



ADDITIONAL HUMAN SUBJECTS PROTECTION REQUIREMENTS BASED ON FEDERAL AGENCY FUNDING

1. Overview

This policy describes additional requirements for human subjects research funded by federal agencies other than the Department of Health and Human Services (DHHS) or the Food and Drug Administration (FDA). The agencies whose requirements are included in this policy are the Department of Defense (DOD), Department of Education (ED), Department of Energy (DOE), Department of Justice (DOJ), and Environmental Protection Agency (EPA).

The purpose of this policy is to describe the requirements, in addition to DHHS and FDA regulations and HRPP policies, for research involving human subjects to be compliant with DOD, ED, DOE, DOJ, or EPA regulations and/or guidance.

2. Definitions

Child/Children (ED): Individual(s) enrolled in research, not above the elementary or secondary education level, who has not reached the age of majority as determined under state law. For purposes of HRPP policy, individuals under 18 years of age are considered children in Ohio unless they meet the definition of emancipated minors. *Note: For the definition of emancipated minors, see the [HRPP Glossary](#).*

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

Prisoner of War (DOD): Individuals under the custody and/or control of the Department of Defense as defined in the *Geneva Convention Relative to the Treatment of Prisoners of War of August 12, 1949*, Articles 4 and 5. In particular, one who, while engaged in combat under orders of his government, is captured by the armed forces of the enemy. *Note: Research involving a detainee (as defined in DOD Directive 2310.01E) as a human subject is prohibited.*

Research Involving a Human Being as an Experimental Subject (DOD): 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. *Note: This definition applies only to activities that are considered to be research involving human subjects and does not include activities that meet the exemption criteria at 32 CFR 219 (Common Rule) or research involving the collection or study of existing data, documents, records, or specimens from living individuals. Research involving a human being as an experimental subject is a subset of research involving human subjects; used only when 10 USC 980 (Limitation on Use of Humans as Experimental Subjects) applies.*

Research or Experimentation Program or Project (ED): Any research program or project that is designed to explore or develop new or unproven teaching methods or techniques.



Specific Component (DOD): Any one of the military branches or organizational entities within the Department of Defense, including the Army, Navy, Air Force, Coast Guard, or Marine Corps.

3. Department of Defense

- A.** All personnel involved in reviewing, approving, supporting, conducting, managing, or overseeing DOD-supported research must complete initial and ongoing research ethics and human subjects protections training appropriate to the individual's involvement, duties, and responsibilities. The DOD-specific component supporting the research (e.g., Department of Navy) may evaluate HRPP training (as described by [Study Team Requirements](#) on the ORRP website) to ensure that an investigator is qualified to perform the research, based its complexity and risk. *Note: DOD may require additional education or professional certification, depending on the research.*
- B.** The definition of "minimal risk," which includes the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" should not be interpreted to include inherent risks certain classes of humans face in their everyday lives. For example, risks in research focused on special populations should not be considered in the context of the inherent risks of their work environments (e.g., emergency responders, pilots, or soldiers in a combat zone) or of having a medical condition (e.g., by having frequent medical tests or constant pain).
- C.** Surveys performed on DOD personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol has been reviewed and approved by the IRB.
- D.** An independent research monitor is required for research involving greater than minimal risk and for some minimal risk studies, when appropriate to provide additional protections for research participants, as described below:
- A research monitor must be appointed by name and independent of the research team; the monitor may be an ombudsman or member of a data and safety monitoring board
 - There may be more than one research monitor (e.g., if different skills or experience are needed) for a study; the duties of the monitor(s) will be based on the risks or specific concerns about the research
 - The IRB must approve a written summary of the research monitor(s)' duties, authorities, and responsibilities
 - The IRB Chair or Institutional Official will communicate with the research monitor(s) to confirm monitor(s)' duties, authorities, and responsibilities
 - Research monitors may perform oversight functions (e.g., observe recruitment, enrollment procedures, and/or the consent process; oversee study interventions or interactions; review monitoring plans and/or unanticipated problems involving risks to subjects or others; oversee data matching, collection, and analysis)
 - Research monitors may discuss the study with researchers, interview research participants, and consult with others outside the study
 - Research monitors may report observations and findings to the IRB or to a designated university official



