Institutional Review Board

University of Missouri-Columbia

Standard Operating Procedure

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 MU 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, including National Institute of Justice
2. Environmental Protection Agency
3. Department of Education
4. Department of Energy
5. Department of Defense

1. Department of Justice

The US Department of Justice is the only federal agency discussed in this policy that has not adopted the revised common rule. Additional information regarding the

adoption of the revised common rule can be found in the "Research Subject to the Revised Common Rule" MU HRPP/IRB SOP.

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

1. 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
2. All researchers and research staff are required to sign employee confidentiality statements, which are maintained by the responsible researcher.
3. A copy of all data must be de-identified and sent to the National Archive of Criminal Justice Data, including copies of the informed consent document, data collection instruments, surveys, or other relevant research materials.

Research Involving the Bureau of Prisons

The organization, IRB, and researchers and research staff must follow the requirements of 28 CFR 512, including:

1. The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
2. The research design must be compatible with both the operation of prison facilities and protection of human participants. The researcher must observe the rules of the institution or office in which the research is conducted.
3. Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the requirements of 28 CFR 512.
4. All research proposals will be reviewed by the Bureau Research Review Board.

Subject Selection and Compensation

1. The selection of participants within any one organization must be equitable.
2. Incentives may not be offered to help persuade inmate participants to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
3. Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research participants who are both:
   (i) No longer in Bureau of Prisons custody.
   (ii) Participating in authorized research being conducted by Bureau employees or contractors.

Researcher Requirements and Responsibilities

1. The researcher must have academic preparation or experience in the area of study of the proposed research.
2. 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.
3. Include the required additional DOJ elements of informed consent disclosure covered in the Informed Consent Requirements SOP.

Research Project and Protocol Requirements

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

When submitting a research protocol, the applicant must provide a summary statement, which includes:

1) Names and current affiliations of the researchers.
2) Title of the study.
3) Purpose of the study.
4) Location of the study.
5) Methods to be employed.
6) Anticipated results.
7) Duration of the study.
8) Number of participants (staff or inmates) required and amount of time required from each.
9) Indication of risk or discomfort involved as a result of participation.

When submitting a research protocol, the applicant must also provide 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 of Prisons.
5) Description of all possible risks, discomforts, and benefits to individual participants or a class of participants, and a discussion of the likelihood that the risks and discomforts will actually occur.
6) Description of steps taken to minimize any risks.
7) Description of physical or administrative procedures to be followed to:
   (A) Ensure the security of any individually identifiable data that are being collected for the study.
   (B) 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 study on organizational programs and operations.
9) Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
10) A statement regarding assurances and certification required by federal regulations, if applicable.

Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research.

Individual Identifiers

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

2. Environmental Protection Agency

Prohibitions and additional protections for pregnant women, nursing women, and children:

1. EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
2. EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as participants in observational research, i.e., research that does not involve intentional exposure to any substance.

3. EPA requires submission of IRB determinations and approval to the EPA human subjects research review official for final review and approval before the research can begin.
4. EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to substances.
5. IRB will review observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B.
6. The IRB may review and approve observational research involving children that does not involve greater than minimal risk only if the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in 26.406.
7. The IRB may review and approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual participants if the IRB finds and documents that:
    (i) The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
    (ii) The risk is justified by the anticipated benefit to the participants.
    (iii) The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
    (iv) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 26.406.

3. US Department of Education

For research funded by the US Department of Education:

(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.

Compliance with Protection of Pupil Rights Amendment (PPRA)

For certain types of research projects **directly funded by the US Department of Education**, no student shall be required, as part of any research project, to submit without **prior consent* to surveys, psychiatric examination, testing, or treatment, or

psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning one or more of the following:

(1) Political affiliations or beliefs of the student or the student's family;
(2) Mental and psychological problems of the student or the student's family;
(3) Sex behavior and attitudes;
(4) Illegal, anti-social, self-incriminating and demeaning behavior;
(5) Critical appraisals of other individuals with whom respondents have 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.

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 not an un-emancipated minor.

