

Columbia University  
Institutional Review Board

# Additional Requirements for Protocols Funded by Specific Federal Agencies or Subject to Specific Federal Policies

Reference Document #356

April 4, 2018

During the review of research that is supported or conducted by specific federal agencies, and/or is subject to the requirements of those agencies, or is subject to specific federal policies, the Columbia IRBs consider the respective requirements as they relate to the protection of human subjects and must make specific determinations, e.g., consent, reporting, monitoring. These requirements are in addition to the requirements for approval of research that the IRB considers for all research involving human subjects.

Awareness by researchers of these regulations, policies, and affiliated required determinations will facilitate inclusion, in the submission to the IRB, of the information that must be considered before these determinations can be made.

The information provided in this document supplements information found in the following sections of the IRB Standard Operating Procedures:

- Introduction.C.1. Standard Operating Procedures, Development
- III.E.18. Submission Materials: Federally-Supported or Conducted Research
- VI.A.1. Initial Review (Review of a New Protocol)
- VI.B.13. Review of Research that is Federally-supported or Conducted, or is Otherwise Subject to Federal Policy

The following regulation is applicable to all research funded by an agency that has adopted Subpart A of 45 CFR 46 (the “Common Rule”), and requires IRB review of all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research:

*45 CFR 46.103(f), An institution with an approved assurance shall certify that each application or proposal for research covered by the assurance and by [§46.103](#) of this Policy has been reviewed and approved by the IRB.*

Select requirements for the following agencies/policies are provided in this document. Investigators, IRB members, and IRB staff who have a role in the design, review, and/or conduct of research that is subject to the requirements of these regulations should review the regulations in their entirety. This information is provided for easy reference but may not be inclusive.

[Environmental Protection Agency](#)

[Department of Defense](#)

[National Institute of Justice](#)

[Bureau of Prisons](#)

[Department of Energy](#)

[Department of Education](#)

- [Family Educational Rights and Privacy Act](#)
- [Protection of Pupil Rights Amendment](#)
- [National Institute on Disability and Rehabilitation Research](#)

New information will be added as necessary and/or as appropriate to research under the aegis of Columbia’s IRBs.

## Environmental Protection Agency

Relevant regulations: [40 CFR 26, U.S. Environmental Protection Agency \(EPA\), Subchapter A \(General\), Protection of Human Subjects](#).

The basic EPA policy for the protection of human subjects (40 CFR 26.121, Subpart A) is the same as the DHHS basic regulations for the protection of human subjects (45 CFR 46, Subpart A, aka “The Common Rule”).

The EPA subparts differ significantly from the subparts in the DHHS regulations, as illustrated by the list that follows:

Subpart B: Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women

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

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

Subpart K: Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults

Researchers, IRB members, and IRB administrative staff must consider these requirements in the design, review, and conduct of research that is supported or conducted by, or otherwise subject to, the EPA regulations, including:

- EPA prohibits research involving the intentional exposure of pregnant women, nursing women, or children to any substance.
- The EPA requires application of 40 CFR 26 Subparts C and D to provide additional protections to pregnant women and children as subjects in observational research, i.e., research that does not involve intentional exposure to any substance.
- EPA policy 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.
- For research not conducted or supported by any federal agency that has regulations for protecting human research subjects and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research subjects apply, including:
  - o EPA extends the provisions of the 40 CFR 26 to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance.

o EPA prohibits the intentional exposure of pregnant women, nursing women, or children to any substance.

- Research involving intentional exposure of pregnant women or children to any substance is prohibited and will not be approved by the IRB.
- For research intended for submission to the EPA, research involving intentional exposure of pregnant women or children to any substance is prohibited and will not be approved by the IRBs.
- The IRBs must review observational research involving pregnant women and fetuses using 40 CFR 26 and 45 CFR 46 Subpart B.
- The IRBs may 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 40 CFR 26.406.
- The IRBs may approve observational research involving children that involves greater than minimal risk but presenting the prospect of direct benefit to the individual subjects if the IRB finds and documents that:
  - o 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.
  - o The risk is justified by the anticipated benefit to the subjects.
  - o The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
  - o Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in 40 CFR 26.406.

## Department of Defense

The Department of Defense (DoD, or DOD) follows the DHHS and FDA regulations on human subjects research, but also applies [DoD Directive \(DoDD\) 3216.02](#) "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research."