- Research monitors have the authority to stop a study in progress, remove individuals from study, and/or take any steps necessary to protect the safety and well-being of participants until the IRB can assess the situation
- E.** Investigators and the IRBs will ensure that consent disclosures for research-related injury follow the requirements of the DOD-specific component.
- F.** For “research involving a human being as an experimental subject” (see “Definitions” above), informed consent must be obtained from the subject, with the following exceptions:
1. Consent may be provided by the experimental subject’s legal representative if the research intends to benefit the individual subject. Note: The determination that research is intended to be beneficial to the individual subject must be made by the IRB.
 2. A waiver of consent may be approved by the Assistant Secretary of Defense (ASD) for Research and Engineering (R&E) only for research meeting all of the following conditions:
 - The research is necessary to advance the development of a medical product for the U.S. Military Services
 - The research may directly benefit the individual experimental subject
 - The research is conducted in compliance with all other applicable laws and regulations.
- Note: The ASD(R&E) may delegate the waiver authority described above to the Heads of the Office of the Secretary of Defense and DOD Components (e.g., Secretary of the Navy) if they have appropriate policies and procedures in their management plans. This authority is further delegable only to a DOD Component official who is a Presidential Appointee with Senate Confirmation.
- G.** Exceptions from the requirements for informed consent in planned emergency research are prohibited unless a waiver is obtained from the Secretary of Defense or his/her delegate (e.g., Secretary of the Navy).
- H.** For research involving pregnant women, fetuses, or neonates, or prisoners, additional requirements (including those described in DHHS Subparts B and C, respectively) apply as described below.
1. For research involving pregnant women, fetuses, or neonates, the following additional requirements apply:
 - When applying Subpart B, the phrase “biomedical knowledge” should be replaced throughout with “generalizable knowledge”
 - The applicability of Subpart B is limited to research involving pregnant women that is greater than minimal risk and that includes interventions or invasive procedures for the woman or the fetus, or to research involving fetuses or neonates
 - Fetal research must comply with [42 USC 289G-1, Research on Transplantation of Fetal Tissue](#).



2. For research involving prisoners, the following additional requirements apply:
 - DOD-supported research involving prisoners cannot be reviewed by an expedited procedure
 - When a previously-enrolled research participant becomes a prisoner, in addition to the procedures described by HRPP policy [[Research Involving Prisoners](#)], all of the following are also required:
 - The convened IRB, upon being notified that a research participant has become a prisoner, will promptly re-review the study to ensure that the rights and well-being of the now prisoner-participant are not in jeopardy
 - The convened IRB may only approve a change to the research to allow the prisoner-participant to continue in the study if the participant can continue to provide consent, he/she is capable of meeting the study requirements, the terms of confinement do not inhibit the ethical conduct of the research, and there are no other significant issues preventing the study from continuing as approved
 - IRB approval is limited to allowing the specific prisoner-participant to continue in the study and does not allow recruitment of additional prisoners
 - The Institutional Official and DOD-specific Component office must review and concur with the convened IRB's approval to change the research to include the prisoner-participant.
- I. When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party, including the following:
 - Statement of work and brief description of the research
 - Responsibility for scientific and IRB review
 - Role of sites in subject recruitment
 - Procedures for obtaining informed consent
 - Provisions for oversight and ongoing monitoring
 - Reporting requirements
 - Document retention
 - Assurance of compliance with all relevant human subjects protection requirements at each site
 - For collaborating institutions relying on another institution's IRB, assurance that such reliance does not compromise any standards or requirements
- J. For international research, the investigator must obtain permission to conduct research in the host country by local IRB or ethics review. All local laws, customs, and practices must be followed.