For certain types of research **not directly funded by the US Department of Education** and conducted in a school that receives funding from the US Department of Education, the investigator working with the school 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 or beliefs of the student or the student's family;
    (2) Mental and psychological problems of the student or the student's family;
    (3) Sex behavior and attitudes;
    (4) Illegal, anti-social, self-incriminating and demeaning behavior;
    (5) Critical appraisals of other individuals with whom respondents have 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.
d. Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
e. The administration of physical examinations or screenings that the school or agency may administer to a student.
f. 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.
g. 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.
h. 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.

Compliance with Family Educational Rights and Privacy Act (FERPA)

FERPA applies when researchers obtain student records or personal education information from an education program as defined as any program principally engaged in the provision of education, including, but not limited to, early childhood education, elementary and secondary education, postsecondary education, special education, job training, career and technical education, and adult education.

Exceptions to Consent

The IRB may grant exceptions to parental or student consent to release student records for research. Exceptions may also be requested from the school where educational information is being requested, or the MU Registrar when utilizing MU educational records.

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

1. Develop, validate, or administer predictive tests.
2. Administer student aid programs.
3. Improve instruction.

A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the organization or researcher conducting the research that specifies:

1. The determination of the exception.
2. The purpose, scope, and duration of the study.
3. The information to be disclosed.
4. That information from education records may only be used to meet the purposes of the study stated in the written agreement and must contain the current requirements in U.S. Department of Education regulations on redisclosure and destruction of information.
5. That the study will be conducted in a manner that does not permit personal identification of parents and students by anyone other than representatives of the organization with legitimate interests.
6. That the organization is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
7. The time period during which the organization must either destroy or return the information.

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

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

See MU IRB FERPA Guidance.

4. Department of Energy

DOE requirements apply to all research conducted with DOE funding, at DOE institutions (regardless of funding source), or by DOE or DOE contractor personnel (regardless of funding source or location conducted), whether done domestically or in an international environment, including classified and proprietary research. DOE

requirements also apply to DOE's semi-autonomous National Nuclear Security Administration (NNSA).

DOE follows the Nuremberg Code, Belmont Report, and the Common Rule, including Subparts B, C, D, and E, except where noted below. DOE also follows FDA regulations.

No human subject research can be initiated without both a FWA or a comparable assurance and approval by the cognizant IRB in accordance with 10 CFR Part 745.103. MU's existing Federalwide Assurance (FWA) of compliance approved by the Office of Human Research Protections (OHRP) meets the DOE requirement that the institution hold a federal assurance.

(i) When research involves contractors, DOE "Contractor Requirements Document" describing contractor responsibilities for protecting human research participants must be included in contracts.
(ii) MU IRB may review classified research. When MU is conducting or reviewing classified research, convened IRB review is required. Exemptions (as per 10 CFR Part 745.104) will not be used. The fact that research meets a particular exemption category may be noted, but review by a convened IRB is required. When conducting or reviewing classified research, the use of the expedited review procedure is prohibited. The fact that research meets a particular expedited category may be noted, but review by a convened IRB is required.

Research that uses social media data must be submitted to the appropriate IRB for human participant research review and determination.

Research that involves the study of humans in a systematically modified environment must be submitted to the appropriate IRB for HSR review and determination.

Classified and unclassified human participant research that is funded through the Strategic Intelligence Partnership Program (SIPP) must be reviewed and approved by the Central DOE IRB-Classified.

Human Terrain Mapping (HTM) is managed as research involving human participants. MU investigators may engage in DOE human terrain mapping research.

NSSA (National Nuclear Security Administration)

The Human Subjects Protection (HSP) Program Manager (and when an NNSA element is involved, the NNSA HSP Program Manager) must be notified in writing prior to initiation of the HSR portion of a new project, even if it meets the regulatory definition of exempt HSR as outlined in 10 CFR Part 745.104, that involves (DOE 0 443.1C, section 4(d)):
(i) An institution without an established IRB.

