

# IRB Guide

## Contents

**IRB Member Conflict of Interest**

**Unanticipated Problem Report**

**Criteria for IRB Approval of Research (46.111)**

**Informed Consent Required Elements (45 CFR 46.116)**

**Criteria for Consent Waiver Determinations**

**Studies involving Children**

**Studies with Pregnant Women**

**Studies involving Prisoners**

**Expedited Review Eligible Categories of Research**

**Clinicaltrials.gov**

**DSMP in Clinical Studies Requirements**

**Federally Funded Research Requirements**

(Departments of Defense, Education, Energy, Justice  
and the Environmental Protection Agency)

**At the end of the meeting, please return this booklet to an  
IRB Program Coordinator.**

## IRB Member Conflict of Interest

IRB member is said to have a conflict of interest whenever that person, his or her spouse, or dependent child falls under any of the following conditions:

1. Is an investigator or sub-investigator on the protocol (IRB members only, not applicable to PIs)
2. Has entered into a financial arrangement with the sponsor or agent of the sponsor, whereby the outcome of the study could influence the value of the economic interest.
3. Acts as an officer or a director of the sponsor or an agent of the sponsor.
4. Has equity interest in the sponsor publicly valued at \$5,000 or greater or any equity interest in a non-publically traded sponsor.
5. Has received payments or other incentives from any sponsor that when aggregated for the member, spouse and dependent children, total of \$5,000 or greater.
6. Has identified him or herself for any other reason as having conflict of interest.

## Unanticipated Problem Report

If the following three conditions apply, then the incident must be reported to OHRP.

1. The event was unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied.
2. The event was related or possibly related to participation in the research (in this guidance document, possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research).
3. The event suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

In consideration of the above items, review the overall study as follows:

- a. Is the risk/benefit ratio still acceptable?
- b. Is a modification needed in the protocol to define or minimize the risk?
- c. Does the consent/permission form appropriately list the current event?
- d. Does the protocol require any revisions?
- e. Does the consent/permission form require any revisions?
- f. Should all research subjects be informed of the event?
- g. Overall, does approval of the study still meet the criteria of 45 CFR 46.111?
- h. Does the event represent an incident of non-compliance?
- i. Should the study continue?

## **Criteria for IRB Approval of Research (46.111)**

In order to approve human subject research the IRB shall determine that all of the following requirements are satisfied:

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

## **Informed Consent Required Elements (45 CFR 46.116)**

1. A statement that the study involves research.
2. An explanation of the purposes of the research.
3. The expected duration of the subject's participation.
4. A description of the procedures to be followed.
5. Identification of which procedures are experimental.
6. A description of reasonably foreseeable risks or discomforts that the subjects may encounter, and if appropriate, a statement that some risks are currently unforeseeable.
7. A description of possible benefits, if any, to the subject and others which may be reasonably expected. It should be stated that since it is an experimental treatment or procedure, no benefits can be guaranteed.
8. A disclosure of appropriate alternative procedures or treatments, if any, which are available and might be advantageous to the subject. One alternate might be to choose not to participate in the research.
9. A statement describing the manner and extent, if any, to which confidentially of records identifying the subject will be maintained and, if applicable, a statement that the IRB, FDA and other entities may inspect the records.
10. For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of or where further information may be obtained.
11. A description of whether or not reimbursement for time, inconvenience, etc. will be given, including the schedule of payments.
12. An explanation of who to contact for answers about the research and in the event there is a research-related injury (This is generally the PI or another staff member closely associated with the study). A separate contact must be named for questions concerning the subject's rights.
13. A statement that the subjects' participation is voluntary, that refusal to participate will not involve penalty or loss of benefits to which the subject is entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is entitled.

