



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Working with Other Agencies

Working with Other Agencies

Effective Date: June 10, 2010
Original Approval Date: June 10, 2010
Revised Date: July 1, 2011
July 15, 2014
March 1, 2015
July 1, 2015

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1.0 Purpose

The purpose of this document is to provide guidance to UMC researchers whose human subject's research is sponsored or supported by the Federal Agencies contained within this policy.

2.0 Scope

The SOP applies to all human subject research falling under the purview of the University of Missouri Institutional Review Board and involving other Federal Agencies.

3.0 Policy/Procedure

A. Department of Justice: Doing Research within the Correctional Setting- Federal Bureau of Prisons

28 CFR 22

§ 22.23 Privacy Certification

(a) Each applicant for BJA, OJJDP, BJS, NIJ, or OJP support either directly or under a State plan shall submit a Privacy Certificate as a condition of approval of a grant application or contract proposal which has a research or statistical project component under which information identifiable to a private person will be collected.

Sec. 22.28 Use of data identifiable to a private person for judicial, legislative or administrative purposes.

(a) Research or statistical information identifiable to a private person shall be immune from legal process and shall only be admitted as evidence or used for any purpose in any action, suit, or other judicial, legislative or administrative proceeding with the written consent of the individual to whom the data pertains.

(b) Where consent is obtained, such consent shall:

- (1) Be obtained at the time that information is sought for use in judicial, legislative or administrative proceedings;
- (2) Set out specific purposes in connection with which information will be used;
- (3) Limit, where appropriate, the scope of the information subject to such consent.

(b) The Privacy Certificate shall briefly describe the project and shall contain assurance by the applicant that:

- (1) Data identifiable to a private person will not be used or revealed, except as authorized under §§ 22.21, 22.22.
- (2) Access to data will be limited to those employees having a need therefore and that such persons shall be advised of and agree in writing to comply with these regulations.
- (3) All subcontracts which require access to identifiable data will contain conditions meeting the requirements of § 22.24.

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- (4) To the extent required by § 22.27 any private persons from whom identifiable data are collected or obtained, either orally or by means of written questionnaire, shall be advised that the data will only be used or revealed for research or statistical purposes and that compliance with requests for information is not mandatory. Where the notification requirement is to be waived, pursuant to § 22.27(c), a justification must be included in the Privacy Certificate.
- (5) Adequate precautions will be taken to insure administrative and physical security of identifiable data.
- (6) A log will be maintained indicating that identifiable data have been transmitted to persons other than BJA, OJJDP, BJS, NIJ, or OJP or grantee/contractor staff or subcontractors, that such data have been returned, or that alternative arrangements have been agreed upon for future maintenance of such data.
- (7) Project plans will be designed to preserve anonymity of private persons to whom information relates, including, where appropriate, name-stripping, coding of data, or other similar procedures.
- (8) Project findings and reports prepared for dissemination will not contain information which can reasonably be expected to be identifiable to a private person except as authorized under § 22.22.

(c) The applicant shall attach to the Privacy Certification a description of physical and/or administrative procedures to be followed to insure the security of the data to meet the requirements of § 22.25.

For research data collected or funded by BJA, OJJDP, BJS, NIJ, OJP researchers are prohibited from disclosing identifiable data, except information regarding future criminal conduct.

28 CFR Part 500.1(c)

Inmate means all persons in the custody of the Federal Bureau of Prisons or Bureau contract facilities, including persons charged with or convicted of offenses against the United States; D.C. Code felony offenders; and persons held as witnesses, detainees, or otherwise.

28 CFR 512: BOP

Form: BP-S606.010 Informed Consent/Consent to Release Information for Research. The language used should be clearly written and easy to read with a ninth grade or lower vocabulary level.

