Disclosure within 30 days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new financial interest.
9. I will comply with applicable federal and state regulations, ethical guidelines, and IIT Institutional policies, including (but not limited to) the Institutional Conflict of Interest, DUA Policy and Guidance, and IIT Research Data Security Policy.

* To protect information I must have a strong password for each of my IIT accounts; including a login for idle sessions and lock out screen for multiple failed log-in attempts. Log in information will not be shared.
* Any system storing information qualifying as Level 2 or ‘non-sensitive’ by the IRB must have updated security patches and virus protection. These systems will only be accessed by those with a current and IRB approved research role.

1. I will maintain adequate and accurate records and make these records available to the IRB for review.
2. I will ensure that IRB-approved study documents, including recruitment materials, consent forms, and study tools, are accurately translated in a language understandable to study participants. If applicable, I will submit locally-approved versions of these materials to the IRB when they become available.

By selecting 'ok' [on the submit activity, in Cayuse], I agree to the above statements and the submission will be forwarded to the next appropriate level of review.

# Key Definitions and Terms

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### Assent: a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

### Award: The provision of funds by a U.S. agency or department, or non-government sponsor, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

### Cayuse: Cayuse is the IRB’s online protocol management system[.](http://irb.harvard.edu/) Cayuse is accessible through my.iit.edu. For problems accessing Cayuse IRB, contact [drichard1@iit.edu](mailto:drichard1@iit.edu). For problems with Cayuse, contact the Cayuse Help Center at [http://support.Cayuse.com/](http://support.cayuse.com/)

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### Center Grants: Center grants are awarded to institutions on behalf of program directors and groups of collaborating investigators. They support long-term, multi-disciplinary programs of research and development.

### CFR: Code of Federal Regulations is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government.

### Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

**Child/Children/Minors:** Persons who have not attained the legal age for consent to be involved in research, under the applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old (19 in AL & NE) to be a child. There may be additional laws in places that define emancipated minors.

### Coded: With respect to private information or human biological specimen, coded means that identifying information that would readily ascertain the identity of the individual to whom the private information or specimens pertain has been replaced with a number, letter, symbol or combination thereof (i.e., the code) and a key to decipher the code exists, enabling linkage of the identifying information with the private information or specimens.

**Confidentiality:** Refers to the investigators agreement with the subject on how a subject’s data will be handled, managed, secured, and disseminated.

**Data Encryption:** Encryption is the conversion of data into a form, through use of an algorithm, which renders electronic data, unusable, unreadable, or indecipherable by unauthorized persons.

### DHHS: Department of Health and Human Services also referred to as HHS.

### Extramural Research: Research supported by a U.S. agency or department through a grant, contract or cooperative agreement.

### FAR: Federal Acquisition Regulations

### Federal-Wide Assurance (FWA): The Federal-Wide Assurance is the only type of assurance accepted and approved by OHRP for institutions engaged in non-exempt human subjects research conducted or supported by DHHS. Under a FWA, an institution commits to DHHS that it will comply with the requirements set forth in 45 CFR 46 as well as the terms of the assurance.

**Generalizable knowledge**: The extent to which research findings and conclusions from a study conducted on a sample population can be applied to the population at large (i.e., extending the results beyond a single individual or an internal unit).

**Guardian:** an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

**Informed Consent:** A person’s voluntary agreement, based on adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

### HIPAA

The Health Insurance Portability and Accountability Act (HIPAA) [Privacy Rule](https://www.hhs.gov/hipaa/for-professionals/privacy/) established national standards for the protection of health information (called “protected health information” or [PHI).](http://www.hhs.gov/hipaa/for-professionals/privacy/special-topics/de-identification/#protected) It applies to organizations such health plans, health insurance companies, health care clearinghouses, and health care providers that conduct health care transactions electronically. These organizations are called “[covered entities.](https://www.cms.gov/Regulations-and-Guidance/Administrative-Simplification/HIPAA-ACA/AreYouaCoveredEntity.html)” There are no covered entities at IIT.