## **Additional Elements of Informed Consent (45 CFR 46.116)**

1. A statement that the particular treatment and/or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;  
*This element should be included when the research involves an investigational drug or device or involves procedures for which the risk profile is not well known.*
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator with or without the subject's consent;  
*Include when there are known circumstances under which the subject's participation may be terminated by the investigator or sponsor.*
3. A description of any additional costs for which the subject will be responsible, that may result from participation in the research study;  
*Include when there are additional costs to subjects, over and above standard care, e.g., additional MRI's radiograph's, DEXA scans; additional visits that may not be covered by insurance/Medicare/Medicaid.*
4. A description of the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;  
*This element should be included when there is a likelihood that abrupt termination from the research would result in adverse events to the subject and alternative procedures/medications should be administered, e.g., study drug would need to be tapered and replaced with an approved drug so that the subject was not placed at increased risk of injury.*
5. A statement that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject;  
*Included when there is likelihood that interim findings might indicate increased risk, lack of efficacy, etc. and a reasonable person would wish to reconsider participation.*
6. The approximate number of subjects that will be involved in the study, totally and at UT Austin.  
*Include when such information might affect a subject's willingness to participate.*

## **Criteria for Consent Waiver Determinations**

### **Waiver of Documentation of Informed Consent (45 CFR 46.117(c))**

An IRB may waive the requirement to obtain a signed consent form provided either:

1. The research presents no more than minimal risk
2. Involves procedures that do not require written consent when performed outside of a research setting

### **OR**

1. The principal risks are those associated with a breach of confidentiality concerning the subject's participation in the research
2. The consent document is the only record linking the subject with the research
3. Each participant will be asked whether the participant wants documentation linking the participant with the research and the participant's wishes govern
4. The study is not FDA regulated

### **Waiver of Informed Consent (45 CFR 46.116(d))**

An IRB may waive informed consent provided:

1. The research presents no more than minimal risk to subjects
2. The waiver will not adversely affect the rights and welfare of subjects
3. The research could not practicably be carried out without the waiver
4. Whenever appropriate, the subjects will be provided with additional pertinent information after they have participated in the study
5. The study is not FDA regulated

## Studies Involving Children

### Definitions

**Minimal Risk Research** is research in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life (of normal subjects) or during the performance of routine physical or psychological examinations or tests.

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

**Consent/Permission** is the agreement of parent(s) or guardian to the participation of their child or ward in research.

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

**Ward** is a child who is placed in the legal custody of the state or other agency, institution or entity consistent with applicable Federal, State, or local law.

### Questions

1. Determine according to the definition of minimal risk shown above if the proposed research investigation minimal or more than minimal risk.
2. Does the proposed research activity hold the prospect of direct benefit to the individual subject?
3. If the study intends to include wards in the research, is the research related to their status as wards or conducted in schools, camps, hospitals, institutions or similar settings in which the majority of children involved as subjects are not wards?
4. Generally assent is required from all children who are enrolled in research activities, has the investigator considered the ages, majority and psychological state of the potential subjects to determine if obtaining assent is a reasonable expectation?
5. If a waiver to obtain assent is being requested is one of the following justifications given:
  - a. The children are not capable of providing assent base on age, maturity or psychological state.
  - b. The capability of the children is so limited that they cannot reasonably assent to the research.
  - c. The interventions or procedures involved in the research holds out a prospect of direct benefit that is important to the health and well-being of the children and is available only in the context of the research.
  - d. Assent is waived using criteria for waiver of informed consent. (45 CFR 46.116(d))
6. Is there a requirement for a written documentation of assent?

### Permissible Categories of Research

Research investigation not involving greater than minimal risk. (45 CFR 46.404) (21 CFR 50.51)

1. Does the research investigation involve no greater than minimal risk?
2. Are adequate provisions made for obtaining assent of the children?
3. The informed permission of the parent(s) or guardian(s) will be obtained?

Research investigation involving more than minimal risk, but presenting the prospect of direct benefit to the individual subjects. (45 CFR 46.405)(21 CFR 50.52)

1. Does the research involve greater than minimal risk?
2. Does the research present the prospect of direct benefit to the individual subject?
3. Are the risks justified by the anticipated benefits?
4. Is the relationship of the anticipated benefit at least as favorable as alternative approaches?
5. Are adequate provisions made for obtaining assent of the children?
6. Will the informed permission of the parent(s) or guardian(s) be obtained?

