Institutional Review Board

Standard Operating Policies
Addendum
Additional regulations for specific funding/oversight offices

Version 1.0
May 1, 2015

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Overview

The IRB follows DoD regulation when reviewing human subject research supported and regulated by the DoD. This addendum to the SOP describes the DoD regulations for reviewing studies that involve greater than minimal risk or has a special consideration(s) e.g., classified research, research with vulnerable populations, etc. The information below provides a brief overview of how the IRB would review such studies. In conducting these reviews, the IRB will refer to and follow the applicable Department of Defense regulations.

Activities overseen by the Human Research Protection Program

Non-exempt classified research must be conducted following the requirements of 3216.02.13. (See references for DoD directive 3216.02.13.).

Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

The definition of minimal risk based on the phrase “ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests” shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example the risks imposed in research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

Research involving an experimental subject is defined as an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving a human being as an experimental subject is a subset of research involving human subjects. This definition relates only to the application of section 980 of Reference (g); it does not affect the application of part 219 of Reference (c). This definition does not include activities that are not considered research involving human subjects, activities that meet the exemption criteria at section 219.101(b) of Reference (c), and research involving the collection or study of existing data, documents, records, or specimens from living individuals.

In general, no Department of Defense component may conduct or use appropriated funds to support research involving a human being as an experimental subject without the prior informed consent of the subject.
Classified Research

For all Department of Defense conducted or supported non-exempt human subject research involving classified information (as defined in Executive Order 13526), additional requirements must be applied. The review of research involving classified information is rare and requires Secretary of Defense approval. Additional requirements are described in the Department of Defense Instruction 3216.02.

Human Subject Research Training

University of Pennsylvania investigators and study staff who conduct human subject research must complete training before the IRB will approve a project(s). Please visit Investigator & Research Staff Training for the current University of Pennsylvania training requirements and options. Training is valid for three (3) years. If research involving a DoD component requires more frequent or other training requirements in addition to those that the University of Pennsylvania requires, the investigator will be responsible for ensuring that the training is completed for those involved in the conduct of the research. Researchers should contact the human research protection officer of the DoD component for their education requirements and obtain documentation confirming the requirements.

Additional Protections for Military Research Personnel

When research involves U.S. military personnel as participants in research, the following guidelines apply:

Recruitment and Enrollment

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

Compensation

- Participants may be compensated for research participation as long as the participant is involved in the research when not on duty. Enrolled individuals may not receive payment of compensation for research participation during duty hours.
• Federal employees while on duty and non-Federally employed individuals may be compensated for blood draws for research up to $50 for each blood draw.
• Non-Federally employed individuals may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB.

**Waiver of Consent**

Research Subject to Department of Defense requirements is prohibited from using an exception from consent in emergency medicine unless a waiver is obtained from the Secretary of Defense.

The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:

• The research is necessarily to advance the development of a medical product for the Military Services.
• The research might directly benefit the individual experimental subject.
• The research is conducted in compliance with all other applicable laws and regulations.
  o For classified research, waivers of consent are prohibited.
  o If the research participant does not meet the definition of “experimental subject,” the IRB is allowed to waive the consent process.

**Informed Consent Process**

The following are additional requirements regarding the informed consent process for DoD conducted or supported studies.

*Disclosure of Research-Related Injury*

Any requirements for disclosure of research-related injury from a DoD component must be included in the informed consent process. See SOP 701 (2.3).

*Consent from a Legally Authorized Representative*

If consent is to be obtained from the legally authorized representative of an experimental subject, the research must be intended to provide direct benefit to the individual participant. The determination that the research is beneficial to the individual experimental subject must first be made by the IRB.
Multi-Centered Research

If an investigator is the lead investigator/site for a multi-centered study, they have additional responsibilities for overseeing the activities at the University of Pennsylvania as well as the other sites participating in the study. To meet DoD requirements (SECNAVINST 3900.39D, section 6f), the investigator must execute an agreement or statement of work with all collaborating sites that delineates each site’s responsibilities. This document should include the following elements:

- A brief description of the research
- Specific roles and responsibilities of each site, including scientific and IRB review; recruitment of participants; and informed consent procedures
- Plan for ongoing data and safety monitoring, reporting requirements, documentation retention, and compliance for the entire research project

If the investigator is not the lead investigator for a multi-centered DoD study, the investigator should ensure to request a copy and sign the study's agreement/statement of work prior to initiating study procedures at the University of Pennsylvania.

