



Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

Federally Sponsored or Supported Research:
Specific Agency Requirements

Federally Sponsored or Supported Research: Specific Agency Requirements

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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

This policy outlines the additional regulations set forth by the following federal agencies:

1. Department of Justice
2. Environmental Protection Agency
3. Department of Education
4. Department of Energy
5. Department of Defense

1. Department of Justice

For research funded by the National Institute of Justice (NIJ) (28 CFR 46 and 28 CFR 22):

1. The confidentiality statement on the consent form must state that confidentiality can only be broken if the participant reports immediate

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- harm to participants or others. See the “Informed Consent Requirements” SOP for elements of consent required by NIJ and DOJ.
2. The research must have a privacy certificate approved by the NIJ Human Subjects Protection Officer. 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. Specifics are available here: <http://www.nij.gov/nij/funding/humansubjects/privacy-certificate-guidance.htm>
 3. All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
 4. Identifiable portions of the data must be destroyed after the three year data retention period has expired and a copy of all de-identified data must be sent to the National Archive of Criminal Justice Data including de-identified informed consent documents, data collection instruments, surveys or other relevant research materials.

28 CFR 22 – Confidentiality of Identifiable Research and Statistical Information

§ 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.

§ 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) 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.
 - (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

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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.

§ 22.25 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.

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.

Research Involving the Bureau of Prisons

Research within the federal Bureau of Prisons is subject to the additional requirements of 28 CFR 512. The regulations apply to any research involving inmates in the custody of the Attorney General, and assigned to the Bureau of Prisons, regardless of the institution in which the inmate is incarcerated (e.g., even if the inmate is resident in a state institution).

28 CFR Part 500.1(c): Definitions

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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: Subpart B, Research

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 Purpose and Scope

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 Requirement for Research Projects and Researchers

(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,

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- 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:

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- (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.

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(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

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

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

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(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) Access to Bureau of Prisons Records

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

Additional elements of consent are also covered in the “Informed Consent Requirements” SOP.

- (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;
 - (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

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- (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.

§ 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.

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How to Apply to Conduct Research at the BOP

Research protocols within the Bureau of Prisons must be approved in advance by the federal Bureau Research Review Board (BRRB), and by the warden of the individual facility in which the research will be conducted.

- (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).

2. 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

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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.

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§ 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.

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- (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.

3. US Department 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.

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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:

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- 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.

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

4. Department of Energy

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”. This checklist is embedded in the Department of Energy Subform associated with the IRB application. Additional required elements of consent are covered in the “Informed Consent Requirements” SOP.

Requirements for Human Participant Protections

Requirements for human participant protections (1) for classified research apply to all research conducted or supported by the DOE including contracts, and including Human Terrain Mapping research; (2) and their accompanying Contractor Requirement Documents (CRDs) apply to all research conducted at DOE institutions regardless of funding source, or by DOE employees/contractor personnel regardless of funding source or location conducted, and whether done domestically or in an international environment, and including Human Terrain Mapping research. DOE employees and contractors are considered vulnerable subjects and shall be afforded additional protections as determined by the MU IRB. The MU IRB will apply similar protections outlined in the “Additional Protections for Vulnerable Populations, International, and Non-English Speaking Participants” SOP where is discusses employees, and will apply any other protections necessary to protect DOE workers.

Self-Assessments

The DOE requires MU to periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements. The MU IRB follows its “MU HRPP Quality Improvement and Community Engagement” SOP when conducting self-assessments.

Classified Research

The use of exemptions is prohibited in classified research. The fact that research meets a particular exemption may be noted, but review by a convened IRB is required. The IRB must have a voting quorum of at least 5 members, which must include both a non-scientist and a non-affiliated member. The non-affiliated member must be a non-governmental member with the appropriate security clearances. This individual cannot be a current federal employee or contractor. Any IRB member can appeal a vote to approve research to the institutional official, Secretary of Energy, and Director of the Office of Science and Technology, in that order. The IRB may not grant a waiver of the consent process or waiver of documentation of consent.

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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
- (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.

5. Department of Defense

GENERAL DESCRIPTION

Research supported by the DoD and “involving a human being as an experimental subject” is subject to the Federal Policy for the protection of human subjects in research, i.e., the Common Rule. However, because of the DoD culture, organizational structure, and population, DoD Directive 3216.02 lays out additional requirements that apply as well. These requirements are designed to cover risks unique to DoD employees that differ from civilians both in the conduct of research and in participation in research (e.g., deployability, personal conduct standards, and duty to report certain personnel actions). The procedures outlined in this SOP ensure that UMC research supported by the DoD complies with DoD regulations governing human research.