Research investigation involving more than minimal risk with no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. (45 CFR 46.406)(21 CFR 50.53)

1. The research involves more than minimal risks to subjects with no prospect of direct benefit to the individual but is likely to yield generalizable knowledge about the subject's disorder or condition?
2. Does the risk represent a minor increase over minimal risk?
3. Is the intervention or procedure present experience commensurate with those inherent in the subjects' actual or expected medical, dental or psychological, social or educational experience?
4. Are adequate provisions made for obtaining assent of the children?
5. Will the informed permission of the parent(s) or guardian(s) be obtained?

NOTE: In order to approve research investigation under this category all questions above must be "Yes".

Research investigation not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. (45 CFR 46.407)(21 CFR 50.54)

1. The IRB must find that the research presents a reasonable opportunity to further the understanding, prevention or alleviation of a serious problem affecting the health or welfare of children?
2. If the IRB makes this determination and the research will be federally funded, a request may be made by the PI through the IRB, to the secretary of Health and Human Services who, after convening a panel of experts and following opportunity for public comment, may approve the research.

## Studies Involving Pregnant Women

### Three Sets of Criteria

#### A. Non-HHS regulated minimal risk research involving pregnant women or fetuses

1. The research is not conducted, funded or otherwise subject to HHS regulations.
2. The research involves no more than minimal risk to pregnant women and fetuses.
3. The research meets one of the criteria for expedited review.

#### B. Non-HHS regulated that is more than minimal risk research.

1. Preliminary studies must be conducted and to provide data for assessing potential risks to pregnant women and fetuses.
2. Any risk is the least possible for achieving the objectives of the research.
3. The research holds the prospect of benefit to the pregnant woman or fetus.
4. Consent of the pregnant women will be obtained.
5. Each woman providing consent is fully informed regarding the reasonably foreseeable impact of the research on her and the fetus.
6. For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D or state law regarding consent by pregnant minors.
7. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
8. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

#### C. HHS regulated that is more than minimal risk research (45CFR 46.204)

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses.
2. One of the following must be true:
  - a. The risk to the fetus is caused by interventions or procedures that hold out the prospect of direct benefit for the woman or fetus.
  - b. If there is no such prospect of benefit to the fetus, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
3. Any risk is the least possible for achieving the objectives of the research.
4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, consent of the mother is obtained.
5. If the research holds out the prospect of direct benefit solely to the fetus, the consent of the pregnant woman and the father is obtained, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
6. Each individual providing consent is fully informed regarding the reasonably foreseeable impact of the research on the fetus.
7. For children who are pregnant, assent and permission are obtained in accord with the provisions of subpart D and state law.

Note: If the research is directly related to the pregnancy, consent/assent is only needed from the pregnant minor who is not married.
8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy.
9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy.

## Studies Involving Prisoners

### 45 CFR 46.305

A. Approval may be given only if the IRB finds that:

1. Any possible advantages accruing to the prisoner through his or her participation in the research, (when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison) that are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired.
2. The risks involved in the research commensurate with the risks that would be accepted by non-prisoner volunteers.
3. Procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners.  
Note: Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project.
4. The information is presented in language which is understandable to the subject population.
5. Assure that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole.
6. Each prisoner is clearly informed in advance that participation in the research will have not effect on his or her parole.
7. When the research requires follow-up beyond the period of incarceration, have provisions been made for locating the individual.
8. Participants informed of how follow-up will take place, if such is required.