Specific aspects of the DoD requirements and the IRB review thereof are provided here for easy reference.

Educational Requirements, when research follows Department of Defense (DoD) requirements:

- Initial and continuing research ethics education is required for all personnel who conduct, review, approve, oversee, support, or manage human subjects research.
  - IRB staff will assess, prior to issuance of IRB approval, that personnel have met the educational requirements of the specific DoD component that is sponsoring or conducting the research; personnel who have not satisfied educational requirements will be restricted from participation in the research until the requirements are satisfied.
  - The DoD component may evaluate the education policies to ensure the personnel are qualified to perform the research, based on the complexity and risk of the research.

Requirement for review by DoD for DoD supported or conducted research:

Research performed on Department of Defense (DoD) personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRBs. Surveys performed on DoD personnel must be submitted, reviewed, and approved by the DoD after the research protocol is reviewed and approved by the IRB. When a survey crosses DoD Components, additional review is required:

- Component requirements (Army, Navy, Air Force) – research that crosses Commands requires additional review by a Component Survey Office
- Research that crosses Components – review by Defense Manpower Data Center and Washington Headquarters Service

Requirements for additional review depends on identification of the appropriate office (command or component) and must be made on a case-by-case basis, when necessary.

When conducting multi-site research, a formal agreement between organizations is required to specify the roles and responsibilities of each party.

Clarification of "minimal risk" and "experimental subject" definitions, specific to DoD regulations:

The definition of minimal risk in Department of Defense-sponsored research based on the phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examination or tests" shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life. For example, the risks imposed in

research involving human subjects focused on a special population should not be evaluated against the inherent risks encountered in their work environment (e.g., emergency responder, pilot, soldier in a combat zone) or having a medical condition (e.g., frequent medical tests or constant pain.)

Experimental subjects are a subset of human subjects, the latter as defined in 45 CFR 46, in 32 CFR 219.101(a), and in DoD Directive 3216.02: a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual or identifiable private information. Experimental subjects are those who are involved in 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, in research that is conducted under 10 USC 980(b):

10 USC 980(b): The Secretary of Defense may waive the prohibition in this section with respect to a specific research project to advance the development of a medical product necessary to the armed forces if the research project may directly benefit the subject and is carried out in accordance with all other applicable laws.

Inclusion of military personnel in DoD supported or conducted research:

When research involves U.S. military personnel, the IRBs determine additional protections for military research subjects exist to minimize undue influence:

- Officers are not permitted to influence the decision of their subordinates.
- Officers and senior non-commissioned officers may not be present at the time of recruitment.
- Officers and senior non-commissioned officers have a separate opportunity to participate.
- When recruitment involves a percentage of a unit, an independent ombudsman is present.

When research involves U.S. military personnel, the IRBs determine that limitations on dual compensation are present:

- Individuals are prohibited from receiving pay of compensation for research during duty hours.
- U.S. military personnel may be compensated for research if the subject is involved in the research when not on duty.
- Federal employees while on duty and non-Federal persons may be compensated for blood draws for research up to \$50 for each blood draw.
- Non-Federal persons may be compensated for research participation other than blood draws in a reasonable amount as approved by the IRBs according to local prevailing rates and the nature of the research.

Informed consent considerations for DoD supported or conducted research:

- Consent documents must include:
  - A statement that the DoD or a DoD organization is funding the study.

- A statement that representatives of the DoD are authorized to review research records.
- The IRBs must determine, relative to coverage of research-related injury, that the disclosure includes provisions for research-related injury that follow the requirements of the Department of Defense component.
- The IRBs must determine, relative to coverage of research-related injury, that the disclosure includes provisions for research-related injury that follow the requirements of the Department of Defense component.
- The Assistant Secretary of Defense for Research and Engineering may waive the requirements for consent when all of the following are met:
  - The research is necessarily to advance the development of a medical product for the Military Services.
  - The research may directly benefit the individual experimental subject.
  - The research is conducted in compliance with all other applicable laws and regulations.
- If the research subject does not meet the definition of “experimental subject,” the IRBs are allowed to waive the consent process.
- If the research subject meets the definition of “experimental subject”, the IRBs must prohibit a waiver of the consent process unless a waiver is obtained from the Assistant Secretary of Defense for Research and Engineering.
- If consent is to be obtained from the experimental subjects’ legal representative, the research must intend to benefit the individual subject.
- The determination that research is intended to be beneficial to the individual experimental subject must be made by an IRB.
- An exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of Defense.