UMC’s existing Federalwide Assurance (FWA) of compliance approved by the Office of Human Research Protections (OHRP) meets the DoD requirement that the institution hold a federal assurance. The existing FWA was augmented with a DoD Addendum (DoD N-A3388) to inform institutions of additional DoD requirements. In the case of human research sponsored by the Department of the Navy, Secretary of the Navy Instructions (SECNAVINST 3900.39D) apply.

The principal investigator (PI), with assistance from the IRB, submits documentation of Institutional Review Board (IRB) approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research, any exemption determinations, or documentation of continuing approval. The DoD applies the provisions in 45 CFR Part 46, Subparts B, C, and D for the protection of vulnerable classes of subjects but prohibits the use of prisoners of war in DoD-sponsored

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research. For non-exempt classified research, the IRB will ensure all requirements outlined in 3216.02.13 have been met.

Non-compliance: Issues related to non-compliance with DoD Directive by any DoD Component, subordinate, or supported activity shall be referred initially to the next higher management echelon to take deliberate action to resolve. All findings of serious non-compliance shall be reported to the Director, Defense Research and Engineering.

Additional safeguards apply when the study involves military personnel or international citizen populations as subjects. Research involving greater than minimal risk [as defined in 32 CFR 219.102(i), reference (c)] requires appointment of an independent research monitor. In certain cases, the DoD applies limitations on the waiver of informed consent.

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

PROCEDURES

Department of Defense Addendum to the Existing FWA

1. The University of Missouri-Columbia updated the existing Federalwide Assurance with a DoD Addendum, identified as DoD N-A3388. The Institutional Official, the appropriate IRB Chair, and the Director of Human Research Protections reviewed and signed the DoD Addendum.
2. The DoD addendum covers all DoD-sponsored research at UMC; however, various DoD Components may use other processes or have additional requirements. The PI, with assistance from IRB is responsible for identifying additional requirements and conveying those requirements to the IRB, as appropriate.
3. Since the University of Missouri-Columbia occasionally conducts research sponsored or supported by the Department of Defense, the Director of Human Research Protections will continue to renew the addendum prior to the scheduled expiration date.

Submission of DoD Supported Research to the IRB

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1. DoD requires scientific review prior to IRB review for all new DoD supported human research. The PI is responsible for obtaining scientific review from his/her Department Chair or designee prior to submission of the application to the IRB. The Department Chair or designee is responsible for conducting the scientific review and signing off on the IRB application.
2. The PI or designee completes an application for IRB review of the protocol and makes the initial determination identifying the research as *supported* by a DoD component (as defined in Department of Defense Directive 3216.02) and submits it to the IRB.
3. The PI is responsible for checking the appropriate DoD-relevant items on the IRB application. The PI indicates in the application whether military personnel or international citizen populations are subjects.
4. Upon receipt of the application, IRB staff screen it for completeness and accuracy and make a preliminary determination that the research is DoD-supported. IRB staff also make preliminary determinations of the level of risk, the type of subjects involved (i.e., military personnel or international citizen populations), and the need for a research monitor (see *Research Monitor* below).
5. IRB staff advise the PI and the IRB of DoD-specific requirements in the Addendum. The PI is responsible for identifying DoD component requirements specified in the grant application guidelines and advising the IRB staff and IRB of the requirements.
6. The PI and study personnel are responsible for completing processes specified in the DOD Addendum or DOD guidelines and submitting documentation, as appropriate, to the IRB as an uploaded document to the IRB application.

Department of Defense Ethics Education Requirements

1. The PI and research team members who conduct, review, approve, oversee, support, or manage human participants research must complete all initial and continuing education requirements for human subjects protections in accordance with UMC policy (see Initial Review SOP).
2. The PI is responsible for identifying specific researcher, research members, IRB staff, chair and members educational or certification requirements of the sponsoring DoD Component by consulting the DoD component and conveying those requirements to the IRB. The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.
3. IRB staff, with assistance from the PI, determine the need for orientation and/or education of the IRB chair, members, and staff as regards to DoD-specific education requirements.
4. IRB staff assist the PI, study personnel, as identified above, in accessing the necessary human subjects training and certifications required for IRB approval.

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5. The PI, study personnel, and IRB members and staff complete DoD-specific research ethics training, as applicable, and the PI submits documentation of training completion to the IRB and to the DoD Component, as appropriate.
6. OSPA staff include relevant certifications, as appropriate, in the sponsored research agreement.
7. The IRB does not approve DoD-supported research until the PI and research team have completed required education and the appropriate certifications are in place.