B. Where the Board finds there may be a need for follow-up the following must be included:

1. Are there potential complications that may result form participation in the research.
2. Is the possible duration of such complications stated.
3. Types of examinations and care that would be typically be needed for such complications.
4. Adequate provisions for such examinations or care to subjects after their participation in the research has ended; taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

### 45 CFR 46.306

Behavioral research conducted or supported by DHHS may involve prisoners as subjects only if it involves:

1. Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
2. Study of prisons as institutional structures or of prisoners as incarcerated persons provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
3. Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study

may proceed only after the Secretary (DHHS) has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the FEDERAL REGISTER, of his or her intent to approve such research (Does the proposed treatment benefit at least as many individuals as the last available standard therapy and that number is greater than any other eligible treatment).

4. Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subjects. In cases in which those studies requires assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups that may not benefit from the research, the study may continue only after the Secretary (DHHS) has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the *Federal Register*, of his or her the intent to approve such research. (Does the proposed treatment benefit at least as many individuals as the last available standard therapy and that number is greater than other eligible treatment).
  
5. In accordance with the federal regulations, the IRB has the authority to waive the requirement that research activities fit in Categories 1-4 listed above if the proposed research meets the following specific criteria: 1) the research involves epidemiologic studies in which the sole purposes are (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease, and (2) the IRB has determined that items A and B have been appropriately addressed and has also determined that (i) the research presents no more than minimal risk and no more than inconvenience to the prisoner-subjects, and (ii) prisoners are not a particular focus of the research.

## **Expedited Review Eligible Categories for Research**

Research activities that present no more than minimal risk and involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.111 and 21 CFR 56.110.

1. Clinical studies of drugs and medical devices only when conditions above are met.
  - a. Research on drugs for which an investigational new drug (IND) 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.
  - b. 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 or 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:
  - a. From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - b. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
  
3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples include:
  - 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 sub-gingival 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 include:
  - a. Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy.
  - b. Weighing or testing sensory acuity.
  - c. Magnetic resonance imaging.
  - d. Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography.
  - e. Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects. 45 CFR 46.111 (b)(4). This listing refers only to research that is not exempt.
6. Collection of data from voice, video, digital, or image recordings made for research purposes.
7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. NOTE: Some research in this category may be exempt from HHS regulations for the protection of human subjects. 45 CFR 46.111 (b)(2) and (b)(3). This listing refers only to research that is not exempt.
8. Continuing review of research previously approved by the convened IRB as follows:
  - a. 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
  - b. Where no subjects have been enrolled and no additional risks have been identified; or
  - c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

## Clinicaltrials.gov

A “responsible party” must register “applicable clinical trials” defined as controlled, clinical investigations, other than Phase I investigations or feasibility studies, of a product subject to FDA regulation subject to sections 505 (drugs), 510(k), 515 or 520(m) (devices) or pediatric post-market surveillance as required under section 522 of the Federal Food, Drug and Cosmetic Act.

In accordance with a statement from the International Committee of Medical Journal Editors (ICMJE), the definition of a **clinical trial** is:

“Any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause-and-effect relationship between a medical intervention and a health outcome.” The definition includes drug, device, surgical, behavioral and process-of-care studies that modify a health outcome.

“**Responsible Party**” with respect to a clinical trial of a drug or device (FDA regulated studies) and other studies that modify a health outcome is defined as:

- (I) the **sponsor** (person or entity who initiates a clinical investigation, but who does not actually conduct the investigation) of the clinical trial; or
- (II) the **principal investigator** of a clinical trial if so designated by a sponsor, grantee, contractor or awardee, so long as the principal investigator is responsible for conducting the trial, has access to and control over the data from the clinical trial, has the right to publish the results of the trial and has the ability to meet all of the requirements under this subsection for the submission of clinical trial information.

Registration must be accomplished prior to enrollment of the first subject.

Consequences for Failure to comply:

1. **FDA Negative Consequence:** In some instances, criminal penalties can be administered. In addition, there are civil penalties for non-compliance (\$10,000) which compound daily (\$10,000/day) until the violation is corrected.
2. **ICMJE Negative Consequence:** Journal editors have stated that manuscripts reporting clinically related research that was not registered on clinicaltrials.gov will not be considered for publication.

