

**IRB Policy and Procedure**

|  |  |
| --- | --- |
| **Wayne State University**  **Institutional Review Board** | |
| **Subject** | **6-7 Additional Regulations for Research Involving other Federal Agencies** |
| **Approvals** | Administrative, Office of General Counsel & IRB Committee Approval: 04/2020, Administrative Approval 11/2024, IRB Approval 3/2025 |

There are several federal agencies that conduct or support human research. A number of these federal agencies have created additional agency-specific regulations for the research they support. Each Institutional Review Board (IRB) is responsible for ensuring that investigators and research staff meet these additional regulations when conducting research supported by a particular agency. This policy provides guidance to Wayne State University (WSU) researchers whose human subjects’ research involves any component of the following federal agencies:

* Department of Justice ([28 CFR 46](https://www.ecfr.gov/cgi-bin/text-idx?SID=70b5ba5c3d495eaca4040e9793c197e4&node=28:2.0.1.1.4&rgn=div5)),
* Department of Energy ([10 CFR 745](https://www.gpo.gov/fdsys/pkg/CFR-2010-title10-vol4/xml/CFR-2010-title10-vol4-part745.xml)),
* Department of Education ([34 CFR 97](https://www.ecfr.gov/cgi-bin/text-idx?SID=393301a7cdccca1ea71f18aae51824e7&node=34:1.1.1.1.31&rgn=div5)),
* Environmental Protection Agency ([40 CFR 26](https://www.govinfo.gov/content/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml)).

Information about research involving the Department of Defense can be found in WSU Policy 06-06 Department of Defense Requirements for Human Subject Research Protection

Investigators must comply with all applicable requirements of the federal agency involved in the conduct of or support of human research in addition to all other applicable regulations, policies, and the requirements of the IRB of record. Investigators are responsible for clearly indicating within their IRB submission materials all federal agencies involved in the conduct or support of the proposed research.

1. **Department of Justice (DOJ)**

DOJ is not currently (as of 3/3/2019) a signatory to the revised Common Rule. Per notice on National Institute of Justice [website](https://nij.ojp.gov/funding/human-subjects-and-privacy-protection), awardees must follow 28 CFR 46, including the exemption categories, and IRB documentation must site 28 CFR 46, NOT 45 CFR 46. Discuss with Heather!

The U.S. Department of Justice (DOJ) is not currently a signatory to the revised Common Rule. DOJ’s regulations for the protection of human subjects at [28 CFR 46](https://www.ecfr.gov/cgi-bin/text-idx?SID=70b5ba5c3d495eaca4040e9793c197e4&node=28:2.0.1.1.4&rgn=div5) are consistent with the pre-2018 Common Rule requirements (when DOJ was a signatory). DOJ has not adopted Subparts B, C and D. The National Institute of Justice (NIJ) and the Office of Justice Programs (OJP) conduct and fund DOJ research. Confidentiality regulations for DOJ research are described at [28 CFR 22](http://www.gpo.gov/fdsys/pkg/CFR-2004-title28-vol1/pdf/CFR-2004-title28-vol1-part22.pdf). Research conducted within the Federal Bureau of Prisons is subject to the requirements described at [28 CFR Part 512](https://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=28:2.0.3.1.7.2).

This section summarizes additional requirements for the conduct and IRB review of human subjects research conducted or supported by DOJ/NIJ/OJP (including funding through grants, sub-grants, contracts, subcontracts, cooperative agreements, and interagency agreements) and human subjects research conducted in the Federal Bureau of Prisons.

## **1.1 Principal Investigator Responsibilities**

In addition to complying with the pre-2018 Common Rule requirements PIs conducting research supported by DOJ/NIJ/OJP have the following responsibilities. PIs must:

1. Have a privacy certificate approved by the NIJ Human Subjects Protection Officer. This is required for all projects.
2. Submit a Privacy Certificate to NIJ to document understanding of investigator’s obligations under the confidentiality regulations found in [28 CFR 22](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl). NIJ provides guidelines for the certificate on it’s [website](https://www.nij.gov/funding/humansubjects/pages/privacy-certificate-guidance.aspx);
3. Comply with the requirements of the Privacy Certificate, including the requirement to obtain [separate written consent](https://www.nij.gov/funding/humansubjects/Pages/faqs.aspx) for the reporting of domestic, child, or elder abuse;
4. Inform subjects (in the confidentiality section of the consent form) that private, identifiable information will be kept confidential and will only be used for research and statistical purposes;
   * If, due to sample size or some unique feature, the identity of the individual cannot be maintained, the subjects need to be explicitly notified.
   * If the investigator intends to disclose any information, the subject needs to be explicitly informed what information would be disclosed, under what circumstances, and to whom. The subject must be informed of any potential risks which may result from this disclosure and must explicitly provide prior written consent
5. When applicable, disclose in the consent form that the research is funded by DOJ/NIJ/OJP;
6. Submit a copy of the IRB approval as well as supporting documentation of the IRB’s institutional affiliation, assurance, etc. to the NIJ prior to initiation of any research activities that are not exempt from the requirements of 28 CFR 46; or