Research Monitor Required: Greater than Minimal Risk Studies

1. For DoD-sponsored research involving greater than minimal risk to subjects, the DOD requires appointment of an independent research monitor, although the IRB or organizational official can require this for a portion of the research or studies involving no more than minimal risk, if appropriate.
2. The duties and authorities of the research monitor are determined on the basis of specific risks or concerns about the research, such as:
 - a. Perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to participants or others, oversee data matching, data collection and analysis);
 - b. Discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study;
 - c. Report observations and findings to the IRB or a designated official. Stop a research study in progress;
 - e. Remove individuals from the study;
 - f. Take any steps to protect the safety and well-being of subjects until the IRB can assess the research monitor's report
3. The PI identifies a candidate for the position of research monitor, taking into account the nature and disciplinary focus of the study and the likely type of medical expertise required.
 - a. The research monitor must be appointed by name and shall be independent of the team conducting the research.
 - b. The monitor may be an ombudsman or a member of the data safety monitoring board.
 - c. There may be more than one research monitor (e.g. if different skills or experience is needed).
 - d. The PI must attach to the IRB application a copy of the monitor's curriculum vitae, a letter from the monitor accepting the role, and a written summary of the monitors' duties, authorities, and responsibilities. The IRB must approve the written summary of the monitors' duties, authorities, and responsibilities.
4. The PI conveys to the monitor relevant DoD-specific orientation/education requirements of the role (see also *Department of Defense Ethics Education*

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above.) The IRB or organizational official shall communicate with the researcher monitor(s) to confirm their duties, authorities, and responsibilities.

5. The IRB reviews the information regarding the monitor and determines whether the individual designated meets the DoD requirements for educational and professional expertise (see *Definitions* above).

Research Involving International Citizen Populations

1. In the IRB application, the PI provides the necessary information, as appropriate, on the subject populations, the cultural context, and the languages understood by the human subjects. The PI is responsible for identifying local laws, regulations, customs and practices and following them when designing and implementing the research.
2. The PI is responsible for determining whether the sponsoring DoD Component requires an additional ethics review by the host country or a local DoD IRB with host country representation. If applicable, the PI submits to the IRB documentation of permission to conduct research in that country by certification or local ethics review.
3. To ensure the IRB has appropriate knowledge of the local context, the IRB uses an ad hoc or cultural consultant in accord with its standard operating procedures outlined in the Initial Review SOP.
4. Additional safeguards may not be applicable to minimal risk social-behavioral research. The PI and/or IRB staff consults with the sponsoring DoD component, as appropriate.

Research Involving U.S. Military Personnel as Research Participants

1. In cases where the research involves U.S. military personnel as subjects, the PI submits with the IRB application a plan for research subject recruitment that incorporates additional safeguards to minimize undue influence from individuals within a potential subject's chain of command. The PI consults the sponsoring DoD Component, as necessary, for assistance.
2. Civilian researchers attempting to access active military volunteers should seek collaboration with a military researcher familiar with service-specific requirements.
3. For research involving greater than minimal risk to subjects *and* involving military personnel, the PI includes procedures in the subject recruitment plan to ensure that officers cannot influence the decision of their subordinates to participate in the research.
4. The PI includes, in the IRB application, procedures in the subject recruitment plan to ensure that officers and senior or other non-commissioned officers cannot be present at the time of recruitment or consent of their subordinates.
5. The PI provides a separate opportunity or recruitment session for officers and senior non-commissioned officers to participate as research subjects.

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6. For studies in which subject recruitment involves a percentage of a unit, the PI ensures an independent ombudsman shall be present during the recruitment process to monitor the voluntary nature of participation and that information provided is adequate and accurate.
7. Unless on leave status during research participation, military personnel may not receive compensation for their participation. The IRB reviews the proposed subject compensation to ensure that the PI does not violate DoD policies limiting dual compensation for U.S. military personnel:
 - a. Prohibit an individual from receiving pay of compensation for research during duty hours.
 - b. May be compensated for research if the participant is involved in the research when not on duty.
 - c. Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
 - d. Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRB according to local prevailing rates and the nature of the research.
 - e. An individual may not receive pay from more than one position for more than 40 hours of work in one calendar week.
 - f. Limits address temporary, part-time, and intermittent appointments.
8. UMC does not apply DoD policies when U.S. military personnel incidentally participate as subjects in a study that is not DoD-sponsored or supported and U.S. military personnel are not the intended target population.