## **DSMP in Clinical Studies Requirements**

All clinical studies submitted to the University IRB are required to have a DSMP. Most pharmaceutical/device manufacturer sponsored studies will have a DSMP and DSMB. For clinical studies that are not industry sponsored, investigators should assure that the following issues are addressed in the plan:

1. The type of data or events that are to be captured under the monitoring provisions.
2. The frequency of assessments of data or events captured by the monitoring provisions (e.g., at certain points in time or after enrollment of a certain number of subjects).
3. The entity or person(s) responsible for monitoring the data collected, including data related to unanticipated problems and adverse events and their respective roles in the research activities (i.e., PIs, research coordinators, statisticians, independent medical monitor, etc.).
4. Procedures for monitoring study progress including specifics of how monitoring the data and safety of subjects will occur.
5. Procedures for minimizing research-related risk.
6. Procedures for analysis and interpretation of the data.
7. The procedures and time frames for reporting adverse events and unanticipated problems to the monitoring entity.
8. The definition of specific triggers or stopping rules that will dictate when some action is required and what the range of possible actions will be.
9. Reporting mechanisms/procedures for the data monitor and others who will communicate the outcome of the reviews of the monitoring entity with the IRBs, the study sponsor (if applicable), the PIs and other appropriate officials.
10. How data accuracy and protocol compliance will be assured.

The IRB will review all DSMPs regardless of research sponsorship. Reports of significant safety issues received by the IRB will be brought to a convened meeting and discussed in detail. The IRB will determine if a study with significant safety concerns should be allowed to continue at the University.

## **Federally Funded Research Requirements**

### **Department of Defense (DoD)**

1. The DoD requires scientific review prior to IRB review so the study must be reviewed by a DRC.
2. If the research is greater than minimal risk the PI must identify a DoD required “Research Monitor” with the authority to:
  - a. Stop research in progress.
  - b. Remove individuals from the study.
  - c. Take any steps necessary to protect the safety and well-being of the subjects until the IRB can assess the monitor’s report.
3. If the research is to be done internationally the study must comply with the IRB Policies and Procedures for Transnational Research.
4. If the researcher is requesting an approved waiver of consent then the protocol must have an approved waiver from the Secretary of Defense.
5. The DoD Component will identify additional requirements if the study list multi-site or collaborating institutions.
6. If the research is not minimal risk then the protocol must comply with the DoD Component’s requirements for “Provisions for Research Related Injury.”
7. If the research includes military personnel as participants then the protocol must incorporate additional safeguards to minimize undue influence from individuals within potential participant’s chain of command.
8. Research involving Prisoners of War is prohibited.
9. The researcher will likely be required to submit copies of approval letters, surveys, and other additional documentation to the DoD Component.

### **Department of Education (ED)**

1. If the research proposing to request a waiver from the requirement to obtain written permission from parents and/or students to disclose personally identifiable information from student’s education records it must meet one of the following requirements:
  - a. Develop, validate, or administer predictive test;
  - b. Administer student aid programs; or
  - c. Improve instruction.
2. If the research meets all of the requirements in number 1 above an agreement with the school district or post-secondary institution and the University or PI must specify the following:
  - a. The determination of the exception.
  - b. The purpose, scope, and duration of the study.
  - c. The information to be disclosed.
  - d. 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.
  - e. 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 University with legitimate interests.

- f. That the University is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
  - g. The time period during which the University must either destroy or return the information.
  - h. 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.
3. If the proposed research and research methodology must satisfy all of these requirements:
- a. Student is not required, as part of any research project, to submit without *prior consent* (means consent of adult or emancipated students or permission of parents for students who are minors) 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.
    - Religious practices, affiliations, or beliefs of the student or student's parent.
  - b. Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.
  - c. In addition, all instructional material - including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.
4. If the PI is requiring a waiver of the requirement to obtain permission for a parent or legal guardian the research must meet the following requirements:
- a. The research meets the provisions for waiver in Section 6.6 of the IRB Policies and Procedures Manual [45 CFR 46.116(d)(1-4)] and if the IRB determines that the research protocol is designed for conditions 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).
  - b. An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism would depend upon the nature and purpose of the

activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

5. For research with students that is not funded by the ED, the IRB must verify compliance with ED regulations regarding the following:
  - a. The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
  - b. Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the same eight items of information noted above.
  - c. The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students.
  - d. The administration of physical examinations or screenings that the school may administer to students.