512.10 For the purpose of this subpart, implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

512.11

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a) Except as provided for in paragraph (b) of this section, the Bureau requires the following:

- (1) In all research projects the rights, health, and human dignity of individuals involved must be respected.
- (2) The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- (3) The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
- (4) The project must minimize risk to subjects; risks to subjects must be reasonable in relation to anticipated benefits. The selection of subjects within any one institution must be equitable. When applicable, informed consent must be sought and documented (see §§512.15 and 512.16).
- (5) Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
 - (i) No longer in Bureau of Prisons custody, and
 - (ii) Participating in authorized research being conducted by Bureau employees or contractors.
- (6) The researcher must have academic preparation or experience in the area of study of the proposed research.
- (7) The researcher must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the researcher.
- (8) Except as noted in the informed consent statement to the subject, the researcher must not provide research information which identifies a subject to any person without that subject'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 pertains.
- (9) The researcher must adhere to applicable provisions of the Privacy Act of 1974 and regulations pursuant to this Act.

(10) 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.

(11) 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 this subpart.

(12) Except for computerized data records maintained at an official Department of Justice site, records which contain non-disclosable information directly traceable to a specific person may not be stored in, or introduced into, an electronic retrieval system.

(13) 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 subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

(14) The researcher must submit planned methodological changes in a research project to the IRB for approval, and may be required to revise study procedures in accordance with the new methodology.

(b) Requests from Federal agencies, the Congress, the Federal judiciary, or State or local governments to collect information about areas for which they are responsible and requests by private organizations for organizational rather than personal information from Bureau staff shall be reviewed by ORE to determine which provisions of this subpart may be waived without jeopardizing the safety of human subjects. ORE shall document in writing the waiver of any specific provision along with the justification.

512.12 Content of research proposal.

When submitting a research proposal, the applicant shall provide the following information:

- (a) A summary statement which includes:
- (1) Name(s) and current affiliation(s) of the researcher(s);
 - (2) Title of the study;
 - (3) Purpose of the project;
 - (4) Location of the project;
 - (5) Methods to be employed;
 - (6) Anticipated results;
 - (7) Duration of the study;
 - (8) Number of subjects (staff/inmates) required and amount of time required from each; and
 - (9) Indication of risk or discomfort involved as a result of participation.

- (b) A comprehensive statement which includes:
- (1) Review of related literature;
 - (2) Detailed description of the research method;
 - (3) Significance of anticipated results and their contribution to the advancement of knowledge;
 - (4) Specific resources required from the Bureau;
 - (5) 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;
 - (6) Description of steps taken to minimize any risks described in (b)(5) of this section.
 - (7) 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, and
 - (ii) Destroy research records or remove individual identifiers from those records when the research has been completed.
 - (8) Description of any anticipated effects of the research project on institutional programs and operations; and
 - (9) Relevant research materials such as vitae, endorsements, sample informed consent statements, questionnaires, and interview schedules.
- (c) A statement regarding assurances and certification required by 28 CFR part 46, if applicable.

§ 512.13 Institutional Review Board.

- (a) The Bureau of Prisons' central institutional review board shall be called the Bureau Research Review Board (BRRB). It shall consist of the Chief, ORE, at least four other members, and one alternate, appointed by the Director, and shall meet a sufficient number of times to insure that each project covered by 28 CFR part 46 receives an annual review. A majority of members shall not be Bureau employees. The BRRB shall include an individual with legal expertise and a representative for inmates whom the Director determines is able to identify with inmate concerns and evaluate objectively a research proposal's impact on, and relevance to, inmates and to the correctional process.
- (b) The Chief, ORE, shall serve as chairperson of the BRRB. If a potential conflict of interest exists for the BRRB chairperson on a particular research proposal, the Assistant Director, Information, Policy, and Public Affairs Division, shall appoint another individual to serve as chairperson on matters pertaining to that project.

§ 512.14 Submission and processing of proposal.

- (a) An applicant may submit a preliminary research proposal for review by the Office of Research and Evaluation, Federal Bureau of Prisons, 320 First Street, NW,

Washington, DC 20534. Staff response to the preliminary proposal does not constitute a final decision.