* Submit supporting documentation of the IRB’s determination that the research qualifies for exemption under 28 CFR 46.101(b);

1. Comply with [NIJ’s policy](https://www.nij.gov/funding/humansubjects/Pages/confidentiality.aspx) for the protection of the privacy and well-being of participants in NIJ research studies through the statutory protection provided to private information under the authority of [42 U.S.C. § 3789g](https://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap46-subchapVIII-sec3789g.htm) and the other DOJ regulations on the Confidentiality of Identifiable Research and Statistical Information found in [28 CFR 22](https://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title28/28cfr22_main_02.tpl);
2. Sign and maintain an Employee Confidentiality Statement for themselves and their research staff. A model employee confidentiality statement can be found at <https://www.nij.gov/funding/humansubjects/employee-confidentiality.htm>; and
3. Send a copy of all de-identified data, including copies of the informed consent document, data collection instruments, surveys and other relevant research materials to the [National Archive of Criminal Justice Data](https://www.nij.gov/funding/data-resources-program/pages/submitting.aspx).

## **1.2 Bureau of Prisons (BOP)**

Additional requirements for research conducted research [within the Bureau](https://www.bop.gov/locations/) are described at [28 CFR Part 512](https://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=28:2.0.3.1.7.2) and in [Program Statement 1070.07](https://www.bop.gov/policy/progstat/1070_007.pdf). Although some research may be exempt from 28 CFR part 46 under 46.101(b)(5), as determined by the Office of Research and Evaluation (ORE) of the Bureau, no research is exempt from 28 CFR Part 512. However, ORE may determine that certain activities are not research (e.g., implementation of Bureau initiatives through a pilot project).

IRB approval must be obtained by the WSU IRB (first) and the BOP IRB.

The following principles and requirements for research conducted within BOP are in addition to those outlined in 28 CFR 46 and will be evaluated during the IRB review.

### **1.2.1 Requirements for Approval:**

1. The PI must have academic preparation or experience in the area of study;
2. The PI must assume responsibility for actions of other research team members;
3. PI’s who are not employees of BOP must sign a [statement of compliance](https://www.bop.gov/resources/pdfs/oreresearcherstatement.pdf);
4. The rights, health, and human dignity of subjects must be respected;
5. The project must have an adequate research design and contribute to the advancement of knowledge about corrections. The research protocol/proposal must have a comprehensive statement that includes:
   * Review of related literature
   * Detailed description of the research method
   * Significance of anticipated results and their contribution to the advancement of knowledge
   * Specific resources required from the Bureau of Prisons
   * 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
   * Description of steps taken to minimize any risks.
6. The research design must be compatible with both the operation of prison facilities and the protection of human subjects. Researchers must observe the rules of the institution or office where the research is conducted;
7. The project may not involve medical experimentation, cosmetic research, or pharmaceutical testing;
8. The project must minimize risk to subjects and risks to subjects must be reasonable in relation to anticipated benefits;
9. The research protocol/proposal must include a description of physical or administrative procedures to be followed to:
   * Ensure the security of any individually identifiable data that are being collected for the study
   * Destroy research records or remove individual identifiers from those records when the research has been completed
10. The research protocol/proposal must include a description of any anticipated effects of the research study on organizational programs and operations
11. Selection of subjects within any one institution must be equitable;
12. IRB Submission documents must include all relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules
13. IRB Submission documents must include a statement regarding assurances and certification required by 28 CFR 46, if applicable
14. Incentives may not be offered to inmate subjects 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 compensation (i.e., do not exceed twice the minimum wage for each hour of the subject's expected participation in the research activity) for time and effort may be offered to non-inmate subjects who are both:
      1. No longer in BOP custody; and
      2. Participating in authorized research conducted by Bureau employees or contractors.