### **Department of Energy (DoE)**

The following items must be addressed in all protocols:

1. Keeping PII confidential.
2. Releasing of PII, where required, only under a procedure approved by the IRB and DoE.
3. Using PII only for purposes of the DoE approved research.
4. Handling and marking documents containing PII as “containing PII” or “containing 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 and DoE, where applicable, and then only:
  - a. In an emergency affecting the health and 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.
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 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 via express overnight service.
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, 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.
14. In addition to other reporting requirements, reporting the loss or suspected loss of PII immediately upon discovery to:
  - a. DoE Project Officer
  - b. IRB

15. Classified projects that use PII must also comply with all the requirements for conducting classified research.

### **Department of Justice (DoJ)**

1. For DoJ funded research, has the investigator complied with or provided assurance that they will comply with all of the following:
  - a. Obtain a privacy certificate approved by the NIH Human Subjects Protection Officer.
  - b. Include a statement in the informed consent document under the section dealing with confidentiality that confidentiality can only be broken if the subject reports the probability of immediate harm to self or others.
  - c. Submit a copy of the IRB approval, as well as supporting documentation of the IRB's institutional affiliation, assurances, etc., to the NIH prior to initiation of any research activities that are not exempt from the requirements of 28 CFR 46.
  - d. Submit supporting documentation of the IRB's approval of the research meeting the criteria for exemption under 28 CFR 46.101(b).
  - e. Sign and maintain an Employee Confidentiality Statement for themselves and their research staff.
  - f. Send a copy of all de-identified data, including copies of the informed consent document, data collection instruments, surveys, and other relevant research materials to the National Archive of Criminal Justice Data.
2. For research conducted within the Bureau of Prisons, has the investigator complied with or provided assurance that they will comply with all of the following:
  - a. Obtain review of the research proposal by the Bureau of Research Review Board (BRRB).
  - b. Sign an agreement to adhere to the provisions of the Bureau of Prisons under 28 CFR 512.
  - c. To respect the rights, health, and human dignity of individuals involved in the research.
  - d. Adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this act.
  - e. Provide a research project design that:
    - i. Contributes to the advancement of knowledge about corrections.
    - ii. Is compatible with both the operation of the prison facilities and protection of human subjects.
    - iii. Does not involve medical experimentation, cosmetic research, or pharmaceutical testing.
  - f. Observe the rules of the institution in which the research is being conducted.
  - g. Provide documentation that:
    - i. The risks to participants are minimized and risks are reasonable in relation to the anticipated benefits.
    - ii. Selection of participants within any one organization is equitable.
    - iii. Incentives may not be offered to help persuade inmates to participate unless snacks or soft drinks are consumed at the test setting.
    - iv. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
      - No longer in the Bureau of Prisons custody.
      - Participating in authorized research being conducted by Bureau of Prisons employees or contractors.
    - v. They have experience in the area of the study of the proposed research.
    - vi. They have reviewed related literature.
    - vii. Research records will be destroyed or individual identifiers will be removed from the records after the research is completed.
  - h. Assume responsibility as the investigator for actions of any research staff engaged to participate in the project.
  - i. Provide documentation for maintaining confidentiality of data preliminary to the research, during and after the conclusion of the research by assuring:
  - j. Records are not in an individually identifiable form.
  - k. Advance written assurance has been provided to the Bureau of Prisons that the records will be used solely for statistical research or reporting.