Consent Process

1. If consent is to be obtained from the experimental subjects' legal representative, the research must intend to benefit the individual participant.
2. The determination that research is intended to be beneficial to the individual experimental subject must be made by the IRB.
3. Additional required elements of consent are covered in the "Informed Consent Requirements" SOP.

Waiver of Consent and Exception from Informed Consent in Emergency Medicine

1. If a research subject meets the definition of "experimental subject," DoD regulations prohibit a waiver of consent unless the PI obtains a waiver from the Secretary of Defense. The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all the following are met:
 - a. The research is necessary to advance the development of a medical product for the Military Services.
 - b. The research might directly benefit the individual experimental subject.
 - c. The research is conducted in compliance with all other applicable laws and regulations.

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2. The IRB makes the determination as to whether the research subject meets the definition of “experimental subject.” The IRB shall not approve a waiver of consent if the research subject meets the definition of “experimental subject” unless the Secretary of Defense has issued a waiver. The IRB may waive the consent process if the research does not meet the definition of “experimental subject.”
3. DoD regulations prohibit an exception from informed consent in emergency medicine research unless the PI obtains a waiver from the Secretary of Defense.
 - a. The IRB shall not approve an exception from informed consent in emergency medicine research unless the PI has obtained a waiver from the Secretary of Defense.
 - b. For classified research, waivers of consent are prohibited.

Multi-Site or Collaborative Research Requirements

1. A PI developing a proposal for DoD funding or other support that involves other collaborating institutions consults the sponsoring DoD Component and IRB staff early in the proposal development process to identify additional requirements for multi-site research.
2. OSPA staff are responsible for negotiating formal agreements with collaborating institutions (see Office of Sponsored Projects Administration/IRB SOP). OSPA staff, in conjunction with the PI, ensure that the formal research agreement between participating institutions includes a statement of work and specifies the roles and responsibilities of each party.
3. For collaborative research involving UMC and DoD researchers, the UMC may choose to rely upon the DoD IRB for review and oversight following the standard operating procedures outlined in the Multi Site Research and IRB Reliance Process SOP. For collaborative research involving UMC and non DoD institutions, UMC follows standard operating procedures outlined in the Multi Site Research and IRB Reliance Process SOP. UMC and the collaborating institution sign an IRB authorization agreement which includes a statement of work specifying the roles and responsibilities of the relied upon IRB. The agreement must be approved by the DoD component prior to the DoD institution’s engagement in the research.
4. In order to ensure consistent protection of subjects under DoD requirements, a PI conducting DoD-sponsored multi-site research submits information to the IRB on the FWA(s) held by collaborating institutions, including the existence of any DoD Addendum or other direct DoD assurance.
5. The PI provides the UMC IRB additional information to ensure ongoing communication among participating IRBs and sites, as indicated in the Multi Site Research and IRB Reliance Process SOP.
6. The involvement of DoD personnel in the conduct of the research must be secondary to that of the non-DoD institution if relying on an collaborating non-DoD institution’s IRB. When relying on a non-DoD IRB, the

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involvement of classified information may be limited to the information needed for IRB approval and oversight of the research; information needed to inform human participants during the consent process; and information provided by human participants during the course of the research.

Provisions for Research-related Injury

1. The PI is responsible for informing IRB staff of the DoD Component's requirements for the provision of care in the case of a research-related injury. If the DoD Component has stricter requirements than the Common Rule or University of Missouri rules, the PI, with assistance from IRB staff, must obtain prior permission from the Institutional Official or designee.
2. The PI includes documentation of the Institutional Official approval of the stricter requirements in the IRB application. The PI includes the appropriate provisions in the informed consent form. The IRB determines the disclosure includes the provisions for research-related injury and follows the requirements of the DoD component.

Prohibition on Involvement of Prisoners of War in Research

1. The definition of "prisoner of war" may vary by DoD Component. The IRB applies the definition in this SOP or the definition for the DoD Component granting the DoD Addendum, as applicable. The PI is responsible for providing the IRB with the applicable definition of "prisoner of war."
2. Under no circumstances shall the IRB approve research involving prisoners of war, as defined by the specific DoD Component granting the DoD Addendum.