- K.** For research involving U.S. military personnel, additional requirements apply as described below.
1. The following protections for military research participants will be implemented to minimize undue influence:
 - Superiors (e.g., military and civilian supervisors, unit officers, and noncommissioned officers) are not permitted to influence the decisions of their subordinates (e.g., junior enlisted personnel and equivalent civilians)
 - Superiors may not be present at the time of recruitment or during the consent process for members of units under their command
 - Superiors will have a separate opportunity to participate in the research
 - An independent ombudsman will be present when recruitment involves a percentage of a unit
 2. The following limitations on compensation for military research participants are required:
 - Federal personnel may not be paid by any source other than their regular salaries while on duty, including compensation for research participation, except for compensation for blood drawing (up to \$50 per blood draw)
 - Federal personnel may be compensated for research participation when not on duty, in a reasonable amount as approved by the IRB, according to local prevailing rates and the nature of the research.
- L.** Research involving detainees (as defined in DOD Directive 2310.01E), including prisoners of war, is prohibited. *Note: This prohibition does not apply to research involving investigational drugs and devices when used for diagnosis or treatment of a medical condition and when the same products would be offered to members of the U.S. Military Services, in the same location for the same condition, and when consistent with established medical practice (and FDA requirements) involving investigational drugs and devices.*
- M.** The following must be promptly reported to the DOD-specific component's human research protection official or office:
- When significant changes to the research are approved by the IRB
 - Results of continuing IRB review
 - Change(s) in reviewing IRB
 - Notification by any federal department, agency, or national organization that any part of the HRPP is under a "for-cause" investigation involving DOD-supported research
 - Serious and/or continuing noncompliance
 - Any unanticipated problem involving risks to subjects or others for DOD-supported research
 - Any suspension or termination of DOD-supported research



- N.** Records documenting compliance (or noncompliance) with DOD regulations will be made accessible for inspection and copying by DOD representatives at reasonable times and in a reasonable manner.
- O.** For DOD-specific component information, see applicable DOD websites, such as the following:
- [US Army Medical Research and Materiel Command Human Research Protection Office](#)
 - [Department of the Navy Human Research Protection Program](#)

4. Department of Education

- A.** For studies funded by the National Institute on Disability and Rehabilitation Research, when an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities, the IRB must include at least one person primarily concerned with the welfare of these research participants.
- B.** The Family Educational Rights and Privacy Act (FERPA) protects the privacy of students' education records and provides parents and "eligible" students (at least 18 years of age or attending a postsecondary educational institution) certain rights to review, seek to amend, and to provide consent to disclosure of personally identifiable information (PII) in education records. Generally, PII from education records cannot be disclosed without written consent. However, FERPA permits an educational agency or institution to disclose education records and information from education records, including PII, *without* consent in certain circumstances, including those described below.
- 1.** An educational agency or institution may disclose PII in education records without consent to organizations conducting studies for, or on behalf of, educational agencies/institutions to develop, validate, or administer predictive tests; administer student aid programs; and/or improve instruction. The following requirements apply to this exception:
 - The study must be conducted in a manner that does not permit personal identification of parents and students by individuals other than representatives of the organization that have legitimate interests in the information
 - The information must be destroyed when no longer needed for the purposes for which the study was conducted
 - The educational agency or institution (or the State or local educational authority or agency) must enter into a written agreement with the organization that specifies all of the following:
 - The purpose, scope, and duration of the study(ies) and the information to be disclosed
 - That the organization may use PII from education records only to meet the purpose(s) of the study stated in the agreement
 - That the organization must conduct the study in a manner that does not permit personal identification of parents and students and must destroy all PII when no longer needed (as described



above), specifying the time period in which the information will be destroyed.

2. An educational agency or institution may disclose PII in education records without consent if the disclosure is information the educational agency/institution has designated as “directory information” (e.g., name, address, telephone number, date and place of birth, honors and awards, dates of attendance, etc.), and the agency/institution has given public notice to parents and eligible students of all of the following:
 - The types of PII that the agency/institution has designated as directory information
 - A parent's or eligible student's right to refuse to let the agency/institution designate any or all of those types of information about the student as directory information
 - The period of time within which a parent or eligible student has to notify the agency/institution in writing that he/she does not want any or all of those types of information about the student designated as directory information.

3. An educational agency or institution may disclose education records or information from education records without consent if the disclosure is after the removal of all PII, provided that the educational agency/institution (or other party that received the information or education records) has made a reasonable determination that a student's identity is not personally identifiable, whether through single or multiple releases, and taking into account other reasonably available information. The personally identifiable information that must be removed under this exception includes all of the following:
 - Student's name and other direct personal identifiers, such as the student's social security number or student number
 - Indirect identifiers, such as the name of the student's parent(s) or other family members
 - Student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable
 - Date and place of birth and mother's maiden name
 - 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
 - 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
 - Other information requested by a person who the educational agency/institution reasonably believes knows the identity of the student to whom the education record relates.