Monitoring of DoD supported or conducted research:

When following Department of Defense requirements the IRBs consider the appointment of a research monitor:

- Required for research involving greater than minimal risk, although the IRBs or organizational official can require this for a portion of the research or studies involving no more than minimal risk if appropriate.
- The research monitor is appointed by name and shall be independent of the team conducting the research.
- There may be more than one research monitor (e.g. if different skills or experience are needed).
- The monitor may be an ombudsman or a member of the data safety monitoring board. The IRBs must approve a written summary of the monitors’ duties, authorities, and responsibilities.
- The IRBs or HRPP official shall communication with research monitors to confirm their duties, authorities, and responsibilities.
- The duties of the research monitor are determined on the basis of specific risks or concerns about the research.

- o May perform oversight functions (e.g. observe recruitment, enrollment procedures, and the consent process, oversee study interventions and interactions, review monitoring plans and unanticipated problems involving risks to subjects or others, oversee data matching, data collection and analysis).
  - o May discuss the research protocol with researchers, interview human subjects, and consult with others outside of the study.
  - o Report observations and findings to the IRBs or a designated official.
- The research monitor has the authority to:
    - o Stop a research study in progress.
    - o Remove individuals from study.
    - o Take any steps to protect the safety and well-being of subjects until the IRBs can assess.

Reporting requirements for DoD supported or conducted research:

The following shall be promptly reported (i.e., no longer than 30 days) to the Department of Defense (DoD) human research protection officer:

- o When significant changes to the research protocol are approved by the IRBs.
  - o The results of the IRBs' continuing review.
  - o Change of reviewing IRB.
  - o When the university is notified by any Federal department, agency or national university that any part of the HRPP is under investigation for cause involving a DoD-supported research protocol.
- Any unanticipated problems involving risks to subjects or others for any DoD-supported research must be promptly (i.e., within 30 days of event or notification of event) reported to the DoD human research protection officer.
  - Any suspension or termination of DoD-supported research must be promptly (i.e., within 30 days) reported to the DoD human research protection officer.
  - Determinations of serious or continuing non-compliance of DoD-supported research must be promptly (i.e., within 30 days) reported to the DoD human research protection officer.
  - Records maintained that document compliance or noncompliance shall be made accessible for inspection and copying by authorized representatives of the Department of Defense at reasonable times and in a reasonable manner as determined by the supporting DoD Component.

Research following DoD requirements is subject to the DHHS Subparts B, C, and D.

- For purposes of applying Subpart B, the phrase "biomedical knowledge" shall be replaced with "generalizable knowledge."
- The applicability of Subpart B is limited to research involving pregnant women as subjects in research that is more than minimal risk and includes interventions or invasive procedures to the woman or the fetus or involving fetuses or neonates as subjects.



- Fetal research must comply with the US Code Title 42, Chapter 6A, Subchapter III, Part H, 289g.
- Research involving prisoners cannot be reviewed by the expedited procedure.
- When the IRBs review research involving prisoners, at least one prisoner representative must be present for quorum.
  - o In addition to allowable categories of research on prisoners in Subpart C, epidemiological research is also allowable when:
    - o The research describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor association for a disease.
    - o The research presents no more than minimal risk.
    - o The research presents no more than an inconvenience to the subject.
- When a prisoner becomes a subject, if the researcher asserts to the IRBs that it is in the best interest of the prisoner-subject to continue to participate in the research while a prisoner, the IRB chair may determine that the prisoner-subject may continue to participate until the convened IRBs can review this request to approve a change in the research protocol and until the organizational official and DoD Component office review the IRB's approval to change the research protocol. Otherwise, the IRB chair shall require that all research interactions and interventions with the prisoner-subject (including obtaining identifiable private information) cease until the convened IRBs can review this request to approve a change in the research protocol. The convened IRBs, upon receipt of notification that a previously enrolled human subject has become a prisoner, shall promptly re-review the research protocol to ensure that the rights and wellbeing of the human subject, now a prisoner, are not in jeopardy. The IRBs should consult with a subject matter expert having the expertise of a prisoner representative if the IRB reviewing the research protocol does not have a prisoner representative. If the prisoner-subject can continue to consent to participate and is capable of meeting the research protocol requirements, the terms of the prisoner-subject's confinement does not inhibit the ethical conduct of the research, and there are no other significant issues preventing the research involving human subjects from continuing as approved, the convened IRBs may approve a change in the study to allow this prisoner-subject to continue to participate in the research. This approval is limited to the individual prisoner-subject and does not allow recruitment of prisoners as subjects.
- Research involving a detainee as a human subject is prohibited.
  - o This prohibition does not apply to research involving investigational drugs and devices when the same products would be offered to US military personnel in the same location for the same condition.
- Research involving children cannot be exempt.
- Research involving prisoners of war is prohibited.
  - o The IRBs are aware of the definition of "prisoner of war" for the DoD component granting the addendum.