- (b) If the study is to be conducted at only one institution, the applicant shall submit a formal proposal to the warden of that institution. Proposal processing will be as follows:
- (1) The warden shall appoint a local research review board to consult with operational staff, to evaluate the proposal for compliance with research policy, and to make recommendations to the warden. The local research review board is encouraged, but not required; to meet the membership requirements of an IRB, as specified in 28 CFR part 46.
 - (2) The warden shall review the comments of the board, make a recommendation regarding the proposal, and forward the proposal package to the Regional Director, with a copy to the Chief, ORE.
 - (3) The Regional Director shall review the proposal and forward recommendations to the Chief, ORE.
- (c) If the study is to be conducted at more than one institution or at any other Bureau location, the applicant shall submit the research proposal to the Chief, Office of Research and Evaluation, Federal Bureau of Prisons, 320 First Street, NW., Washington, DC 20534. The Chief, ORE, shall determine an appropriate review process.
- (d) All formal proposals will be reviewed by the BRRB.
- (e) The BRRB chairperson may exercise the authority of the full BRRB under an expedited review process when another official IRB (either within or outside the Bureau) has approved the research, or when, in his/her judgment, the research proposal meets the minimal risk standard and involves only the following:
- (1) The study of existing data, documents, or records; and/or
 - (2) The study of individual or group behavior or characteristics of individuals, where the investigator does not manipulate subjects' behavior and the research will not involve stress to subjects. Such research would include test development and studies of perception, cognition, or game theory. If a proposal is processed under expedited review, the BRRB chairperson must document in writing the reason for that determination.
- 46.110 on expedited reviews is similar except that the BOP will give a full board review to a number of categories on HHS's expedited list and BOP does NOT exempt any proposals (512.14(e))

Eligible for Expedited Review

Data collected through noninvasive means (routinely practiced in clinical settings)
Materials that are collected or will be collected for non-research purposes
Individual or group behavior surveys, interviews, and oral histories.
Collection of blood samples (routine methods).
Non-invasive collection of biological specimens

***BOP accepts some proposals as expedited reviews for example archival data.
BOP does not Exempt any proposal.**

(f) The Chief, ORE, shall review all recommendations made and shall submit them in writing to the Director, Bureau of Prisons.

(g) The Director, Bureau of Prisons, has final authority to approve or disapprove all research proposals. The Director may delegate this authority to the Assistant Director, Information, Policy, and Public Affairs Division.

(h) The approving authority shall notify in writing the involved region(s), institution(s), and the prospective researcher of the final decision on a research proposal.

512.15 (c) 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 (5 U.S.C. 552a(b)(5)).

§ 512.16 Informed consent

(a) Before commencing a research project requiring participation by staff or inmates, the researcher shall give each participant a written informed consent statement containing the following information:

- (1) Identification of the principal investigator(s);
- (2) Objectives of the research project;
- (3) Procedures to be followed in the conduct of research;
- (4) Purpose of each procedure;
- (5) Anticipated uses of the results of the research;
- (6) A statement of benefits reasonably to be expected;

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- (7) A declaration concerning discomfort and risk, including a description of anticipated discomfort and risk;
 - (8) 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);
 - (9) 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 himself/herself or someone else, or, if the subject is an inmate, indicates an intent to leave the facility without authorization.
 - (10) A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility;
 - (11) An offer to answer questions about the research project; and
 - (12) Appropriate additional information as needed to describe adequately the nature and risks of the research.
- (b) A researcher who is an employee of the Bureau shall include in the informed consent statement a declaration of the authority under which the research is conducted.
- (c) A researcher who is an employee of the Bureau, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent, when:
- (1) The subject's activity requires something other than response to a questionnaire or interview; or
 - (2) The Chief, ORE, determines the research project or data-collection instrument is of a sensitive nature.
- (d) A researcher who is a non-employee of the Bureau, in addition to presenting the statement of informed consent to the subject, shall also obtain the subject's signature on the statement of informed consent prior to initiating the research activity. The researcher may not be required to obtain the signature if the researcher can demonstrate that the only link to the subject's identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed. The signed statement shall be submitted to the chairperson of the appropriate local research review board.

For research funded by the National Institute of Justice (NIJ):

- 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 do not have to report child abuse unless the participant signs another consent form to allow child abuse reporting.
- All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.

§ 512.19 Reports.

The researcher shall prepare reports of progress on the research and at least one report of findings.

(a) At least once a year, the researcher shall provide the Chief, ORE, with a report on the progress of the research.

(b) At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the BRRB, the regional director, and the warden of each institution which provided data or assistance. The researcher shall include an abstract in the report of findings.

§ 512.20 Publication of results of research project.

(a) A researcher may publish in book form and professional journals the results of any research project conducted under this subpart.

(1) In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.