International Research

If the DoD research is conducted in a foreign country, the investigators must submit verification of the local ethics review (i.e. approval to conduct research). The investigator must abide by the local laws, regulations and customs as applicable. For more guidance, please see the International Research section of the Guide to Daily Operations.

Serious and Continuing Noncompliance

Determinations of serious or continuing non-compliance of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Records maintained that document compliance or non-compliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD at reasonable times and in a reasonable manner as determined by the supporting DoD component.

Reporting Requirements

The following shall be promptly (no longer than within 30 days) reported to the DoD human research protection officer:
• When significant changes to the research protocol are approved by the IRB.
• The results of the IRB continuing review.
• Change of reviewing IRB.
• When the organization is notified by any Federal department, agency or national organization that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.

Any unanticipated problems involving risks to participants or others for any DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Any suspension or termination of DoD-supported research must be promptly (no longer than within 30 days) reported to the DoD human research protection officer.

Data and Safety Monitoring

The IRB considers the appointment of a research monitor:
• Required for research involving greater than minimal risk, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk if appropriate.
• The research monitor is appointed by name and shall be independent of the team conducting the research.
• There may be more than one research monitor (e.g. if different skills or experience are needed.)
• The monitor may be an ombudsman or a member of the data safety monitoring board. The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.
• The IRB or HRPP official shall communicate with research monitors to confirm their duties, authorities, and responsibilities.
• The duties of the research monitor are determined on the basis of specific risks or concerns about the research, such as:
  o Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis).
  o Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
  o Report observations and findings to the IRB or a designated official.
• The research monitor has the authority to:
  o Stop a research study in progress.
  o Remove individuals from study.
  o Take any steps to protect the safety and well-being of participants until the IRB can assess.
Vulnerable Populations (Subparts B, C and D)/Prisoners of War

Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D:

- For purposes of applying Subpart B, the phrase “biomedical knowledge” shall be replaced with “generalizable knowledge.”
- The applicability of Subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and included interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
- Research involving prisoners cannot be reviewed by the expedited procedure.
- When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.

In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:

- The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
- The research presents no more than minimal risk.
- The research presents no more than an inconvenience to the participant.

If a participant becomes a prisoner, and if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB’s approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol.

The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol
requirements, the terms of the prisoner-participant’s confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-participant to continue to participate in the research. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.

- Research involving a detainee as a human participant is prohibited.
- This prohibition does not apply to research involving investigational drugs and devises when the same products would be offered to US military personnel in the same location for the same condition.
- Research involving children cannot be exempt.
  - If consent is to be obtained from the experimental subjects’ legal representative, the research must intend to benefit the individual participant.
  - The determination that the research is intended to beneficial to the individual experimental subject must be made by an IRB.
- Research involving a prisoner of war is prohibited
  - A prisoner of war is a person captured in war; especially: a member of the armed forces of a nation who is taken by the enemy during combat

REFERENCES

Overview

The IRB follows Department of Education regulation when reviewing human subject research supported and regulated by the Department of Education. The information below provides a brief overview of how the IRB would review such studies. In conducting these reviews, the IRB will refer to and follow the applicable Department of Education regulations.

IRB Membership Requirements

For research funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

FERPA

- The IRB verifies that the research is in compliance with the Family Educational Rights and Privacy Act (FERPA) by securing this certification from the researcher and the participating schools.
- The IRB works with the organization (e.g., a FERPA committee) to grant exceptions to parental/student consent to release student records for research.
  - An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
    - Develop, validate, or administer predictive tests.
    - Administer student aid programs.
    - Improve instruction.
- A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the organization or researcher conducting the research that specifies:
  - The determination of the exception.
  - The purpose, scope, and duration of the study.
  - The information to be disclosed.
  - That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in 34 CFR 99.31(a)(6) on re-disclosure and destruction of information.
That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.

That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.

The time period during which the organization must either destroy or return the information.

**Records**

Education records may be released without consent under FERPA if all personally identifiable information has been removed including:

- Student’s name and other direct personal identifiers, such as the student’s social security number or student number.
- Indirect identifiers, such as the name of the student’s parent or other family members; the student’s or family’s address, and personal characteristics or other information that would make the student’s identity easily traceable; date and place of birth and mother’s maiden name.
- Biometric records, including one or more measurable biological or behavioral characteristics that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
- Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.