Additional DoD Review Required Prior to Initiation of Study

1. After the IRB completes its review and issues approval, the PI submits documentation of IRB approval, the risk level, and the expiration date of the research to the DoD Component sponsoring or supporting the study.
2. The DoD may also request additional documentation to verify compliance with federal and DoD policies, including minutes related to the research. As appropriate, IRB staff provide the PI any additional information pertinent to IRB review, which may not be under a PI's purview. The PI sends requested information to the DoD.
3. The PI may not initiate the study until the human research protection officer (HRPO) within the sponsoring DoD Component reviews and approves the IRB approval and other submitted documentation. The DoD component must conduct an appropriate administrative review of the research involving human subjects. This must be conducted before the research involving human subjects can begin, to ensure compliance with all applicable regulations and policies, including any applicable laws and requirements and cultural

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sensitivities of a foreign country when the research is conducted in a foreign country.

4. If the study is for DoD-sponsored survey research or survey research within the DoD that involves DoD personnel, including military personnel, the PI, with assistance from IRB staff, identifies any requirements for an additional level of DoD review of the study. Surveys typically require DoD Survey Review and approval. The PI submits surveys and all required documentation relevant to survey research review to the requesting DoD Component.
5. The PI notifies OSPA and IRB staff upon receipt of relevant HRPO authorization and/or DoD Survey Review approval, as appropriate. OSPA staff establishes the account only after receiving certification of final human subjects and survey review and approval from the HRPO or relevant DoD designee.

Scientific Review for Substantive Amendments of Approved Protocols: Prior Scientific Review Required

1. DOD requires that all substantive amendments to approved DoD research involving human subjects receive scientific review prior to IRB review.
2. For substantive amendments to the study protocol, the Department Chair or designee conducts a scientific review of the amended protocol.
3. When the PI submits a modification review application, he/she submits a cover memo from the Department Chair. The Department Chair's or designee's signature on the memo attests to this new scientific review and approval of the amended protocol.

Research involving Pregnant Women, Prisoners, and Children

1. Research involving pregnant women, prisoners, and children are subject to the DHHS Subparts B, C, and D.
2. For purposes of applying subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge".
3. The applicability of subpart B is limited to research involving pregnant women as participants in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as participants.
4. Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
5. Research involving prisoners cannot be reviewed by the expedited procedure.
6. When the IRB reviews research involving prisoners, at least one prisoner representative must be present for quorum.
7. In addition to allowable categories of research on prisoners in subpart C, epidemiological research is allowable when:

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- a. The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
 - b. The research presents no more than minimal risk.
 - c. The research presents no more than an inconvenience to the participant.
8. If a participant becomes a prisoner, if the researcher asserts to the IRB that it is in the best interest of the prisoner-participant to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-participant may continue to participate until the convened IRB can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-participant (including obtaining identifiable private information) cease until the convened IRB can review this request to approve a change in the research protocol. The convened IRB, upon receipt of notification that a previously enrolled human participant has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy.
- a. The IRB should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-participant can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-participant's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human participants from continuing as approved, the convened IRB may approve a change in the study to allow this prisoner-participant to continue to participate in the research. This approval is limited to the individual prisoner-participant and does not allow recruitment of prisoners as participants.
 - i. Research involving a detainee as a human participant is prohibited.
 - ii. This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military in the same location for the same condition.
9. Research involving children cannot be exempt.

Recordkeeping

1. IRB staff secure and maintain IRB records for DoD-sponsored research in accord with the provisions of the IRB Recordkeeping SOP. In addition, the PI determines, in conjunction with IRB, whether the DoD Component requires submission of IRB records to the DoD for archiving. The PI submits the relevant IRB records to the DoD, as appropriate with assistance from ORI staff.

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

Reporting 32 CFR 219

1. The contract will be reviewed with the assistance of the Office of Sponsored Programs. All reporting requirements stated in the contract will be reported. Each Department within the Department of Defense has their own reporting contacts. See Reporting Requirements SOP.
2. For DoD-supported research, the PI must report promptly (within 30 days) to the DoD human research protection officer:
 - a. When significant changes to the research protocol are approved by the IRB.
 - b. The results of the IRB continuing review.
 - c. Change of reviewing IRB.
3. When the organization is notified by any Federal department, agency, or national organization that any part of an HRPP is under investigation for cause involving a DoD supported research protocol.

DoD REFERENCES

Department of Defense Directive, DoD 3216.02, March 25, 2002, Certified Current as of April 24, 2007

10 United States Code 980

SECNA VINST 3900.39D

24 United States Code 30

45 CFR 46, Subparts B, C, and D (f)

References:

Combined Policies January 21, 2019:

Working with Other Agencies

Approval Dates: June 10, 2010; July 1, 2011; July 15, 2014; March 1, 2015;

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June 8, 2017