(ii) A foreign country.
(iii) A potential for significant controversy (e.g., negative press or reaction from stakeholder or oversight groups).
(iv) Research subjects in a protected class (prisoners, children, individuals with impaired decision making, or DOE/NNSA federal or DOE/NNSA contractor employees as human subjects, who may be more vulnerable to coercion and undue influence to participate) that is outside of the reviewing IRB's typical range/scope.
(v) The generation or use of classified information.

Personally Identifiable Information

(a) Personally identifiable information collected and/or used during human participant research projects must be protected in accordance with the requirements of DOE Order 206.1, Department of Energy Privacy Program.
(b) Any breach involving Personally Identifiable Information must be reported:
(i) Immediately upon a finding of a suspected or confirmed data breach involving Personally Identifiable Information (PII) in printed or electronic form, the incident must be reported to the DOE-Cyber Incident Response Capability in accordance with the requirements of DOE O 206.1.
(ii) Within 48 hours the DOE or NNSA HSP Program Manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions.

Consent Process

(a) DOE and DOE site employees are considered vulnerable subjects when participating in research and additional care must be taken to ensure their participation is truly voluntary (e.g., by ensuring they do not report to members of the research team) and that data collected about them is kept confidential.
(b) MU IRB will follow the "Additional Protections for Vulnerable Populations, International, and Non-English Speaking Participants" SOP covering additional employees protections when studies involve DOE or DOE site employees.

The IRB must determine if participants need access to classified information to make a valid consent decision.

Informed consent may only be waived for classified research if the work meets one of the categories of the minimal risk human participant research addressed at 10 CFR Part 745.104.

Additional required elements of consent are covered in the "Informed Consent Requirements" SOP.

Noncompliance and Significant Noncompliance

The HSP Program Manager at DOE or NNSA must be notified by the investigator within 48 hours, with a description of corrective actions taken, of any known or potential incidents of noncompliance. Researchers must report the following within 48 hours to the HSP Program Manager any significant noncompliance with HRPP procedures or other requirements. The MU IRB Noncompliance SOP and Reporting SOP will be followed for DOE research.

Unanticipated Problems

The HRP Program Manager at DOE or NNSA must be notified:
(i) Immediately upon learning of a serious adverse event. The HSP Program Manager(s) shall also be informed of any corrective actions taken and consulted regarding the plan for any remaining corrective actions
(ii) Within 48 hours, with a description of corrective actions taken, of:
(A) Unanticipated problems.
(B) Significant adverse events, and
(C) Complaints about the research.

The MU IRB Unanticipated Problems SOP and Reporting SOP will be followed for DOE research.

Suspensions or Terminations

The HSP Program Manager at DOE or NNSA must be notified within 48 hours, with a description of corrective actions taken, of:
(i) Suspensions of IRB approval
(ii) Terminations of IRB approval

The MU IRB Suspensions and Terminations SOP and Reporting SOP will be followed for DOE research.

Sharing Oversight with Another Organization

(a) Research involving human participants involving multiple DOE sites (e.g., members of the research team from more than one DOE site and/or data or human subjects from more than one DOE site) must be reviewed and approved by one of the Central DOE IRBs prior to initiation, unless review by another appropriate IRB of record is authorized by the DOE and/or NNSA HSP Program Manager.
(b) If authorized by the DOE and/or NNSA HSP Program Manager, research may be reviewed by other appropriate IRB of record. In all cases, an IRB Authorization Agreement (IAA) or Memorandum of Understanding (MOU) must be in place between the organization(s) conducting the HSR and the organization

responsible for IRB review. The MU IRB Multi-Site Research and IRB Reliance Process SOP will be followed for multi-site DOE research.

Resources:

- 10 CFR 745 (Common Rule)
- DOE O 443.1C Protection of Human Research Subjects (November 2019)
- Presidential Memorandum, Strengthened Protections for Human Subjects of Classified Research (March 27, 1997)
- Executive Order 12333 codified at 50 CFR Parts 2406 and 2511 (Regarding classified research involving human participants).

5. Department of Defense

GENERAL DESCRIPTION

Department of Defense adopted the revised common rule (32 CFR 219) including Subparts B, C, D, and E. DoD also follows FDA regulations.

MU'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.

DEFINITIONS AND ACRONYMS

COHRP: Component Office for Human Research Protections.

