SOP: 603G
Other Federal Agencies

1. POLICY

Several of the federal agencies that have adopted the Common Rule have policies and regulations that differ from the Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) Department of Health and Human Services (DHHS) requirements. The agency-specific requirements must be met when reviewing, approving and conducting human research projects supported or funded by these specific federal agencies.

SPECIFIC POLICIES

A. Department of Defense (DoD) (see SOP 603F: Department of Defense)

B. Department of Education (ED)

1. For human participant research funded by the **National Institute on Disability and Rehabilitation Research**,that purposefully require inclusion of children with disabilities or individuals with mental disabilities as research participants, the board reviewing the project shall include at least one member who is primarily concerned with the welfare of these research participants.

2. The **Family Educational Rights and Privacy Act (FERPA)** applies when researchers obtain student records or personally identifiable education information from an education program (defined as any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education and adult education).

    a) Under FERPA, an educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is part of an agreement between organizations or researchers conducting studies for, or on behalf of, educational agencies or institutions to:

        1) Develop, validate, or administer predictive tests.

        2) Administer student aid programs.

        3) Improve instruction.

    b) A school district or postsecondary institution that uses an exception for this disclosure is required to enter into a written agreement with the University that specifies:

        1) The determination of the exception for this disclosure.

2) The purpose, scope, and duration of the study.

3) The information to be disclosed.

4) That information from education records may be used only to meet the purposes of the study stated in the written agreement and must contain the current requirements in ED regulations on re-disclosure and destruction of information.

5) 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.

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

7) The time period during which the University must either destroy or return the information.

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

1) Student's name and other direct personal identifiers, such as the student's social security number or student number.

2) 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; and date and place of birth and mother's maiden name.

3) 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.

4) 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. For certain types of research directly funded by ED, the **Protection of Pupil Rights Amendment (PPRA)** applies.

a) PPRA prohibits students from being required, as part of a 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:

1) Political affiliations or beliefs of the student or the student's parent.

2) Mental or psychological problems of the student or the student's family.

3) Sex behavior or attitudes,

4) Illegal, anti-social, self-incriminating, or demeaning behavior.

5) Critical appraisals of other individuals with whom respondents have close family relationships.

6) Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.

7) Religious practices, affiliations, or beliefs of the student or student's parent.

8) Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program.

**Prior consent: (1) prior consent of the student if the student is an adult or emancipated minor or (2) prior written consent of the parent or guardian, if the student is not an emancipated minor.*

b) For certain types of research **not directly funded by ED** and conducted in a school that receives funding from ED: policies and procedures shall include a process to verify compliance with ED regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

1) 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.

2) 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.

3) Arrangements to protect student privacy that are provided by ED 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):

    i. Political affiliations or beliefs of the student or the student's parent.

ii. Mental or psychological problems of the student or the student's family.

iii. Sex behavior or attitudes.

iv. Illegal, anti-social, self-incriminating, or demeaning behavior.

v. Critical appraisals of other individuals with whom respondents have close family relationships.

vi. Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers.

vii. Religious practices, affiliations, or beliefs of the student or the student's parent.

viii. Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

ix. 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.

x. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.

xi. The administration of physical examinations or screenings that the school or agency may administer to a student.

xii. 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.

xiii. 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.

xiv. 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.

C. Department of Energy (DOE)

1. For research funded or supported by the DOE:

a) Research involving human participants includes studies of the intentional modification of the human environment.

b) When considering if a DOE project meets the definition of research, generalizable should be viewed in terms of the contribution to knowledge within the specific field of study. The term 'generalizable' includes:

1) The study of tracer chemical, particles, or other materials to characterize airflow.

2) Studies in occupied homes or offices that manipulate the environment to achieve research aims.

3) Test new materials

4) 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. Investigators must promptly (within 30 days) report the following to the DOE Human Subject Research Program Manager:

a) Any significant adverse events, unanticipated risks; and complaints about the research with a description of any corrective actions taken or to be taken.

b) Any suspension or termination of IRB approval of research.

c) Any significant non-compliance with HRPP procedures or other requirements.

d) Any compromise of personally identifiable information must be reported immediately, but in no case beyond 24 hours.

D. Department of Justice (DOJ)

1. Bureau of Prisons: For research conducted within the Bureau of Prisons, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

a) General Requirements

1) The project must have an adequate research design and contribute to the advancement of knowledge about corrections.

2) The University, IRB, Investigators, and Research Staff shall apply the requirements of 28 CFR 512, including:

i. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.

ii. The research design must be compatible with both the operation of prison facilities and protection of human participants.

iii. The Investigator must observe the rules of the institution or office in which the research is conducted.

iv. Any Investigator who is a non-employee of the Bureau must sign a statement in which the Investigator agrees to adhere to the requirements of 28 CFR 512.

v. All research proposals must be reviewed by the Bureau Research Review Board.

b) Confidentiality of Data

1) 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.

2) Except as noted in the consent statement to the participant, the Investigator 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.

3) Except for computerized data records maintained at an official DOJ 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.

4) If the Investigator 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 Investigator 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.

The following elements must be disclosed by the Investigator to the participants:

i. Identification of the researchers.

ii. Anticipated uses of the results of the research.

iii. 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).

iv. A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, an Investigator 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.

v. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.

c) Participant Selection:

1) The selection of participants within any one institution must be equitable.

2) Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.

3) Reasonable accommodations such as nominal monetary compensation for time and effort may be offered to non-confined research participants who are both:

i. No longer in Bureau of Prisons custody.

ii. Participating in authorized research being conducted by Bureau employees or contractors.

d) Additional Investigator Requirements:

1) At least once a year, the Investigator must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.

2) At least 12 working days before any report of findings is to be released, the Investigator must 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 Investigator must include an abstract in the report of findings.

3) In any publication of results, the Investigator must acknowledge the Bureau's participation in the research project.

4) The Investigator must 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 Investigator must provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

6) The Investigator must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the Investigator.

2. For National Institute of Justice (NIJ)-funded research:

a) All projects are required to have a privacy certificate approved by the NIJ human subjects protection officer.

b) All Investigators and Research Staff are required to sign employee confidentiality statements available from NIJ, which are maintained by the responsible Investigator.

c) The consent form for NIJ-funded research shall include:

1) The name(s) of the funding agency(ies).

2) A statement describing the extent to which confidentiality of records identifying the subject will be maintained. For studies sponsored by NIJ the research participant should be informed that private, identifiable information will be kept confidential and will be used only for research and statistical purposes. If, due to sample size or some unique feature, the identity of the individual cannot be maintained in confidence, the research participant needs to be explicitly notified.

3) If the Investigator intends to disclose any information, the research participant needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The participant must be informed of any risks that might result from this disclosure and must explicitly provide written consent prior to participating in the research.

4) Under an NIJ privacy certificate, researchers and staff are not required to report child abuse unless the participant signs another consent document to allow child abuse reporting. However, because Oklahoma state law does require reporting of actual or suspected child abuse, only those individuals who agree in advance to allow for such reporting and sign a separate consent document available from the IRB that acknowledges such reporting may occur may be enrolled in OU research funded by NIJ and subject to an NIJ privacy certificate."

5) The Investigator shall ensure that a copy of all data is 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.

E. Environmental Protection Agency (EPA)

1) For human participant research conducted or supported by the EPA:

   a) EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.

   b) For observational research (i.e., research that does not involve intentional exposure to a substance), EPA requires application of 40 CFR 26 Subparts B, C and D to provide additional protections to pregnant women, fetuses, and children.

   c) EPA requires submission of IRB determinations and approval to the EPA human participant research review official for final review and approval before the research can begin.

2) For human participant 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:

   a) EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to substances.

3) Research involving children: The IRB may review and 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:

   a) The intervention or procedure holds out the prospect of direct benefit to the individual research participants or is likely to contribute to the research participant's well-being.

   b) The risk is justified by the anticipated benefit to the research participants.

   c) The relation of the anticipated benefit to the risk is at least as favorable to the research participants as that presented by available alternative approaches.

   d) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406.

   e) Adequate provisions must be made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 40 CFR 26.406.

2. SCOPE

These policies and procedures apply to all research involving human participants conducted or supported by the following federal agencies: Department of Energy (DOE), Department of Justice (DOJ), Environmental Protection Agency (EPA), and Department of Education (ED).

3. RESPONSIBILITY

The Investigator is responsible for assisting the IRB with identifying applicable agency requirements and submitting relevant documentation to the IRB, implementing the research consistent with the agency requirements, and for complying with the specific agency human participant protection regulations. See the agency-specific responsibilities listed in Section 1.

The IRB, IRB Chair/Designee, and HRPP Director and staff are responsible for applying applicable agency requirements to the IRB review and approval process.

4. APPLICABLE REGULATIONS AND GUIDELINES

40 CFR 26.304
40 CFR 26.404 - 405
34 CFR 98, 99
34 CFR 350, 356
10 CFR 745
DOE O 443.1.B.
28 CFR 22
28 CFR 512

5. REFERENCES TO OTHER APPLICABLE SOPS

SOP 603F: Department of Defense
SOP 202: Management of IRB

6. ATTACHMENTS

203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist
301-A Study Application

7. PROCESS OVERVIEW

A. The Investigator reviews the requirements of the applicable agency to verify the agency specific requirements. At the time of submission to the IRB, the Investigator shall identify on the IRB application that the research involves one of the following agencies: DOE, DOJ, EPA, or ED and uploads supporting documents to comply with the specific requirements.

B. HRPP staff conducts a pre-review, identifies the agency-specific requirements, and forwards this information to the IRB Chair/Reviewer.

C. The IRB Chair/Reviewer reviews the research project as it applies to the following:

1. Department of Education (ED) - (34 CFR 97 Subpart A and D, 34 CFR 98, 99, and 34 CFR 350, 356)

2. Department of Energy (DOE) – (10 CFR 745.103, DOE O 443.1.B, DOE Memo dated April 25, 2013, Checklist for IRBs to Use in Verifying that HS Research Protocol Are In Compliance with DOE Requirements).

3. Department of Justice (DOJ) Bureau of Prisons – (28 CFR 46, 28 CFR 512), National Institute of Justice (28 CFR 22)

4. Environmental Protection Agency (EPA) – (40 CFR 26)

D. The IRB documented findings as required by the applicable federal agency and communicates them to the Investigator.

E. The Investigator submits reports and documentation to the federal agency as required.

APPROVED BY:_____ **DATE: 09/09/2016**

NEXT ESTABLISHED REVIEW DATE: AUGUST 2018