**Pupil Rights Amendment**

- The IRB verifies that the research is in compliance with the Protection of Pupil Rights Amendment:
- No student shall be required, as part of any research project, to submit without prior consent to surveys, psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:
  - Political affiliations.
  - Mental and psychological problems potentially embarrassing to the student or his or her family.
  - Sex behavior and attitudes.
  - Illegal, anti-social, self-incriminating and demeaning behavior.
  - Critical appraisals of other individuals with whom the student has close family relationships.
  - Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
o Religious practices, affiliations, or beliefs of the student or student’s parent.
o Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.
o Prior consent means:
  ▪ Prior consent of the student, if the student is an adult or emancipated minor; or
  ▪ Prior written consent of the parent or guardian, if the student is an unemancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

• The IRB must verify compliance with U.S. Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
o The right of a parent of a student to inspect, upon the request of the parent, a survey created by a third party before the survey is administered or distributed by a school to a student.
o Any applicable procedures for granting a request by a parent for reasonable access to such survey within a reasonable period of time after the request is received.
o Arrangements to protect student privacy that are provided by the agency in the event of the administration or distribution of a survey to a student containing one or more of the following items (including the right of a parent of a student to inspect, upon the request of the parent, any survey containing one or more of such items):
  ▪ Political affiliations or beliefs of the student or the student’s parent.
  ▪ Mental or psychological problems of the student or the student’s family.
  ▪ Sex behavior or attitudes.
  ▪ Illegal, anti-social, self-incriminating, or demeaning behavior.
  ▪ Critical appraisals of other individuals with whom respondents have close family relationships.
  ▪ Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.
  ▪ Religious practices, affiliations, or beliefs of the student or the student’s parent.
  ▪ Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
o The right of a parent of a student to inspect, upon the request of the parent, any instructional material used as part of the educational curriculum for the student.
o Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
o The administration of physical examinations or screenings that the school or agency may administer to a student.

o The collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling that information (or otherwise providing that information to others for that purpose), including arrangements to protect student privacy that are provided by the agency in the event of such collection, disclosure, or use.

o The right of a parent of a student to inspect, upon the request of the parent, any instrument used in the collection of personal information before the instrument is administered or distributed to a student.

o Any applicable procedures for granting a request by a parent for reasonable access to such instrument within a reasonable period of time after the request is received.

References:
Overview

The IRB follows Department of Energy regulation when reviewing human subject research supported and regulated by the Department of Energy. The information below provides a brief overview of how the IRB would review such studies. In conducting these reviews, the IRB will refer to and follow the applicable Department of Energy regulations.

Department of Energy IRB Review Checklist

The IRB reviews and approves the “Checklist for IRBs to Use in Verifying That HHS Research Protocols Are in Compliance with DOE Requirements” submitted by the researchers to verify compliance with the DOE requirements for the protection of personally Identifiable Information.

The following items must be addressed in all protocols:
1. Keeping PII confidential;
2. Releasing PII, where required, only under a procedure approved by the responsible IRB(s) and DOE;
3. Using PII only for purposes of this project;
4. Handling and marking documents containing PII as “containing PII or PHI;”
5. Establishing reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of PII;
6. Making no further use or disclosure of the PII except when approved by the responsible IRB(s) and DOE, where applicable, and then only under the following circumstances: (a) in an emergency affecting the health or safety of any individual; (b) for use in another research project under these same conditions and with DOE written authorization; (c) for disclosure to a person authorized by the DOE program office for the purpose of an audit related to the project; (d) when required by law; or (e) with the consent of the participant/guardian;
7. Protecting PII data stored on removable media (CD, DVD, USB Flash Drives, etc.) using encryption products that are Federal Information Processing Standards (FIPS) 140-2 certified;
8. Using passwords to protect PII used in conjunction with FIPS 140-2 certified encryption that meet the current DOE password requirements cited in DOE Guide 205.3-1;
9. Sending removable media containing PII, as required, by express overnight service with signature and tracking capability, and shipping hard copy documents double wrapped;
10. Encrypting data files containing PII that are being sent by e-mail with FIPS 140-2 certified encryption products;
11. Sending passwords that are used to encrypt data files containing PII separately from the encrypted data file, i.e. separate e-mail, telephone call, and separate letter;
12. Using FIPS 140-2 certified encryption methods for websites established for the submission of information that includes PII;
13. Using two-factor authentication for logon access control for remote access to systems and databases that contain PII. (Two-factor authentication is contained in the National Institute of Standards and Technology (NIST) Special Publication 800-63 Version 1.0.2 found at: http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-63-2.pdf.
14. Reporting the loss or suspected loss of PII immediately upon discovery to: 1) the DOE funding office Program Manager or, if funded by a DOE laboratory, the DOE laboratory Program Manager; and 2) the DOE Human Subjects Protection Program Manager, SC-23, and the NNSA Human Subjects Protection Program Manager, NA-SH. If the above individuals are unreachable, immediately notify the DOE-CIRC (1-866-941-2472, by FAX: at 702-932-0189, or by e-mail at: circ@jc3.doe.gov). For additional information, see: http://energy.gov/cio/office-chief-information-officer/services/incident-management/jc3-incident-reporting.
15. Classified projects that use PII must also comply with all requirements for conducting classified research.