DOHRP: DoD Office for Human Research Protections.

Minimal Risk: The definition of minimal risk in 32 CFR 219 does not include the inherent occupational risks that certain participants face in their everyday life, such as those:

(ii) Encountered by Service members, law enforcement, or first responders while on duty.
(iii) Resulting from or associated with high-risk behaviors or pursuits.
(iv) Experienced by individuals whose medical conditions involve frequent tests or constant pain.

The additional protections described below are focused on those most applicable to non-DoD organizations (i.e. University of Missouri) engaged in research conducted or supported by the DoD:

Determining When Activities are Overseen by the MU HRPP

(a) Human participant research involving the testing of chemical or biological agents is prohibited, pursuant to Section 1520a of Title 50, United States Code (U.S.C.). Some exceptions for research for prophylactic, protective, or other peaceful purposes apply. Before any excepted testing of chemical or biological agents involving human participant research can begin, the DoD component seeking to conduct such research must obtain explicit written approval from the DoD Office for Human Research Protections (DOHRP). (DoDI 3216.02 section 1.2)

(i) MU may permit research involving chemical or biological agents under an exception, and if such research is allowed, the investigator is responsible for obtaining approval and the process they go through. MU researchers must upload the approval before the study will be opened to enrollment. Refer here to ensure no other export control restrictions apply: https://research.missouri.edu/export-controls/federal-regulations-exclusions-exemptions

(b) "Research involving a human being as an experimental subject" is conducted in accordance with 10 USC 980, as implemented by DoDI 3216.02, section 3.11.

(i) Research involving an "experimental subject" is an activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction. Research involving "experimental subjects" is a subset of research involving human participants. This definition relates only to the application of Section 980 of Title 10, U.S.C.; it does not affect the application of 32 CFR 219.

(ii) MU may conduct research involving experimental subjects.

(c) Classified research is defined in DoDI 3216.02 section 3.13.

(i) MU may allow the conduct of classified research. Investigators will be responsible for working through the appropriate processes as described: https://www.umsystem.edu/ums/ecas/research#classified. The investigator must upload final approval to the application before the study will be opened to enrollment.

Scientific or Scholarly Validity

(i) The IRB must consider the scientific merit of the research.

(ii) The IRB may rely on outside experts to provide an evaluation of the scientific merit. The MU IRB may accept written documentation from a Department Chair regarding the presence of scientific merit.

Confirming Approval by the Appropriate DoD Component

The MU IRB will confirm approval by the appropriate DoD component prior to research starting when required. When confirmation is required, investigators will be asked to upload documentation of such approval. DoD component-level administrative review (CLAR) must be conducted when (DoDI 3216.02 section 3.6):

(i) Human participants research is conducted in a foreign country, unless conducted by a DoD overseas institution, or only involves DoD-affiliated personnel who are US citizens.
(ii) The research requires a waiver of informed consent pursuant to 10 USC 980, Subsection (b).
(iii) The research is fetal research, as described in 42 USC 289g-289g-2.
(iv) Large scale genomic data (LSGD) is collected from DoD-affiliated personnel. LSDG includes data derived from genome-wide association studies; single nucleotide polymorphisms arrays; genome sequencing; transcriptomic, metagenomic, epigenomic analyses; and gene expression data; etc. (See definition in DoDI 3216.02 G.2 Definitions)
(v) The research constitutes classified research involving human participants (DoDI 3216.02 section 3.13).
(vi) The research is required to be approved by the DOHRP (in addition to the COHRP) in accordance with DoDI 3216.02.

When conducting emergency medicine research, the investigator must obtain approval from the DOHRP on behalf of the Secretary of Defense for a waiver of the advance informed consent provision of 10 USC 980.

If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.