To learn more about how the Rule may affect your research, see the section in this manual on [HIPAA](#_2pcmsun) and refer to the NIH booklet [Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule.](https://privacyruleandresearch.nih.gov/pdf/HIPAA_Privacy_Rule_Booklet.pdf)

**Human Subject as Defined by DHHS:** The federal regulations define a *human subject*as “a **living**individual **about whom**an investigator conducting research  (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; **or** (2) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens”

* **“Living individual”**refers to data collected from living subjects.
* **“About whom”**refers to the fact that the information collected must be personal information about an individual. For example, a survey that collects data about the activities of an organization, rather than its members, is not human subjects research.
* **“Intervention”**includes physical procedures and manipulations of the subject or the subject's environment for research purposes. For example, taking a saliva or blood sample from a subject or having a subject view a video would be considered a research intervention.
* **“Interaction”** refers to communication between the researcher and the subject. For example, research that includes face‐to-face, mail, internet and phone interactions (e.g. surveys), as well as other modes of communication would be considered an interaction.
* **“Identifiable private information or biospecimen”** means the identity of the subject is or may be readily ascertained by the researcher or others or associated with the information. For example, research with a de‐identified data set is not research with human subjects because the data are not individually identifiable.
* **“Private information”**includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Private information must be individually identifiable in order to be considered information to constitute research involving human subjects.

If requested, the IRB will review the proposed activities and make a formal “Not Human Subjects Research” determination.

**Intervention:** A manipulation of the human subject or subject’s environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints.

**Investigational New Drug (IND):** A new drug or biological drug that is used in a clinical investigation.

**IRB:** The Institutional Review Board (IRB) is a committee that is required by federal law to protect the rights and welfare of human subjects participating in research activities. The committee meets this mandate by reviewing proposed and ongoing human research activities, ensuring they meet specific criteria required for approval.

**IRB Authorization Agreement (IAA):** A formal written document that details an agreement for an institution engaged in nonexempt human subjects research to rely on the IRB of another institution.

**IRB of Record**: A reviewing IRB that assumes IRB oversight for another organization that meets the regularity definition of engaged in human subjects research. If federal funds are supporting this research, the organization is designated to do so through an approved Federalwide Assurance (FWA) on file with the Federal Office of Human Research Protection (OHRP).

**Key personnel:** includes all persons named on a research application who are responsible for the design, conduct, data analysis or reporting for the study.

**Legally Authorized Representative (LAR)**: An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Limited Data Set**

'A “limited data set” is a limited set of identifiable patient information as defined under the Health Insurance Portability and Accountability Act, better known as “HIPAA”. A “limited data set” of information may be disclosed to an outside party without a patient’s authorization if certain conditions are met.

All the following identifiers must be removed in order for health information to be a “limited data set”:

|  |  |
| --- | --- |
| * names | * health plan beneficiary numbers |
| * street addresses, other than town, city, state & zip code | * account numbers |
| * telephone numbers | * certificate license numbers |
| * fax numbers | * vehicle identifiers and serial numbers, including license plates |
| * e-mail addresses | * device identifiers and serial numbers |
| * Social Security numbers | * URLs |
| * medical records numbers | * IP address numbers |
| * health plan beneficiary numbers | * biometric identifiers (including finger and voice prints) |
| * Social Security numbers | * full face photos (or comparable images). |
| * medical records numbers |  |

**Minor Modifications**: - Modifications to a research project and/or consent documents that pose no additional risk to subjects (i.e., changes in title, personnel, funding sources). If the modification is an addition or modification of procedures they must fall into one of the categories eligible for expedited review. To be considered a minor modification, it must also maintain similar or increased safeguards to protect the subject.

**MOU:** Memorandum of Understanding is a formal, written agreement between two or more parties that establishes a partnership.

**National Institutes of Health (NIH):** NIH is the primary agency of the U.S. government responsible for biomedical and public health research and is part of DHHS. The NIH conducts its own scientific research through the NIH Intramural Research Program (IRP) and provides major biomedical research funding to non-NIH research facilities through its Extramural Research Program. The NIH comprises 27 separate institutes and centers of different biomedical disciplines.

**National Science Foundation (NSF):** NSF is an independent agency of the U.S. government that supports fundamental research and education in all the non-medical fields of science and engineering such as mathematics, computer science, economics, and the social sciences.