### **1.2.2 Access to BOP Records:**

1. Employees, including consultants, of the BOP who are conducting authorized research projects may be provided access to those records relating to the subject which are necessary to the purpose of the research project without having to obtain the subject’s consent (with a waiver of consent approved by the IRB);
2. Except as described below, non-employees of the BOP are limited in access to information to that information available under the Freedom of Information Act (FOIA);
3. A non-employee of the BOP may receive records that are not individually identifiable when advance written assurance that the record(s) will be as a statistical research or reporting record is provided to the agency. [[28 CFR 512.15](https://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=28:2.0.3.1.7.2#se28.2.512_115)]

### **1.2.3 Informed Consent Requirements:**

1. Informed consent must be sought, when applicable (See [28 CFR 512.15](https://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=28:2.0.3.1.7.2#se28.2.512_115) and [512.16](https://www.ecfr.gov/cgi-bin/text-idx?rgn=div6&node=28:2.0.3.1.7.2#se28.2.512_116)) and follow the requirements outlined in [BP-S606](https://www.bop.gov/resources/pdfs/orebp_s606.pdf);
2. Additional required consent elements for research conducted within the BOP:
   1. Identification of the researchers;
   2. Anticipated uses of the results of the research;
   3. 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);
   4. 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 participant indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the participant is an inmate, indicates intent to leave the facility without authorization; and
   5. A statement that participation in the research project will have no effect on the inmate participant's release date or parole eligibility.
3. Documentation of consent –
   1. Researchers (not employed by the BOP) must 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 must be submitted to the Chairperson of the appropriate BOP IRB. See [Program Statement 1070.07](https://www.bop.gov/policy/progstat/1070_007.pdf) for requirements that apply when consent is obtained by an employee or contractor of BOP;
   2. The original of any signed consent form must be placed in the specific research project's file at the institution where the research is conducted. A copy of any signed consent form which grants a researcher access to an Inmate's Central File must be placed in the non-disclosable portion of the Inmate Central File and a copy must be offered to the inmate.

### **1.2.4 Post-Approval Requirements:**

1. Except as noted in the informed consent form, researchers may not provide identifiable research information to any person without the subject’s prior written consent to release the information (e.g., identifiable research information cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without written consent);
2. Except for computerized data records maintained at an official Department of Justice 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;
3. 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.
4. At least once a year, the PI must provide the Chief, Office of Research and Evaluation, with a report on the progress of the research.
5. At least 12 working days before any report of findings is to be released, the PI must distribute one copy of the report to each of the following: The Chair of the BOP Research Review Board, the Regional Director, and the Warden of each institution that provided data or assistance. The PI must include an abstract in the report of findings.
6. The PI must assume responsibility for actions of any person engaged to participate in the research project as an associate, assistant, or subcontractor to the investigator.
7. 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;
   1. In any publication of results, the PI must acknowledge the Bureau's participation in the research project; and
   2. The PI must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
   3. The PI must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.

# Department of Energy (DOE)

The U.S. Department of Energy (DOE) is a signatory to the Common Rule with regulations equivalent to 45 CFR 46 published under [10 CFR 795](https://www.gpo.gov/fdsys/pkg/CFR-2010-title10-vol4/xml/CFR-2010-title10-vol4-part745.xml). Research conducted or supported by DOE, or performed in DOE facilities, is subject to additional requirements for investigators and for reviewing IRBs. These requirements are outlined in this section.

**2.1 Definitions:**

DOE expands upon the definitions provided in the Common Rule with the following additional or modified definitions:

**Adverse Event.** Any unfavorable medical occurrence in a human subject, including any abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subjects participation in the research, whether or not considered related to the subject’s participation in the research. A significant adverse event is an adverse event that is unexpected and substantively impacts the human subjects.

**De-identified Data.** A data set that has no, or limited, identifiers and for which a person with current knowledge of generally accepted scientific principles determines that the risk that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient, to identify an individual who is a subject of the information, has been reduced to the extent practicable. A graded approach must be used in balancing de-identification of the datasets and the usability of the dataset to accomplish the needed research.

**Generalizable**. Information/research findings that can be applied to populations or situations beyond that studied.

**Personally Identifiable Information (PII).** Any information collected or maintained about an individual, including but not limited to, education, financial transactions, medical history and criminal or employment history, and information that can be used to distinguish or trace an individual’s identity, such as his/her name, Social Security number, date and place of birth, mother’s maiden name, biometric data, and any other personal information that is linked or linkable to a specific individual.

**Research.** A systematic investigation, including research development, testing and evaluation, designed to contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.