Expedited and Convened IRB Review

a) Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD Information Management Control Officer (IMCO) after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD components, additional review is required.
(i) The investigator must obtain approval by IMCO and upload documentation via an Amendment Form.
(b) For DoD-supported research, the following must be promptly (within 30 days) reported by the investigator to the COHRP. (DoDI 3216.02 section 3.6)
(i) When significant changes to the research protocol are approved by the IRB:
(A) Changes to key investigators or institutions.
(B) Decreased benefit or increased risk to participants in greater than minimal risk research.
(C) Addition of vulnerable populations as participants.
(D) Addition of DoD-affiliated personnel as participants.
(ii) Change of reviewing IRB.
(iii) When the organization is notified by any federal body, state agency, official governing body of a Native American or Alaskan native tribe, other entity, or

foreign government that any part of an HRPP is under investigation for cause involving a DoD-supported research protocol.
(iv) Any problems involving risks to participants or others, suspension or termination of IRB approval, or any serious or continuing noncompliance pertaining to DoD-supported human participant research.
(v) The results of the IRB's continuing review, if required.
(vi) Change in status when a previously enrolled participant becomes pregnant, or when the researcher learns that a previously enrolled participant is pregnant, and the protocol was not reviewed and approved by the IRB in accordance with 45 CFR 46, Subpart B.
(vii) Change in status when a previously enrolled participant becomes a prisoner, and the protocol was not reviewed and approved by the IRB in accordance with 32 CFR 219, Subpart C.
(viii) Closure of a DoD-supported study.

Pregnant Women, Fetuses, and Neonates

For purposes of applying Subpart B, the phrase "biomedical knowledge" is replaced with "generalizable knowledge".

(i) The applicability of Subpart B is limited to research involving pregnant women as participants in research that is greater than minimal risk and includes interventions or invasive procedures involving the woman or the fetus as participants, or fetuses or neonates as human participants.
(ii) Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g:

(A) Research or experimentation may not be conducted, in the United States or in any other country, on a nonviable living human fetus ex utero or a living human fetus ex utero for whom viability has not been ascertained unless the research or experimentation:

(1) May enhance the well-being or meet the health needs of the fetus or enhance the probability of its survival to viability; or
(2) Will pose no added risk of suffering, injury, or death to the fetus and the purpose of the research or experimentation is the development of important biomedical knowledge which cannot be obtained by other means.

(B) The risk standard must be the same for fetuses which are intended to be aborted and fetuses which are intended to be carried to term.

For human participant research that would not otherwise be approved but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates, written approval from the DOHRP must be obtained through the COHPR prior to research starting.

Prisoners

In addition to the categories of permissible human participant research involving prisoners identified in DHHS regulations Subpart C, two additional categories are permissible (DoDI 3216.02 section 3.9 (c)):

(i) Epidemiological research is permitted under the following conditions:
(A) Where the sole purpose of the research is to describe the prevalence or incidence of a disease by identifying all cases, or study potential risk factor associations for a disease.
(B) The research presents no more than minimal risk.
(C) The research involves no more than inconvenience to the prisoner-participants.
(D) Prisoners are not a particular focus of the research.
(ii) Human participant research involving prisoners that would otherwise meet exemption criteria may be conducted, but must first be approved by an IRB and meet the requirements of Subpart C and DoDI 3216.02.

DoD organizations conducting research involving prisoners must demonstrate to the senior designated official that the IRB has fulfilled its duties in accordance with Subpart C.

When a previously enrolled human participant becomes a prisoner, and the protocol has not been reviewed and approved by the IRB in accordance with Subpart C, the researcher must promptly notify the IRB.
(i) For DoD-conducted research, the human protections director must notify the COHRP.
(ii) For DoD-supported research, the non-DoD organization must notify the DOHRP and other federal agencies.
(iii) The DOHRP must concur with the IRB before the participant can continue to participate while a prisoner.

Detainee or Prisoner of War

Research involving a detainee or a prisoner of war as a human participant is prohibited. (DoDI 3216.02 section 3.9 (g)):
(i) This prohibition does not apply to activities covered by investigational new drug or investigational device provisions of FDA regulations, when the purpose is for diagnosis or treatment of a medical condition in a patient.
(ii) Such treatment may be offered to detainees or prisoners of war with their informed consent when the medical products are subject to FDA regulations, and only when the same product may be available to DoD-affiliated personnel consistent with established medical practices.