**Resources for additional information:**

[Information for Investigators: Headquarters, U. S. Army Medical Research and Materiel Command \(USAMRMC\) Office of Research Protections \(ORP\) Human Research Protections Regulatory Requirements](#)

The [Department of the Navy Human Research Protection Program website](#) provides regulations, instructions, and guidance for DON supported or conducted research.

**DON-Supported Research** includes all research for which the Navy or Marine Corps provides:

- personnel (including researchers or subjects), or
- materiel (including nonpublic information used to identify or contact prospective subjects), or
- property / facilities, or
- funding, regardless of source (intramural or extramural)

[Additional Requirements for Institutions Conducting or Collaborating with Others on DON-Supported Human Subjects Research \(Appendix\)](#)

# Information for Investigators: Headquarters, U. S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP) Human Research Protections Regulatory Requirements

## ORP Human Research Protection Office (HRPO)

### 1. Department of Defense (DOD) Human Subjects Protection Regulatory Requirements

a. DOD regulations require that the DOD include specific language in contracts or other comparable agreements (e.g., grants, assistance agreements, and cooperative research and development agreements) that might include research involving human subjects. This language identifies the awardee requirements and responsibilities, and requires that any research involving human subjects supported by the award be approved by a DOD Human Research Protection Official (DHRPO) prior to implementation of the research.

b. The **awardee** is responsible for overseeing execution of the research and must include similar language in subcontracts that support research involving human subjects. In addition, this language:

(1) Allows DOD representatives to independently review and inspect the awardee's research. This may include access to identifiable information or protected health information (thus, subjects must be informed);

(2) Allows DOD representatives to prohibit research that is determined to present unacceptable hazards or is non-compliant with DOD regulatory requirements;

(3) Applies to all human subjects research, whether or not it is determined to be exempt from the regulations.

c. The DHRPO must perform an administrative review of the research before the activities that involve human subjects can begin (e.g., human subject recruitment and data collection). At a minimum, the DHRPO must:

(1) Concur with the extramural institution regarding activities they have determined to be either (a) research not involving human subjects; or (b) research involving human subjects that is exempt from the regulatory provisions of 32 CFR 219.

(2) Confirm the institution has a Federal assurance appropriate for the conduct of the non-exempt research involving human subjects in question. If DOD institutions are engaged in the extramural research, they must have a DOD Assurance.

(3) Review the research protocol for compliance with DOD Instruction (DODI) 3216.02 "Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research," accept the IRB determination of level of risk, ensure that the study is compliant with applicable DOD regulatory requirements and approve the protocol prior to implementation.

(4) Review and accept IRB-approved substantive changes to an approved research protocol before they are implemented.

(5) Ensure the IRB conducts an appropriate continuing review at least annually.

(6) When the research involving human subjects is being conducted in a foreign country, confirm all applicable national laws and requirements of the foreign country have been met and confirm the IRB considered the cultural sensitivities in the setting where the research will take place.

d. The USAMRMC ORP HRPO has designated approval authorities to meet the DHRPO approval requirement for DOD supported research.