**Unanticipated Problem.** In general, to be classified as an unanticipated problem, any incident, experience, or outcome should meet all three of the following criteria:

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

**2.1.1 Expansion of Definition of Research with Human Subjects for Research Involving Intentional Modification of the Human Environment:**

DOE has expanded the definition of human subjects research found at 45 CFR 46 as follows:

1. Research involving human participants also includes studies that involve the intentional modification of the human environment; generalizable includes the study of tracer chemicals, particles, or other materials to characterize airflow,
2. Generalizable also includes studies in occupied homes or offices that:
3. Manipulate the environment to achieve research aims,
4. Test new materials,
5. Involve collecting information on occupants’ views of appliances, materials, or devices installed in their homes or their energy-saving behaviors through surveys and focus groups.
6. Human Terrain Mapping (HTM) – HTM is defined by DOE as: research and data gathering activities primarily conducted for military or intelligence purposes to understand the “human terrain,”—the social, ethnographic, cultural, and political elements of the people among whom the U.S. Armed Forces are operating and/or in countries prone to political instability. This work includes observations, questionnaires, and interviews of groups of individuals, as well as modeling and analysis of collected data, and may become the basis for U.S. military actions in such locations. In addition to HTM, such activities are often referred to as human social culture behavior (HSCB) studies.

**2.2 Protection of Data**

Research involving human subjects must also comply with Federal and DOE-specific requirements for protecting Personally Identifiable Information (PII). Protocols for research involving PII or PHI must address DOE’s specific requirements for the protection of such information, these requirements are currently outlined on DOE’s website “[Frequently Asked Questions for Researchers](https://science.osti.gov/ber/human-subjects/About/Researchers/Frequently-Asked-Questions#Section2).” Additional information on DOE’s requirements for the protection of research data is available on DOE’s website “[DOE-Specific Requirements](https://science.osti.gov/ber/human-subjects/Regulations-and-Requirements/DOE-Specific-Requirements#top)”.

The IRB will review the investigator’s plan for the protection of data and may accept the plan as proposed or require changes to enhance protections and ensure compliance with DOE and other applicable requirements.

Any breach involving PII must be reported:

* Immediately upon a finding of a suspected or confirmed data breach involving 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 Order 206.1
* Within 48 hours the DOE or the National Nuclear Security Administration (NNSA) Human Subject Protection (HSP) Program manager must also be notified of any corrective actions taken and consulted regarding the plan for any remaining corrective actions. Corrective actions must also be reported to the IRB(s) of record in accordance with their policies and procedures. The IRB may enhance the plan as appropriate to ensure the protection of human subjects but may not remove or diminish any component of the plan that DOE has accepted or required.

See IRB Policy 13-1 Unanticipated Problems & Other Reportable Events for information about IRB reporting requirements for a breach of confidentiality.

**2.2.1 Requirements include:**

1. Keeping PII confidential;
2. Releasing PII only under a procedure approved by the responsible IRB and DOE;
3. Using PII only for purposes of the IRB-approved project; handling and marking documents containing PII as “containing PII or containing Protected Health Information (PHI)”;
4. Establishing and documenting safeguards to prevent unauthorized use or disclosure of PII and PHI;
5. Protecting PII stored on removable media using encryption procedures that are compliant with Federal standards (FIPS-140-2 certified);
6. Sending removable media containing PII by express overnight service with signature and tracking capability;
7. Sending passwords to encrypted files separately from the files; and
8. Using 2-factor authentication for log-on access for remote systems.

Investigators must describe the measures that they will employ to protect the confidentiality of subject information and certify compliance with the above requirements on their IRB application. The IRB may accept the plan as described by the investigator or require changes to enhance data protections and ensure compliance with the above.

Loss or suspected loss of PII/PHI must be reported **immediately** upon discovery, (**as soon as aware of incident**), to the DOW and the IRB.

## **2.3 Classified Research**

Per Wayne State University Code University Research policy section 2.41.01.140: Classified research, that is any research placed under restrictions that prevent it from being freely described and its results openly published in the traditional manner, shall be excluded. This provision may be waived in a national emergency, and then only in circumstances that require University participation. A sponsor, upon request, may have the privilege of reviewing a report of the results of an investigation prior to publication, but publication delays beyond 90 days are not acceptable. Additional details about this process is described in the Wayne State University policy titled: Requesting a Waiver for Restricted and Proprietary Research.