DoD Affiliated Personnel, Military and Civilian Supervisors, Officers, and others in the chain of command (3216.02 Section 3.9(f)):

(i) Are prohibited from influencing their subordinates to participate in research involving human participants.
(ii) Must not be present at any human participant recruitment sessions or during the consent process for DoD-affiliated personnel. Excluded supervisors or those in the chain of command may participate in separate recruitment sessions, if applicable.
(iii) May participate in separate human participant research recruitment sessions.

Research Involving DoD Affiliated Personnel

If the research involves DoD-affiliated personnel, the researcher must receive command or component approval to execute the research.

Service members and DoD-affiliated personnel are considered vulnerable to coercion and undue influence by the DoD due to the nature of the command structure of the organization. Therefore, additional protections for DoD-affiliated personnel are required.

Service members and all Reserve component and National Guard members in a federal duty status are considered adults. If a Service member, Reserve component or National Guard member in federal duty status, student at a Service Academy, or trainee is under 18 years of age, the IRB must carefully consider the HSR recruitment process and the necessity of including such member as a human participant.

For greater than minimal risk research involving DoD-personnel, when recruitment and consent occurs in a group setting, the IRB must appoint an ombudsperson. The ombudsperson:

(i) Must not have a conflict of interest with the research or be a part of the research team.
(ii) Must be present during human participant recruitment, monitoring that the recruitment and informed consent explain that participation is voluntary, and that the information provided about the research is consistent with the IRB-approved script and materials, including digitally provided materials.
(iii)Should be available to address DoD-affiliated personnel's concerns about participation.

Civilian researchers attempting to access military volunteers should seek collaboration with a military researcher familiar with Service-specific requirements.

Research involving large-scale genomic data from DoD-affiliated personnel is subject to additional requirements (DoDI 3216.02 section 3.10):

(i) The disclosure of DoD-affiliated personnel's genomic data may pose a risk to national security; accordingly, written materials must describe

administrative, technical, and physical safeguards commensurate with risk, including the secondary use or sharing of de-identified data or specimens.
(ii) All research involving large-scale genomic data collected from DoD-affiliated personnel must have a certificate of confidentiality from DHHS (Title 42, U.S.C., and Public Law 114-255).
(iii) Research involving large-scale genomic data collected from DoD-affiliated personnel is subject to DoD component security review to ensure the adequacy of the proposed administrative, technical, and physical safeguards, including the secondary use or sharing of de-identified data or specimens.

Children

When research fits under 45 CFR 46.407 and/or 21 CFR 50.54, MU must demonstrate to the senior designated official and seek approval that the IRB has fulfilled its duties in accordance with DHHS Subpart D, 45 CFR 46. 407 and 21 CFR 50.54.

When research involves U.S. military personnel, limitations on dual compensation (DoDI section 3.9):

(i) Prohibit an individual from receiving pay of compensation for research during duty hours.
(ii) U.S. military personnel may be compensated for research if the participant is involved in the research when not on duty, provided payment does not conflict with prohibitions about dual compensation or other prohibitions in federal law.
(iii) Federal employees while on duty and non-federal persons may be compensated for blood draws for research up to $50 for each blood draw.
(iv) 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.

Consent Processes

If the research involves a human being as an experimental subject and is supported by DoD-appropriated funds, informed consent must be obtained from the participant in advance, in accordance with 10 USC 980.

(i) If the participant is unable to provide informed consent and consent will be obtained in advance from the participant's legal representative, the research must be intended to benefit the individual participants.
(ii) An IRB may waive or alter some elements of informed consent for research involving human beings as experimental subjects, so long as it preserves the informed consent of the participant (i.e., the consent indicates that participation in the research is voluntary, and the participant/representative is informed of research risks).

(iii) The DOHRP may waive the requirements for prospective consent for research involving human beings as "experimental subjects" when all of the following are met:

(A) The research is necessary to advance the development of a medical product for the Military Services.

(B) The research may directly benefit the individual "experimental subject".

(C) The research is conducted in compliance with all other applicable laws and regulations.