(2) The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

(b) Prior to submitting for publication the results of a research project conducted under this subpart, the researcher shall provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.

How to Apply to Conduct Research at the BOP

- (1) Refer to website: <http://www.bop.gov>

- (2) On the top of screen click on Resources
- (3) In left box click on Research and Reports
- (4) Right screen: go to “Apply to Conduct Research”
- (5) The Bureau accepts for review well-designed research proposals*. If you are interested in submitting a proposal:
- (6) Read the Belmont Report.
- (7) Read the BOP Program Statement on Research.
- (8) Familiarize yourself with Department of Justice regulations for protecting human subjects (28 CFR 46).
- (9) Complete a Researcher Statement (one for each researcher listed in the proposal).
- (10) Prepare a research proposal as described in the Program Statement (see additional instructions regarding informed consent).
- (11) Submit the complete proposal and Researcher Statement(s) to the appropriate BOP office (for more information, see the process described in the Program Statement or contact the IRB Coordinator).

B. Environmental Protection Agency

Adds three subparts (Subparts B-D) that incorporate prohibitions and additional protections for pregnant women, nursing women, and children in research conducted or supported by EPA

§ 26.101 To what does this policy apply?

(a) Except as provided in paragraph (b) of this section, this policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any Federal department or agency which takes appropriate administrative action to make the policy applicable to such research. This includes research conducted by Federal civilian employees or military personnel, except that each department or agency head may adopt such procedural modifications as may be appropriate from an administrative standpoint. It also includes research conducted, supported, or otherwise subject to regulation by the Federal Government outside the United States.

(1) Research that is conducted or supported by a Federal department or agency, whether or not it is regulated as defined in §26.102(e), must comply with all sections of this policy.

(2) Research that is neither conducted nor supported by a Federal department or agency but is subject to regulation as defined in §26.102(e) must be reviewed and approved, in compliance with §26.101, §26.102, and §26.107 through §26.117 of this policy, by an institutional review board (IRB) that operates in accordance with the pertinent requirements of this policy.

26.203 Prohibition of research conducted or supported by EPA involving intentional exposure of any human subject who is a pregnant woman (and therefore her fetus), a nursing woman, or child.

Notwithstanding any other provision of this part, under no circumstances shall EPA 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.

- The IRB will not approve research intended for submission to the EPA, research involving intentional exposure of pregnant women or children to any substance.

Subpart C—Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

Source: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.301 To what does this subpart apply?

(a) Except as provided in paragraph (b) of this section, this subpart applies to all observational research involving human subjects who are pregnant women (and therefore their fetuses) conducted or supported by the Environmental Protection Agency (EPA). This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) The exemptions at §26.101(b)(1) through (b)(6) are applicable to this subpart.

(c) The provisions of §26.101(c) through (i) are applicable to this subpart. References to State or local laws in this subpart and in §26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments.

(d) The requirements of this subpart are in addition to those imposed under the other subparts of this part.

§ 26.302 Definitions.

The definitions in §§26.102 and 26.202 shall be applicable to this subpart as well. In addition, *observational research* means any human research that does not meet the definition of *research involving intentional exposure of a human subject* in §26.202(a).

§ 26.303 Duties of IRBs in connection with observational research involving pregnant women and fetuses.

The provisions of 45 CFR 46.203 are applicable to this section.

§ 26.304 Additional protections for pregnant women and fetuses involved in observational research.

The provisions of 45 CFR 46.204 are applicable to this section.

§ 26.305 Protections applicable, after delivery, to the placenta, the dead fetus, or fetal material.

The provisions of 45 CFR 46.206 are applicable to this section

Subpart D—Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

Source: 71 FR 6168, Feb. 6, 2006, unless otherwise noted.

§ 26.401 To what does this subpart apply?

(a) This subpart applies to all observational research involving children as subjects, conducted or supported by EPA. References to State or local laws in this subpart and in §26.101(f) are intended to include the laws of federally recognized American Indian and Alaska Native Tribal Governments. This includes research conducted in EPA facilities by any person and research conducted in any facility by EPA employees.