- l. Agree not to provide research information that identifies a subject to any person (i.e., cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceedings) without the subject's prior written consent to release the information.
  - m. Agree not to maintain records electronically that contain non-disclosable information directly traceable to a specific person at the institution.
  - n. Negotiate arrangements, prior to the beginning of the data collection of the project, to provide non-identifiable computerized data on individual subjects along with documentation to the Office of Research and Evaluation if requested.
  - o. Obtain informed consent of subjects prior to initiating the research activity.
  - p. Submit planned methodological changes in the research to the IRB for review and approval prior to initiation and revise study procedures in accordance with the new methodology, if required.
  - q. Provide, at least yearly, a report on the progress of the research and at least one report of findings to the Chief, Office of Research and Evaluation.
  - r. Acknowledge the Bureau of Prisons participation in any publication of the results.
  - s. Include a disclaimer in the results for publication that the approval or endorsement of the published material is an expression of the policies and view of the Bureau of Prisons.
  - t. Provide, at least 12 working days before any report of findings to be released, one (1) copy of the report, which shall include an abstract of the findings, to each of the following:
    - i. Chairperson of the BRRB.
    - ii. The Regional Bureau of Prisons Director.
    - iii. The Warden of each institution which provided data or assistance.
  - u. Submit two (2) copies of the results of the research project for informational purposes only to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons prior to submission of publication.
3. The research proposal has a summary statement that includes:
    - a. Name(s) and current affiliation(s) of the researcher.
    - b. Title of the study.
    - c. Purpose of the study.
    - d. Location of the study.
    - e. Methods to be employed.
    - f. Anticipated results.
    - g. Duration of the study.
    - h. Number of subjects (staff/inmates) required and the amount of time required from each.
    - i. Indication of risk or discomfort involved as a result of participation.
  4. The research proposal has a comprehensive statement which includes:
    - a. Review of related literature.
    - b. Detailed description of the research method.
    - c. Significance of anticipated results and their contribution to the advancement of knowledge.
    - d. Specific resources required from the Bureau.
    - e. Description of all possible risks, discomforts, and benefits to individual subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    - f. Description of steps taken to minimize any risks.
    - g. Description of physical and/or administrative procedures to be followed to:
      - i. Ensure the security of any individually identifiable data that are being collected for the project.
      - ii. Destroy research records or remove individual identifiers from those records when the research has been completed.
    - h. Description of any anticipated effects of the research projects on institutional programs and operations.
    - i. Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.
    - j. A statement regarding assurances and certification required by 28 CFR part 46, if applicable.
  5. The submitted consent form contains all of the following:
    - a. Identification of the principal investigator.
    - b. Objectives of the research project.

- c. Procedures to be followed in the conduct of research.
- d. Purpose of each procedure.
- e. Anticipated uses of the results of the research.
- f. A statement of benefits reasonably to be expected.
- g. A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk.
- h. 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).
- i. 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 subject indicates intent to commit future criminal conduct or harm themselves or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization. Under the privacy certificate investigators and research staff do not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.
- j. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
- k. An offer to answer questions about the research project.
- i. Appropriate additional information as needed to describe adequately the nature and risks of the research.

### **Environmental Protection Agency (EPA)**

1. The EPA does not conduct or support research involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or a child. Other adults who voluntarily choose to participate are protected under the EPA's rule, "Protections for Subjects in Human Research", which requires proposed protocols describing intentional exposures be reviewed by EPA and its Human Studies Review Board.
2. Observational research involving pregnant women or fetuses is allowable if the IRB determines that all conditions are met under Section 11 of the IRB Policies and Procedures Manual.
3. Observational research not involving greater than minimal risk is allowable 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. (See Section 11 of the IRB Policies and Procedures Manual)
4. Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects is allowable only if the IRB finds that (See Section 11 of the IRB Policies and Procedures Manual):
  - a. The intervention or procedure holds out the prospect of direct benefit to the individual subject or is likely to contribute to the subject's well-being;
  - b. The risk is justified by the anticipated benefit to the subjects;
  - c. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
  - d. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.