## 2. Requirements for Approval of Extramural Human Subjects Research

a. **Federal Assurance of Compliance.** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) FWA or DOD Assurance. An IRB review by one of the IRBs listed on the institution's assurance or identified in an Institutional Agreement for IRB Review must be provided. To avoid delays in the HRPO approval process, verify that the institutions engaged in the research have active assurances. The Institution's IRB office or the HRPO can assist in determining if engaged institutions have active assurances and obtaining an assurance is required.

b. **Investigator Qualifications.** A CV or biosketch of the Principal Investigator (PI) must be provided to the HRPO. Documentation of human subjects protection training (per local policy) for the Principal Investigator and all Associate Investigators (AIs) must be provided to the HRPO prior to approval. A description of roles and responsibilities of study personnel will be requested during the review process to assist in determination of which institutions are engaged in the research.

c. **When applicable, the following DOD unique requirements must be addressed prior to approval:**

(1) 10 United States Code 980. The requirements of Title 10 United States Code 980, which are applicable to DOD sponsored research, must be considered. 10 USC 980 requires that "Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless- (1) the informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject."

Note that the definition of experimental subject is found in DODI 3216.02 and has a much narrower definition than human subject. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an experimental subject in a DOD-supported experiment unless participation in the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements.

***[NOTE: 10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, blood draws, and tissue collections. Contact the HRPO for further clarification regarding applicability of 10 USC 980 to the proposed research project.]***

(2) **Research Monitor.** For research determined to be greater than minimal risk, DODI 3216.02 requires **that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.** The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report their observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution.

Research monitor functions may include:

- observing recruitment and enrollment procedures and the consent process for individuals, groups or units,
- overseeing study interventions and interactions,
- reviewing monitoring plans and UPIRTSO reports;
- overseeing data matching, data collection, and analysis

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board.

At a minimum, the research monitor:

- may discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report;
- shall have the responsibility to promptly report their observations and findings to the IRB or other designated official and the HRPO.

A biographical sketch or CV and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest and the monitor cannot be under the supervision of the PI or other investigators or research staff. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study Health Information Portability and Accountability Act authorization.

**(3) Recruitment of Military Personnel.** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator who will be familiar with service-specific requirements.

A letter of support from Commanders of military facilities or units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order Service members to participate in a research study. For greater than minimal risk research, DODI 3216.02 requires that an ombudsman be employed when conducting group recruitment briefings with Active Duty personnel to ensure that they understand that participation is voluntary. The use of an ombudsman may be recommended in other situations as well, especially when young enlisted service

members, who are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized if possible.

**(4) Payment to Federal Employees and Military Personnel.** Under 24 USC 30, payment to Federal Employees and Active Duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. They may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

#### **(5) USAMRMC Required Protocol and Consent Form Language;**

The following must appear in the consent form:

- A statement that the DOD or a DOD organization is funding the study.
- A statement that representatives of the DOD are authorized to review research records.
- In the HIPAA Authorization or HIPAA authorization section of the consent form, representatives of the DOD must be listed as one of the parties to whom private health information may be disclosed.
- If the protocol is greater than minimal risk, the research monitor must also be listed in the HIPAA Authorization as one of the parties to whom private health information may be disclosed.

**(6) For Development of Medical Products.** Product information must be provided with the protocol submission. The HRPO will assess protocols involving medical products for applicability of FDA regulations. Additional documentation may be requested for investigational products. If the FDA, the IRB, or another regulatory office has determined that the protocol does not require an IND or IDE, provide any documentation available related to this determination.

### **3. USAMRMC ORP HRPO Submission and Administrative Review Process**

a. DOD research programs submit proposals selected for funding to the USAMRMC ORP HRPO for human subjects protection regulatory review. A **Proposal Submission Form**, designed to facilitate the protocol review process, is also submitted for review. This submission form contains information that the USAMRMC funding program may need to solicit from the **Proposal PI** before the proposal is submitted to USAMRMC ORP HRPO.

b. Once the proposal and completed **Proposal Submission Form** have been submitted and triaged, a HRPO staff member will contact the Principal Investigator (PI) to provide the HRPO **Protocol Submission Form** and request the Institutional Review Board (IRB) approved protocol (or an estimate of when the protocol will be submitted for review). The PI must complete the information requested on the **Protocol Submission Form**. Any information that is unknown at the time of protocol submission will be obtained during the review process.