(b) Exemptions at §26.101(b)(1) and (b)(3) through (b)(6) are applicable to this subpart. The exemption at §26.101(b)(2) regarding educational tests is also applicable to this subpart. However, the exemption at §26.101(b)(2) for research involving survey or interview procedures or observations of public behavior does not apply to research covered by this subpart, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

(c) The exceptions, additions, and provisions for waiver as they appear in §26.101(c) through (i) are applicable to this subpart.

§ 26.402 Definitions.

The definitions in §26.102 shall be applicable to this subpart as well. In addition, the following terms are defined:

(a) For purposes of this subpart, *Administrator* means the Administrator of the Environmental Protection Agency and any other officer or employee of the Environmental Protection Agency to whom authority has been delegated by the Administrator.

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

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State, Tribal, or local law to consent on behalf of a child to general medical care.

(f) *Observational research* means any research with human subjects that does not meet the definition of research involving intentional exposure of a human subject in §26.202(a).

(g) *Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

§ 26.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review observational research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

§ 26.404 Observational research not involving greater than minimal risk.

EPA will conduct or fund observational research in which the IRB finds that no greater than minimal risk to children is presented, 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.

§ 26.405 Observational research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.

If the IRB finds that an intervention or procedure presents more than minimal risk to children, EPA will not conduct or fund observational research that includes such an intervention or procedure unless the IRB finds and documents that:

- (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, as set forth in §26.406.

§ 26.406 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, when in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the observational research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the observational research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with §26.116(d).

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by §26.116, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §26.404 or §26.405.

(c) In addition to the provisions for waiver contained in §26.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may replace the consent requirements in subpart A of this part and paragraph (b) of this section with provided an appropriate, equivalent mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate, equivalent 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.

(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §26.117.

(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.

C. US Dept. of Education

PART 356—DISABILITY AND REHABILITATION RESEARCH

34 CFR 356.3

2) When an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

34 CFR 98.3 Access to instructional material used in a research or experimentation program.

- (a) 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 research
- (b) Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques
- (c) Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age of majority as determined under State law

98.4 Protection of students' privacy in examination, testing, or treatment.

The Process to Comply with the Protection of Pupil Rights Amendment

(a) For research funded by the US Department of Education, no student shall be required, as part of any program specified in § 98.1 (a) or (b), to submit without prior consent to 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;

- (2) Mental and psychological problems potentially embarrassing to the student or his or her family;
 - (3) Sex behavior and attitudes;
 - (4) Illegal, anti-social, self-incriminating and demeaning behavior;
 - (5) Critical appraisals of other individuals with whom the student has close family relationships;
 - (6) Legally recognized privileged and 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 a program.
- (b) As used in paragraph (a) of this section, *prior consent* means:
- (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 an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.

For research not funded by the US Department of Education, the IRB must verify compliance with US Department of Education regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:

- a. 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.
 - i. 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.
- b. 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):
 - (1) Political affiliations;
 - (2) Mental and psychological problems potentially embarrassing to the student or his or her family;
 - (3) Sex behavior and attitudes;
 - (4) Illegal, anti-social, self-incriminating and demeaning behavior;
 - (5) Critical appraisals of other individuals with whom the student has close family relationships;
 - (6) Legally recognized privileged and 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 a program.
- c. 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.
 - i. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
- d. The administration of physical examinations or screenings that the school or agency may administer to a student.
- e. 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.
- f. 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.
 - i. 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.

For use of student records for research purposes: See *Family Educational Rights Privacy Act (FERPA) Guidance*.

D. Department of Energy

DOE Checklist (addendum) – All items must be addressed in the protocol.

Researchers are required to follow DOE requirements for the protection of personally identifiable information by completing and complying with the requirements of the “Checklist for IRBs to Use in Verifying that HS Research Protocols are in Compliance with DOE Requirements”.

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e. Reporting.

(1) HSR projects must be reported annually to the HSR Projects Database in accordance with directions and schedules provided by the HSR Program Manager.

(2) The HSR Program Manager will be notified in writing and within a reasonable time of:

- (a) significant adverse events, unanticipated risks, and complaints about the research, with a description of corrective actions taken and/or to be taken;
- (b) suspension or termination of IRB approval of research; and

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(c) known or potential incidents of noncompliance with requirements of this Order, 10 CFR 745, 45 CFR 46, and any approved plan for correcting a noncompliance.

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