**No-Cost Extension:** An extension of time to a project period and/or budget period to complete work on the grant under that period, without additional Federal or competition.

**Office for Human Research Protections (OHRP):** The DHHS office overseeing human subject protection for DHHS-supported research.

**Office of Research Integrity (ORI):** DHHS office promoting integrity in biomedical and behavioral research supported by the Public Health Service (PHS) by monitoring institutional investigations of scientific misconduct and facilitating the responsible conduct of research.

**Parent:** a child's biological or adoptive parent.

**Personally Identifiable Information (PII):** Information that can be used to distinguish or trace an individual’s identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

**Postdoctoral Scholar:** An individual who has received a doctoral degree and is engaged in a temporary and defined period of mentored advanced training to enhance the professional skills and research independence needed to pursue his or her chosen career path.

**Principal Investigator:** The individual designated by the applicant organization to have the appropriate level of authority and responsibility to direct the project or program to be supported by the award.

**Protocol:** Formal description and design for a specific research project.

**Public Health Service (PHS):** An organization in the U.S. Government consisting of eight DHHS health agencies, the Office of Public Health and Science, and the Commissioned Corps. NIH is the largest agency within PHS.

**Responsible Conduct of Research:** The use of honest and verifiable methods in proposing, performing, and evaluating research. Reporting research results with particular attention to adherence to rules, regulations, and guidelines. Adhering to commonly accepted professional codes or norms.

**Research Misconduct:** the fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person’s ideas, processes, results, or words without giving appropriate credit. Research misconduct does not include honest error or differences of opinion.

**Scope of Work (SOW):** The aims, objective, and purposes of a grant; as well as the methodology, approach, analyses or other activities; and the tools, technologies, and timeframes needed to meet the grant’s objectives.

**Voluntary:** Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's informed decision to participate (or to continue to participate) in a research activity.

**Ward:** Any child who is placed in the legal custody of the state or other agency, institution, or entity, consistent with the applicable federal, state, and local laws and regulations. In Illinois, a ward of the state includes but is not limited to a child placed by court under the guardianship of the Illinois Department of Children and Family Services. In Illinois, children placed in foster care are wards of the state.

**Worksheets/Checklists/Templates/Forms**



# Useful Resources

#### Federal Agencies/Departments

Department of Health and Human Services (HHS) - [http://www.hhs.gov](http://www.hhs.gov/) Centers for Disease Control and Prevention (CDC) - [http://www.cdc.gov](http://www.cdc.gov/)

*Human Participant Protection in CDC Research -* <https://www.cdc.gov/os/integrity/hrpo/index.htm>

National Institutes of Health (NIH) - <http://grants.nih.gov/grants/policy/hs/index.htm> Certificate of Confidentiality Kiosk - <http://grants.nih.gov/grants/policy/coc/>

Office of Civil Rights (HIPAA policy) - <http://www.hhs.gov/ocr/privacy/index.html> Office of Human Research Protection (OHRP) - <http://www.hhs.gov/ohrp/>

*Regulations* - <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm> *Decision Charts -* <http://www.hhs.gov/ohrp/policy/index.html#decision> *Guidance and Policy -* <http://www.hhs.gov/ohrp/policy/>

*FAQs -* <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/index.html>

*International Research Policies -* <http://www.hhs.gov/ohrp/international/index.html#NatlPol> Food and Drug Administration (FDA) - <http://www.fda.gov/>

Department of Education - <http://www.ed.gov/>

*Human Subjects Research* - <http://www.ed.gov/about/offices/list/ocfo/humansub.html> *Family Policy and Compliance Office (FERPA and PPRA)* <https://www.2.ed.gov/policy/gen/guid/fpco/ferpa/index.html>

National Science Foundation - [http://www.nsf.gov](http://www.nsf.gov/)

*FAQs on Interpreting the Common Rule for the Protection of Human Subjects for Social and Behavioral Research -*

<http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp>

National Science and Technology Council Report on Expedited Review of Social and Behavioral Research Activities - <http://www.ostp.gov/galleries/NSTC%20Reports/Expedited%20Review%20For%20Web.pdf>