Under such national security circumstances, investigators who seek to engage in classified research must obtain special permission from WSU’s Institutional Official (IO) who will engage other appropriate organizational leaders in the decision-making process. Upon approval from the IO, classified research must adhere to the following DOE restrictions:

When DOE research is classified, the following requirements and restrictions apply:

1. IRB Review
   1. Convened IRB review is required, even when a study would otherwise qualify for expedited or exempt review;
   2. If the IRB believes that the proposed research can be thoroughly reviewed in an unclassified manner, a waiver of the requirements of this part can be requested via submission of a waiver request, using the appropriate form and signed by the IRB Chair, to the DOE HSP Program Manager
   3. In addition to the IRB membership and quorum requirements outlined elsewhere in this manual, an unaffiliated nongovernmental (i.e., not a Federal employee or a DOE contractor) voting member with appropriate security clearance must be in attendance;
   4. The IRB must determine whether potential human subjects need access to classified information in order to decide whether to participate;
   5. Any IRB member can appeal an approval decision to the DOE IO, Secretary of Energy, and Director of the Office of Science and Technology Policy, in that order;
   6. After IRB approval, the DOE IO must review proposed projects and determine whether to brief the Secretary, approve, or disapprove the project; and
   7. Annually, no later than October 15th, the IRB must submit information about classified reviews that took place during the DOE fiscal year by submitting the appropriate form to the DOE and NNSA Program Manager
2. Informed Consent
   1. When conducting classified research, the IRB may not grant a waiver of the consent process or waiver of documentation of consent.
   2. 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 745.104.For Classified human subjects research (in whole or in part):
      1. Exemptions (as per 10 CFR 745.107) and expedited review cannot be used. If the research meets a particular exemption or expedited category it many be noted, but full IRB review is required.
      2. A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR 745.104.
   3. The identity of the sponsoring Federal agency must be disclosed to subjects, unless the Sponsor requests that the information is not disclosed because doing so could compromise intelligence sources or methods, and the research involves no more than minimal risk, and the IRB determines that subjects will not be adversely affected by not disclosing the Sponsor’s identity;
   4. The informed consent document must state that the project is classified and what that means for the purposes of the proposed project and what part of the research that applies to.
   5. The IRB must determine if participants need access to classified information to make a valid decision about whether to provide informed consent.
   6. Consent documents must include additional DOE elements of disclosure.

## **2.4 DOE Employees, Contractors, and Students**

DOE considers DOE personnel (employees, contractors, and students) to be vulnerable to pressures to cooperate with research conducted by their managers and/or coworkers. The IRB must consider whether the proposed plan for the recruitment, consent, and ongoing participation adequately protects vulnerable populations. The IRB must consult with the DOE Human Subjects Protection Manager (HSP) to determine whether there are any [DOE site-specific requirements](https://science.energy.gov/~/media/ber/human-subjects/pdf/rules/DOE_Institutional_Official_Letter.pdf) that should be taken into consideration.

## **2.5 Reporting Requirements**

In addition to the IRB’s reporting requirements outlined in WSU IRB policy 13-1 Unanticipated Problems and Other Reportable Events, investigators must report the following **within 48 hours** to the IRB and the DOE HSP Manager when conducting DOE research:

1. Any significant adverse events, unanticipated problems, and complaints about the research;
2. Any non-compliance with applicable regulations, IRB requirements, DOE HSP program procedures or other requirements; and
3. Any suspension or termination of IRB approval.

Investigators must **immediately** (as soon as aware) report any finding of a suspected or a confirmed data breach involving PII.

Reports should include a description of any corrective actions to be taken. The HSP Program Manager and IRB will review the report and may accept or modify the corrective action plan and take any other actions necessary to ensure the protection of human subjects and the integrity of the research.

# 3. Department of Education (ED)

The U.S. Department of Education (ED) is a signatory to the Common Rule with regulations equivalent to 45 CFR 46 published under [34 CFR 97](https://www.ecfr.gov/cgi-bin/text-idx?SID=393301a7cdccca1ea71f18aae51824e7&node=34:1.1.1.1.31&rgn=div5).

ED has not adopted Subpart B (Pregnant Women, Fetuses, or Neonates) or Subpart C (Prisoners) of the Common Rule.

ED requires reporting of alleged (1) unanticipated problems involving risks to subjects or others; and, (2) serious or continuing noncompliance with the Common Rule or Subpart D (protection of children in research).

# Related Policies

# WSU IRB Policy 8-2 Vulnerable Participants: Children as Research Participants

# 3.1 Definitions

**Children:** Per Department of Education 34 CFR 97.402(a) children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

**Instructional Material** means instructional content that is provided to a student, regardless of its format, including printed or representational materials, audio-visual materials, and materials in electronic or digital formats (such as materials accessible through the Internet). The term does not include academic tests or academic assessments.

**Invasive Physical Examination** means any medical examination that involves the exposure of private body parts, or any act during such examination that includes incision, insertion, or injection into the body, but does not include a hearing, vision, or scoliosis screening.

**Personal Information** means individually identifiable information including: (1) a student’s or parent’s first and last name; (2) a home or other physical address (including a street name and the name of a city or town); (3) a telephone number; or, (4) a Social Security Number.