(iv) Waivers of consent are prohibited for DoD classified research (Section 2.10 of Executive Order 12333)

(a) The disclosure for research-related injury follows the requirements of the DoD component.

(i.) For greater than minimal risk research, consent documents must include the disclosure that participants may, for the duration of the study, be eligible for health care services for research-related injuries at a military treatment facility, and this eligibility for health care services extends beyond participants' participation in the study to such time after the study has ended.

(ii.)The consent must document a plan for participants with research related injuries, including injuries that are the direct result of activities performed by DoD-affiliated personnel in studies that are collaborative with a non-DoD institution.

(b) If the research involves DoD-affiliated personnel as participants, in addition to the basic and required consent disclosures, consent documents must include:
(i) If the research involves risks to their fitness for duty (e.g., health, availability to perform job, data breach), the informed consent document (ICD) must inform DoD-affiliated personnel about these risks and that they should seek command or component guidance before participating.
(ii) If applicable, a statement of potential risks for the revocation of clearance, credentials, or other privileged access or duty.
(iii) A statement that the DoD or a DoD organization is funding the study.
(iv) A statement that representatives of the DoD are authorized to review research records.

Confidentiality Protections (DoDI 3216.02 section 3.14)

(a) Data or information acquired by the DoD component under a pledge of confidentiality for exclusively statistical purposes must be used exclusively for statistical purposes and may not be disclosed in identifiable form for any other purpose, except with the informed consent of the respondent.
(b) All studies involving large scale genomic data collected on/from DoD-affiliated personnel will apply an DHHS Certificate of Confidentiality.

Sharing Oversight of Research with Another Organization

When serving as the reviewing IRB for a DoD-covered research study, a written, reliance agreement must define the responsibilities of the DoD organization and non-DoD reviewing IRB, including but not limited to:
(a) DoD institutions collaborating with non-DoD institutions (i.e. University of Missouri) may rely on a collaborating non-DoD institution's IRB if the following conditions are met (DoDI 3216.02 section 3.5):

(i) Each institution engaged in non-exempt human participant research must have a current federal assurance of compliance.
(ii) The non-DoD institution's IRB is registered in accordance with Subpart E of 45 CFR 46.
(iii) The DoD institution reviews the protocol to ensure all applicable local and DoD requirements are addressed in the protocol.
(iv) The DoD institution, non-DoD institution, and the non-DoD institution's IRB have a written agreement defining the responsibilities and authorities of each institution in complying with all legal requirements. This agreement must specify that the non-DoD IRB will apply the DoD requirements specified in DoDI 3216.02, including but not limited to non-DoD institutional responsibilities defined under DoDI 3216.02 section 3.6(b).
(v) If the research constitutes classified human participant research, the COHRP must approve the agreement to rely on the non-DoD institution's IRB.
(vi) See the Multi-Site Research & IRB Reliance Process SOP for additional information regarding reliance procedures.

Non-Compliance, Unanticipated Problems, Suspensions and Terminations

See the MU Non-Compliance, Unanticipated Problems, Suspensions and Terminations, and Reporting SOP for DoD Reporting Requirements.

DoD Documentation/Records

Records maintained by MU that document compliance or noncompliance with DoD requirements shall be made accessible for inspection and copying by representatives of the DoD.

<u>DoD REFERENCES</u>

DoDI 3216.02 (April 15, 2020), which incorporates other laws, regulations, and DoD Instructions, including but not limited to requirements under:
o US Code Title 50, Section 1520a (Restrictions on use of human participants for testing of chemical or biological agents)

- o 10 USC 980 (Limitation on use of humans as "experimental subjects")
- o 10 USC 139 (Inclusion of women and minorities in clinical research projects)
- o Executive Order 12333 of December 4, 1981 as amended, section 2.10 (Regarding classified research involving human participants).

References:

Combined Policies January 21, 2019:
Working with Other Agencies
Approval Dates: June 10, 2010; July 1, 2011; July 15, 2014; March 1, 2015; July 1, 2015; June 8, 2017
Department of Defense
Approval Dates: June 10, 2010; July 1, 2011; March 1, 2015; July 1, 2015; June 8, 2017