c. When the IRB approved protocol and **Protocol Submission Form** are received, the project will be assigned to a Human Subjects Protection Scientist (HSPS). The HSPS will be the main HRPO point of contact for the PI for information regarding initial review and approval of the protocol, in addition to life cycle reporting requirements. The HSPS will review the protocol for compliance with federal, DOD and state or host nation regulatory requirements and assist the PI with addressing any outstanding issues prior to submission for final HRPO approval. If revisions to the protocol or consent form are required to

bring the protocol into compliance, the revised documents must be approved by the IRB prior to HRPO approval.

d. For protocols involving multiple research sites and/or multi-institutional collaborations on a single study, the HRPO must review and approve site specific documentation prior to participation in human research activities. Note: For protocols involving multiple institutions, the review will proceed much faster if a flow chart or map is provided that outlines the protocol and indicates how each institution is involved.

e. If the project involves execution of all or part of the research outside of the United States the HRPO must confirm all applicable host national laws and requirements of the foreign country have been met and confirm the IRB considered cultural sensitivities in the setting where the research will take place. The Principal Investigator must provide adequate information to the HRPO regarding national laws and requirements and the cultural context in which the research will take place. This information can be provided through completion of applicable sections of the HRPO International Research Submission Form, or through inclusion of applicable information in the protocol.

f. Standard reporting requirements to HRPO are outlined at the end of this document. Additional protocol specific reporting requirements may be included in the HRPO approval memorandum.

#### **4. Reporting Requirements and Responsibilities of the Principal Investigator to the USAMRMC ORP HRPO**

a. The protocol will not be initiated until written notification of approval of the research project is issued by the HRPO.

b. The Principal Investigator has a duty and responsibility to foster open and honest communication with research subjects. The USAMRMC strongly encourages the Principal Investigator to provide subjects with a copy of the research protocol, if requested, with proprietary and personal information redacted as needed.

c. The Principal Investigator must comply with the following minimum reporting requirements. Specific reporting requirements for the protocol will be included in the HRPO Approval Memorandum. Failure to comply could result in suspension of funding.

(1) Substantive modifications to the research protocol and any modifications that could potentially increase risk to subjects must be submitted to the HRPO for approval prior to implementation. The USAMRMC ORP HRPO defines a substantive modification as a change in Principal Investigator, change or addition of an institution, elimination or alteration of the consent process, change to the study population that has regulatory implications (e.g. adding children, adding active duty population, etc), significant change in study design (i.e. would prompt additional scientific review) or a change that could potentially increase risks to subjects.

(2) Any changes of the IRB used to review and approve the research will be promptly reported to the USAMRMC ORP HRPO.

(3) All unanticipated problems involving risk to subjects or others must be promptly reported by telephone (301-619-2165), by email ([HRPO@amedd.army.mil](mailto:HRPO@amedd.army.mil)), or by facsimile (301-619-7803) to the HRPO. A complete written report will follow the initial notification. In addition to the methods above, the complete report can be sent to the U.S. Army Medical Research and Materiel Command, ATTN: MCMR-RP, 504 Scott Street, Fort Detrick, Maryland 21702-5012.

(4) Suspensions, clinical holds (voluntary or involuntary), or terminations of this research by the Institutional Review Board (IRB), the institution, the Sponsor, or regulatory agencies will be promptly reported to the USAMRMC ORP HRPO.

(5) A copy of the continuing review approval notification by the IRB of Record must be submitted to the HRPO as soon as possible after receipt. For greater than minimal risk research, a copy of the continuing review report approved by the IRB must also be provided. Please note that the HRPO also conducts random audits at the time of continuing review. Additional information and documentation may be requested at that time.

(6) The final study report, including any acknowledgement documentation and supporting documents, must be submitted to the HRPO when available.

(7) The knowledge of any pending compliance inspection/visit by the FDA, DHHS Office of Human Research Protections (OHRP), or other government agency concerning this research, the issuance of Inspection Reports, FDA Form 483, warning letters or actions taken by any regulatory agencies including legal or medical actions and any instances of serious or continuing noncompliance with the regulations or requirements, must be promptly reported to the HRPO.

**Please Note:** The USAMRMC, ORP, HRPO conducts site visits as part of its responsibility for compliance oversight. Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.

For questions regarding the HRPO human research protocol review requirements email [hrpo@amedd.army.mil](mailto:hrpo@amedd.army.mil) or leave a voicemail at 301-619-2165 and a staff member will contact you.