4. An educational agency or institution, or a party that has received education records or information from education records, may release student level data from education records for education research by attaching a code to each record that may allow the recipient to match information received from the same source when all of the following requirements are met:
 - The educational agency or institution (or other party that releases data as described above) does not disclose any information about how it generates and assigns a record code, or information that would allow a recipient to identify a student based on the code
 - The record code is not used for any purpose other than identifying a record for purposes of education research and cannot be used to ascertain personally identifiable information about a student
 - The record code is not based on a student's social security number or other personal information.
- C. The Protection of Pupil Rights Amendment (PPRA) and No Child Left Behind Act of 2001 provide parents and students certain rights regarding the conduct of surveys, collection and use of information for marketing purposes, and certain physical exams. Also under PPRA, instructional materials must be made available for inspection by parents if the materials will be used in connection with a survey, analysis, or evaluation in which their children participate. Consent or parental permission is required before students are required to complete a survey, evaluation, or analysis involving one or more of the protected areas ("protected information survey") as described below.
1. No student will be required as part of any research project to submit without prior consent to surveys or psychiatric or psychological examination, testing, or treatment in which the primary purpose is to reveal information concerning one or more of the following:
 - Political affiliations or beliefs of the student or the student's parent(s)
 - Mental or psychological problems of the student or the student's family
 - Sex behavior or attitudes
 - Illegal, anti-social, self-incriminating, or demeaning behavior
 - Critical appraisals of other individuals with whom respondents have close family relationships
 - Legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers
 - Religious practices, affiliations, or beliefs of the student or student's parent(s)
 - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
 2. All instructional material, including teachers' manuals, films, tapes, or other supplementary instructional material, that will be used in connection with any research or experimentation program or project must be available for inspection by the parents or guardians of the children involved in the research.



3. Parents of students have the right to inspect, upon the request of the parent, any the following:
 - A survey created by a third party, before the survey is administered or distributed by a school to a student (and within a reasonable period of time after the request is received), including arrangements to protect student privacy in the event of the administration or distribution of a protected information survey to a student
 - Any instructional material used as part of the educational curriculum for the student
 - Any instrument used in the collection of personal information for the purpose of marketing or for selling or other distribution of that information (or providing the information to others for that purpose), before the instrument is administered or distributed to a student (and within a reasonable period of time after the request is received), including arrangements to protect student privacy in the event of collection, disclosure, or use of the student's personal information.
4. Parents of students have the right to opt out of (remove their child from participation in) any of the following:
 - Activities involving the collection, disclosure, or use of personal information collected from students for the purpose of marketing or for selling or other distribution of that information, or providing the information to others for that purpose
 - The administration of any third party (non-Department of Education funded) protected information survey
 - Any non-emergency, invasive physical examination or screening that is required as a condition of attendance, administered by the school or its agent and scheduled by the school in advance, and not necessary to protect the immediate health and safety of the student or of other students, except for hearing, vision, or scoliosis screenings, or any physical exam or screening permitted or required under State law.
5. The requirements concerning activities involving the collection and disclosure of personal information from students for marketing purposes do 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, such as the following:
 - College or other postsecondary education recruitment, or military recruitment
 - Book clubs, magazines, and programs providing access to low-cost literacy products
 - Curriculum and instructional materials used by elementary schools and secondary schools
 - Tests and assessments used by elementary schools and secondary schools to provide cognitive, evaluative, diagnostic, clinical, aptitude, or achievement information about students



- The sale by students of products or services to raise funds for school-related or education-related activities
- Student recognition programs

D. For more information on FERPA or PPRA, including model notifications of parents' and students' rights, see [Family Policy Compliance Office](#) on the [ED website](#).

5. Department of Energy

A. All protocols must address DOE requirements for the protection of personally identifiable information (PII). For additional information on DOE requirements for protecting data in research involving human subjects, see [The U. S. Department of Energy Specific Requirements for Human Subjects Research](#) on the [DOE website](#).