**Research or Experimentation Program or Project** means any program or project in any program that is designed to explore or develop new or unproven teaching methods or techniques.

**3.2 Family Educational Rights and Privacy Act (FERPA)**

The [Family Educational Rights and Privacy Act](https://studentprivacy.ed.gov/) (FERPA) is a Federal law that protects the privacy of student education records at educational entities that receive funds from the ED. In general, schools must have written permission from the parent or eligible student to release any information from a student’s education record.

The IRB does not have any legal or regulatory responsibility in its role related to FERPA, however the best practices is for the IRB to recognize when FERPA applies, and alert researchers of their obligations when FERPA applies the research under review.

When FERPA allows schools to disclose personally identifiable information from an education record of a student without consent:

1. Develop, validate, or administer predictive tests;
2. Administer student aid programs; or
3. Improve instruction. [[34 CFR 99.31(a)(6)](https://www.gpo.gov/fdsys/pkg/CFR-2010-title34-vol1/xml/CFR-2010-title34-vol1-sec99-31.xml)]

A written agreement with the receiving organization is required, including:

1. The purpose, scope, and duration of the study(ies);
2. The information to be disclosed;
3. A requirement that the receiving organization uses the personally identifiable information from the educational records only for the purpose(s) of the study as stated in the agreement;
4. A requirement that the receiving organization conducts the study in a manner that does not permit personal identification of students and parents by anyone other than representatives of the organization with legitimate interests; and
5. A requirement that the receiving organization destroys or returns all personally identifiable information when the information is no longer needed for the purposes for which the study was conducted and that specified the time period in which the information must be returned or destroyed.

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

1. Students’ names and other direct identifiers, such as students’ Social Security Numbers or student numbers;
2. Indirect identifiers, such as the name of students’ parents or other family members, the students’ or families addresses, and personal characteristics or other information that would make the students’ identities easily traceable, and dates and places of birth and mothers’ maiden names;
3. Biometric records, including 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; and
4. Other information that, alone, or in combination, is linked or linkable to a student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify to student with reasonable certainty.

When FERPA applies, investigators must provide the IRB with information describing how they will ensure compliance with the rule. A letter of support or other documentation from the school supporting the conduct of the research should be provided. The IRB will review the information provided to verify compliance, including verification that permission for the use of the records will be obtained or that it is not required under an allowed use or exception.

**3.3 Protection of Pupil Rights Amendment (PPRA)**

The [Protection of Pupil Rights Amendment](https://studentprivacy.ed.gov/topic/protection-pupil-rights-amendment-ppra) (PPRA) affords parents of elementary and secondary students certain rights regarding the conduct of survey, collection and use of information for marketing purposes, and certain physical exams. PPRA applies to the programs and activities of a state educational agency (SEA), local educational agency (LEA), and any other recipient of ED funds.

The IRB does not have any legal or regulatory responsibility in its role related to PPRA, however the best practices is for the IRB to recognize when PPRA applies, and alert researchers of their obligations when PPRA applies the research under review.

**3.3.1 Rights under PPRA**

When research is funded by ED, no student can be required to submit without prior consent to a survey that concerns one or more of the following protected areas:

1. Political affiliations or beliefs of the student or the student’s parent;
2. Mental and psychological problems of 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; or
8. Income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program.

Parents have the right to receive notice and an opportunity to opt a student out of:

1. Any other survey that concerns any of the above protected areas, regardless of funding;
2. Any non-emergency, invasive physical exam or screening required as a condition of attendance, administered by the school or its agent, that is not necessary to protect the health and safety of a student, except for hearing, vision, or scoliosis screenings, or any physical exam or screening permitted or required under state law; and
3. Activities involving collection, disclosure, or use of personal information collected from students for marketing or to sell or otherwise distribute the information to others. (This does not apply to the collection, disclosure, or use of personal information collected from students for the exclusive purpose of developing, evaluating, or providing educational products or services for, or to, students or educational institutions.)

Parents also have the right to inspect upon request and before administration or use:

1. Surveys that concern any of the protected areas and surveys created by third parties;
2. Instruments used to collect personal information from students for any of the above marketing, sales, or other distribution purposes;
3. Any instructional material used as part of the educational curriculum for the student; and
4. Instructional material, including teachers’ manuals, films, tapes, or other supplementary instructional material, which will be used in conjunction with any research or experimentation program or project.