Reporting Requirements:

Researchers must promptly (no longer than within 30 days) report the following to the human subject research program manager:
o Any significant adverse events, unanticipated risks, and complaints about the research, with a description of any corrective actions taken or to be taken.
o Any suspension or termination of IRB approval of research.
o Any significant non-compliance with HRPP procedures or other requirements.
o The time frame for “promptly” is defined.
o Any compromise of personally identifiable information must be reported immediately.
  ▪ The time frame for “immediately” is defined.

References:
http://humansubjects.energy.gov/other-resources/pii.htm
Overview

The IRB follows Department of Justice regulation when reviewing human subject research supported and regulated by the Department of Justice. The information below provides a brief overview of how the IRB would review such studies. In conducting these reviews, the IRB will refer to and follow the applicable Department of Justice regulations.

- **For National Institute of Justice (NIJ) funded research:**
  
  - All projects are required to have a privacy certificate approved by the NIJ Human Subjects Protection Officer.
  - All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
  - The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate harm to participants or others.
  - Under a privacy certificate, researchers and research staff does not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.

- **For research conducted with the Bureau of Prisons:**
  
  - Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered research.
  - A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
  - Except as noted in the consent statement to the participant, the researcher must not provide research information that identifies a participant to any person without that participant’s prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
  - Except for computerized data records maintained at an official Department of Justice site, records that contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.
If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

Required Elements of Disclosure
- Identification of the researchers.
- Anticipated uses of the results of the research.
- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable).
- A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization.
- A statement that participation in the research project will have no effect on the inmate participant’s release date or parole eligibility.
- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
- Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
- All research proposals will be reviewed by the Bureau Research Review Board.

Guidance for Investigators:

- For research conducted within the Bureau of Prisons, the researcher must have academic preparation or experience in the area of study of the proposed research.
- For research conducted within the Bureau of Prisons, when submitting a research proposal, the applicant shall provide the following information:
  - A summary statement, which includes:
    - Names and current affiliations of the researchers.
    - Title of the study.
Purpose of the study.
Methods to be employed.
Anticipated results.
Duration of the study.
Number of participants (staff or inmates) required and amount of time required from each.
Indication of risk or discomfort involved as a result of participation.
A comprehensive statement, which includes:

- Review of related literature.
- Detailed description of the research method.
- Significance of anticipated results and their contribution to the advancement of knowledge.
- Specific resources required from the Bureau of Prisons.
- Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
- Description of steps taken to minimize any risks.

Description of physical or administrative procedures to be followed to:

- Ensure the security of any individually identifiable data that are being collected for the study.
- Destroy research records or remove individual identifiers from those records when the research has been completed.

Description of any anticipated effects of the research study on organizational programs and operations.

Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
EPA 500 ENVIRONMENTAL PROTECTION AGENCY

Overview

The IRB follows Environmental Protection Agency regulation when reviewing human subject research supported and regulated by the Environmental Protection Agency. The information below provides a brief overview of how the IRB would review such studies. In conducting these reviews, the IRB will refer to and follow the applicable Environmental Protection Agency regulations.

Additional Regulatory Requirements

- EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
- The EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.
- EPA policy requires submission of IRB determinations and approval to the EPA human subject research review official for final review and approval before the research can begin.
- For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:
  - EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.
  - EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.
- Research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB.
- For research intended for submission to the EPA, research involving intentional exposure of pregnant women or children to any substance is prohibited and not approved by the IRB.
- The IRB review must review and approve observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B.
- The IRB must review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 26.406.
The IRB may only approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:
  o The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
  o The risk is justified by the anticipated benefit to the participants.
  o The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
  o Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 26.406.