B. The following must be promptly reported (within 48 hours) to the DOE Human Subjects Research (HSR) Program Manager:

- Significant adverse events, unanticipated problems, or complaints about the research, with a description of any corrective actions taken (or to be taken)
- Suspension or termination of IRB approval of research
- Significant noncompliance with HRPP procedures or other requirements

C. Any loss, potential loss, or compromise of PII or PHI must be immediately reported (upon learning of the incident) to:

- The DOE funding office Program Manager, or, if funded by an outside organization, the Program Manager at that institution;
- The applicable DOE site or central IRB. If the DOE Program Manager and/or IRB is unreachable, immediately notify the [DOE Joint Cybersecurity Coordination Center \(JC3\)](#) (1-866-941-2472). See Attachment 1 for the "Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements."

6. Department of Justice

A. Additional requirements for research conducted in the Bureau of Prisons (BOP) are described below.

1. Implementation of BOP programmatic or operational initiatives through pilot projects is not considered to be research.
2. Specific requirements apply to research conducted in the Bureau of Prisons, including the following:
 - The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
 - The research design must be compatible with both the protection of human subjects and operation of prison facilities, and the investigator must observe the rules of the specific institution or office in which the research is conducted.



- The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
 - Incentives may not be offered to help persuade inmates to participate; however, soft drinks and snacks to be consumed at the test setting may be offered. Note: Reasonable accommodations, such as nominal monetary compensation (e.g., not exceeding twice the minimum wage for each hour of the subject's expected participation) for time and effort, may be offered to non-confined research participants who are both no longer in Bureau of Prisons' custody and participating in authorized research being conducted by Bureau employees or contractors.
 - All research projects must be reviewed by the Bureau Research Review Board. Note: The Director, Bureau of Prisons, has final authority to approve or disapprove all research projects.
3. Research protocols must include all of the following:
- A summary statement, which includes names and current affiliations of the investigators; study title, purpose, and location; methods to be employed and study duration; number of participants (staff or inmates) required and amount of time required from each; an indication of risk or discomfort involved as a result of participation; and anticipated results
 - A comprehensive statement, which includes a review of related literature; detailed description of research method(s); significance of anticipated results and their contribution to the advancement of knowledge; specific resources required from the Bureau of Prisons (if any); description of all possible risks, discomforts, and benefits to individual participants or to a class of participants, and a discussion of the likelihood that the risks or discomforts will actually occur; steps taken to minimize any risks; description of physical or administrative procedures that will be followed to ensure the security of any individually identifiable data being collected for the study and to destroy research records or remove individual identifiers from those records when the research has been completed; description of any anticipated effects of the research on organizational programs and operations; and relevant research materials (e.g., vitae, endorsements, sample consent statements, questionnaires, interview schedules)
 - A statement regarding assurances and certification required by federal regulations, if applicable.
4. The following additional elements of consent disclosure are required:
- Anticipated uses of the results of the research
 - Participation is completely voluntary and that the subject may withdraw consent and end participation at any time without penalty or prejudice (and the inmate will be returned to regular assignment or activity as soon as practicable)
 - Exceptions to any guarantees of confidentiality required by federal or state law (e.g., a researcher may not guarantee confidentiality when the subject indicates an intent to commit future criminal conduct or harm)



himself/herself or someone else, or when the subject is an inmate who indicates an intent to leave the facility without authorization)

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

(See [Form BP-A606.010 Informed Consent/Consent to Release Information for Research](#) for more information.)

5. Regarding potentially identifiable information of research participants, the following requirements apply:

- A non-employee of the Bureau of Prisons may receive records in a form not individually identifiable when advance "adequate written assurance" that the record will be used solely as a statistical research or reporting record is provided to the agency.
- Except as noted in the informed consent statement(s), investigators 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 pertains.
- 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.
- If an investigator is conducting a study of special interest to the BOP Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the investigator may be asked to provide ORE with the computerized research data, not identifiable to individual participants, accompanied by detailed documentation. Note: These arrangements must be negotiated prior to the beginning of the data collection phase of the project.