# 4. Environmental Protection Agency (EPA)

The Environmental Protection Agency (EPA) ) is a signatory to the Common Rule with regulations equivalent to 45 CFR 46 published under [40 CFR 26](https://www.ecfr.gov/cgi-bin/text-idx?SID=4e00524a27ed5c83e9596a79db1326c8&mc=true&node=sp40.1.26.a&rgn=div6) (Subpart A). EPA has outlined additional regulations that apply to EPA research in the following subparts:

[Subpart B](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.b&rgn=div6) – Prohibition of Research Conducted or Supported By EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

[Subpart C](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.c&rgn=div6) – Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA

[Subpart D](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.d&rgn=div6) – Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA

[Subpart K](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.k&rgn=div6) – Basic Ethical Requirements for Third Party Human Research for Pesticides Involving Intentional Exposure of Non-Pregnant, Non-Nursing Adults

[Subpart L](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.l&rgn=div6) – Prohibition of Third Party Research Involving Intentional Exposure to a Pesticide of Human Subjects who are Children or Pregnant or Nursing Women

[Subpart M](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.m&rgn=div6) – Requirements for Submission of Information on the Ethical Conduct of Completed Human Research

[Subpart O](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.o&rgn=div6) – Administrative Actions for Noncompliance

[Subpart P](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.p&rgn=div6) – Review of Proposed and Completed Human Research

[Subpart Q](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.q&rgn=div6) – Standards for Assessing Whether to Rely on the Results of Human Research in EPA Actions

Additional EPA requirements for human research are outlined in [EPA Order 1000.17A](https://www.epa.gov/sites/production/files/2016-06/documents/2016_policy_order_revision_6-10-16.pdf) “Policies and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research” and [EPA Order 1000.17B](https://www.epa.gov/sites/production/files/2019-09/documents/order_1000_17b.pdf) “Policy for Increasing Access to Results of EPA-Funded Extramural Scientific Research”.

EPA regulations and requirements for the protection of human subjects apply to research supported or conducted by the EPA **and** to research in which the intent is submission of data to the EPA or when the results of the research may be held for later inspection by the FDA.

The information provided in this section summarizes key EPA standards and requirements.

### **4.1 EPA Definitions:**

**Intentional Exposure** - Research involving intentional exposure of a human subject means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study.

**Observational Research -** Observational research means any human research that does not meet the definition of research involving intentional exposure of a human subject.

**Observational Human Exposure Studies.** As defined in [Scientific and Ethical Approaches for Observational Exposure Studies](https://cfpub.epa.gov/si/si_public_record_report.cfm?Lab=NERL&dirEntryId=191443) (SEAOES), observational human exposure studies are studies that involve the collection of environmental samples, data, and information from study participants in their everyday environments as they go about their normal activities. They involve neither the deliberate exposure of participants nor the control of environmental conditions in a way that impacts the participants’ naturally occurring exposures.

**Pesticide -** Pesticide means any substance or mixture of substances meeting the definition in 7 U.S.C. 136(u) (Federal Insecticide, Fungicide, and Rodenticide Act, section 2(u)).

**Substance –** A substance includes any chemical, biological organism, or physical property tracked or regulated by the EPA or identified in an environmental statute. The [Substance Registry Services (SRS)](http://ofmpub.epa.gov/sor_internet/registry/substreg/home/overview/home.do) is the EPA’s central system for information about substances tracked or regulated by EPA.

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

**Child –** A child is a person who has not attained the age of 18.

**Guardian** **-** 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.

**Parent -** Parent means a child's biological or adoptive parent.

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

### **4.2 EPA Human Subjects Research Review Official (HSRRO) Approval**

All human subjects research conducted or supported by EPA must either be approved or be acknowledged as exempt research by the EPA Human Subjects Research Review Official (HSRRO) before any work involving human subjects research can begin.

To obtain approval or a concurrence of exemption by the HSRRO, researchers must submit the IRB-approved research package or documentation of exemption, including evidence of IRB approval and any correspondence between the IRB and the researchers. Researchers must also provide evidence of a Federalwide Assurance (FWA) on file with the U.S. Department of Health and Human Services (HHS) or other agency that their institution or organization will comply with regulatory provisions in the Common Rule.

Information about HSRRO review can be found on the following EPA website: <https://www.epa.gov/osa/basic-information-about-human-subjects-research-0>.

Documentation of the HSRRO approval or concurrence of exemption must be submitted to the IRB as an amendment before the research can begin.

### **4.3 PI Reporting Requirements**

After research is approved, PIs are responsible for notifying EPA and the HSRRO (and HSO where applicable) of IRB suspension or termination of the research, of Unanticipated Problems Involving Risk to Subjects or Others that the IRB deems reportable, and any event that is significant enough to result in the removal of a subject from the study. In addition, for grantees of EPA, the PI must notify his/her Project Officer promptly, according to the terms specified by the IRB of record for the project.