6. The following additional reporting and publication requirements apply:

- At least once a year, an investigator will provide the Chief, Office of Research and Evaluation, with a progress report on the research, meeting the following requirements:
 - At least 12 working days before any report of findings is to be released, an investigator will distribute a copy of the report to the Chair of the Bureau Research Review Board, BOP Regional Director, and the warden of each institution providing data or assistance
 - An abstract should be included in the report of findings
- In any publication of results, an investigator will acknowledge the Bureau's participation in the research project and comply with the following additional requirements:



- An investigator must expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau of Prisons
 - Prior to submitting the results of a research project for publication, an investigator will provide two copies of the material, for informational purposes only, to the Chief, Office of Research and Evaluation, Central Office, Bureau of Prisons.
7. Investigators who are non-employees of the Bureau must sign a statement agreeing to adhere to the requirements of 28 CFR 512 and Program Statement 1070.07. (See [Researcher Statement Form BP-S604.010](#) for more information.)
 8. For more information on conducting research in the Bureau of Prisons, see the [BOP website](#).
- B.** Additional requirements for research funded by the National Institute of Justice (NIJ) are described below.
1. All projects must have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer, regardless of whether the project involves collection of identifiable data. (For more information, see the [Model Privacy Certificate](#).)
Note: A Privacy Certificate is not the same as a Certificate of Confidentiality issued by NIH; identifiable data collected under an approved Privacy Certificate is immune from any legal action under the DOJ confidentiality statute (42 USC 3789g).
 2. All investigators and research staff are required to sign employee confidentiality statements, which are maintained by the responsible investigator. (For more information, see the [Model Employee Confidentiality Statement](#).)
 3. The confidentiality statement on the consent document must state that confidentiality can be broken only if the participant reports immediate harm to participants or others.
 4. Under a Privacy Certificate, investigators and research staff do not have to report current or past abuse unless the participant signs another consent document to allow abuse reporting.
 5. 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, and other relevant research materials. Note: Data sets must be submitted 90 days before the end of the project period.
 6. For more information on DOJ, Office of Justice Programs, or NIJ regulations and policies on the protection of human subjects and confidentiality requirements, see the [NIJ website](#).

7. Environmental Protection Agency

- A.** Research involving the intentional exposure of pregnant women, nursing women, and children to pesticides or any other environmental substance is prohibited.



- B. To provide additional protections for pregnant women and children in observational research, studies involving these participants must comply with 40 CFR 26 [Subpart C-Observational Research: Additional Protections for Pregnant Women and Fetuses Involved as Subjects in Observational Research Conducted or Supported by EPA](#) and [Subpart D-Observational Research: Additional Protections for Children Involved as Subjects in Observational Research Conducted or Supported by EPA](#), as applicable.
- C. IRB determinations and approval must be submitted to the EPA Human Subjects Research Review Official (HSRRO) for final review and approval before beginning the research. For more information on HSRRO review, see [Basic Information about Human Subjects Research](#) on the [EPA website](#).

8. Applicable Regulations/Guidance

10 CFR 745, 10 USC 980, 15 CFR 46, 28 CFR 22, 28 CFR 512, 32 CFR 219, 34 CFR 97, 34 CFR 98, 34 CFR 99, 34 CFR 350, 34 CFR 356, 40 CFR 26, 42 USC 3789, [DOD Directive 3216.02 Protection of Human Subjects and Adherence to Ethical Standards in DOD-Supported Research](#) (11/08/11, updated 10/15/2018), [DOE O 443.1B, Protection of Human Research Subjects](#) (03/17/11), [DOJ BOP Program Statement 1070.07 \(05/12/99\)](#), [DON SECNAV Instruction 3900.39D \(11/06/06\)](#), [EPA Order 1000.17 A1 Policy and Procedures on Protection of Human Research Subjects in EPA Conducted or Supported Research \(06/15/2016\)](#)

9. History

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**Attachment 1.****Checklist for IRBs to Use in Verifying that HS Research Protocols are In Compliance with DOE Requirements**

Research involving human subjects must also comply with Federal and DOE-specific requirements for protecting the personally identifiable information (PII) generated in such research. Methods for protecting such data must be specified in the application.

Requirements include:

- keeping PII confidential;
- releasing PII only under a procedure approved by the responsible IRB and DOE;
- 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)”;
- establishing and documenting safeguards to prevent unauthorized use or disclosure of PII and PHI;
- protecting PII stored on removable media using encryption procedures that are compliant with Federal standards (FIPS-140-2 certified);
- sending removable media containing PII by express overnight service with signature and tracking capability;
- sending passwords to encrypted files separately from the files; and
- using 2-factor authentication for log-on access for remote systems.