The IRB’s reporting requirements are outlined in WSU IRB policy 13-1 Unanticipated Problems and Other Reportable Events

### **4.4 Intentional Exposure**

EPA outlines requirements and restrictions applicable to research involving intentional exposure to substances or pesticides in the following subparts:

* [Subpart B](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.b&rgn=div6) **prohibits** research involving intentional exposure (see definition above) of pregnant women, nursing women, or children.
* [Subpart L](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.l&rgn=div6) **explicitly extends the prohibition** to include intentional exposure of pregnant women, nursing women, or children to a **pesticide**.
* [Subpart K](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.k&rgn=div6) describes the requirements for third-party research involving intentional exposure of non-nursing, non-pregnant adults to substances and pesticides.

Among other provisions, Subpart K requires that:

1. Informed consent is obtained from subjects (there is no provision for LARs or for waiver or alteration of consent);
2. Informed consent must be documented using a written consent form or short form method (there is no provision for waiver of documentation of consent);
3. If the research involves intentional exposure to a pesticide, the prospective subject must be informed of the identity of the pesticide and the nature of its pesticidal function (as an element of consent); and
4. The proposed research must be submitted to the EPA for approval after approval by the IRB(s). The submission requirements are outlined in [§26.1125](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.k&rgn=div6#se40.1.26_11125).

### **4.5 Observational Research**

EPA outlines requirements and restrictions applicable to observational research involving in the following subparts:

* [Subpart C](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.c&rgn=div6) describes the rules that apply to observational research conducted or supported by EPA that involves pregnant women (and thus their fetuses). In summary, such research is subject to the Common Rule Subpart B requirements stipulated at [45 CFR 46.203](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.203) (Duties of IRBs), [45 CFR 46.204](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.204) (Research Involving Pregnant Women or Fetuses), and [45 CFR 46.206](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.206) (Research Involving, After Delivery, the Placenta, the Dead Fetus, or Fetal Material).
* [Subpart D](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.d&rgn=div6) describes the rules that apply to observational research conducted or supported by EPA that involves children. In summary, the subpart stipulates that IRBs may only approve (and that EPA will only fund or conduct) research that satisfies all applicable conditions outlined in the subpart, including that:

1. 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.
2. EPA **will not** conduct or fund observational research that **involves an intervention or procedure that involves greater than minimal risk** to children **unless** the IRB finds and documents that:
   1. 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;
   2. The risk is justified by the anticipated benefit to the subjects;
   3. 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
   4. 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. [§26.406](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=se40.1.26_1406&rgn=div8) describes the requirements for permission from parents (or guardians) and for assent from children. The EPA requirements are consistent with the requirements outlined in [§46.408](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/index.html#46.408) of 45 CFR 46. For each of the allowable categories (above) of observational research involving children, the IRB may determine that the permission of one parent is sufficient.

### **4.6 Observational Human Exposure Studies**

All human observational exposure studies conducted or supported by EPA will adhere to the principles set forth in [SEAOES](https://cfpub.epa.gov/si/si_public_record_report.cfm?dirEntryId=191443). SEAOES addresses six major topic areas:

1. Identifying elements to be considered in study conceptualization;
2. Ensuring protection of vulnerable groups;
3. Addressing privacy and other concerns related to observational human exposure studies;
4. Creating an appropriate relationship between the participant and investigator;
5. Building and maintaining appropriate community and stakeholder relationships; and
6. Designing and implementing strategies for effective communication.

### **4.7 Other EPA Regulations**

* [Subpart M](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.m&rgn=div6) describes the requirement for submission of information about the ethical review and conduct of research whenever a report containing the results of the research is submitted to the EPA for consideration for consideration in connection with actions that may be performed by EPA.
* [Subpart O](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.o&rgn=div6) describes the actions that EPA may take when they find that an IRB, institution, or investigator are not compliant with EPA’s requirements.
* [Subpart P](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.p&rgn=div6) describes the requirements and procedures for EPA’s and EPA’s Human Studies Review Board review of proposed and completed human research under [§26.1125](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=se40.1.26_11125&rgn=div8) and [§26.1701](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=se40.1.26_11701&rgn=div8).
* [Subpart Q](https://www.ecfr.gov/cgi-bin/text-idx?SID=69d436274403f133221d686beac730dd&mc=true&node=sp40.1.26.q&rgn=div6) describes the standards EPA applies in deciding whether to rely upon the results of research involving intentional exposure to substances or pesticides in EPA actions.