## Department of the Navy

### Human Research Protection Program

#### **DoD-Navy Addendum to Federalwide Assurance (FW A) of Protection for Human Subjects Citations for Department of the Navy (DON) Additional Requirements For Institutions Conducting or Collaborating with Others on DON-supported Human Subject Research**

#### **Background**

The DON supports research with human subjects conducted by DON commands; by extramural performers through contracts, grants, cooperative agreements, or other arrangement; and by collaborators with the DON. The DON implements human research protection requirements through Common Rule (32 CFR 219), Department of Defense (DoD) directives (DoDD 3216.2), and DON instructions (SECNA VINST 3900.39D).

The DoD and DON mandate additional requirements for research with human subjects. The key additional requirements and the corresponding specific citation are listed after "Applicability and Scope."

#### **Applicability and Scope**

[DoDD 3216.2, para 2.2 and 4.3.1; SECNAVINST 3900.39D para 4a(l) and 6g]

#### **DoDD 3216.2**

2.2: Applies to research involving human subjects, as defined herein, conducted by a DoD Component (i.e., intramural) and other research that is supported by a DoD Component (i.e., extramural) through a contract, grant, cooperative agreement, or other arrangement.

4.3.1: The Department of Defense has joined with other Federal Agencies to adopt the "Common Rule" Federal policy for protection of human subjects in research. 32 CFR 219 is the Department of Defense's implementation of the Common Rule. All DoD-supported and DoD-conducted research shall comply with 32 CFR 219 and this Directive.

#### **SECNA VINST 3900.39D, para 4a( 1) and 6g**

4a(l): This instruction applies to: All biomedical and social-behavioral research involving human subjects conducted by Navy and Marine Corps activities or personnel, involving naval military personnel and DON employees as research subjects, or supported by naval activities through any agreement (e.g., contract, grant, cooperative agreement, or other arrangement), regardless of the source of funding, funding appropriation, nature of support, performance site, or security classification. It also applies to human subject research using DON property, facilities, or assets.

6g: DON supports research with human subjects conducted at non-federal institutions. Any research grants, contracts, cooperative agreements, Cooperative Research and Development Agreements (CRADAs), or other transactions must include the additional DoD and DON requirements for human subject protections.

#### **Specific Citations for Key Additional Requirements**

1. Initial and continuing research ethics training for all personnel who conduct, review, approve, oversee, support, or manage human subject research

[DoDD 3216.2, para. 4.5; SECNAVINST 3900.39D, para. 6a(2)]

DON HRPP- Addendum to FW A Addl Requirement List- FINAL- 13 Feb 2007.doc

2. Written determination by a designated official (other than investigators) whether research meets criteria for exemption [SECNAVINST 3900.39D, para. 6c]

3. New research protocols and substantive amendments to approved research must undergo scientific approval prior to ethics (IRB) review

[SECNAVINST 3900.39D, para. 8c(6)]

4. Procedures for addressing conflicting and competing interests  
[DoDD 3216.2, para. 4.4.4; SECNAVINST 3900.39D, para. 6b]
5. Appointment of Medical Monitor [DoDD 3216.2, para. 4.4.3]
6. Provisions for research-related injury [DoDD 3216.2, para. 5.3.4; SECNAVINST 3900.39D, para 6a(5)]
7. Additional protections for military research subjects to minimize undue influence  
[DoDD 3216.2, para. 4.4.4; SECNA VINST 3900.39D, para 6a(6)]
8. Additional protections for pregnant women, prisoners, and children (Subparts B, C, and D of 45 CFR 46)  
[DoDD 3216.2, para. 4.4.1; SECNAVINST 3900.39D, para. 6a(6)]
9. Additional safeguards for research conducted with international populations  
[DoDD 3216.2, para. 4.9; SECNAVINST 3900.39D, para. 6i]
10. Limitations on research where consent by legally authorized representatives is proposed  
[DoDD 3216.2, para. 4.2.; SECNAVINST 3900.39D, para. 6a(3);10 U.S.C 980]
11. Limitation on exceptions from informed consent in emergency medicine research  
[DoDD 3216.2, para. 4.2; SECNAVINST 3900.39D, para. 6a(3)and 7a(l); 10 U.S.C. 980]
12. Limitations on compensation for U.S. military personnel [Dual Compensation Act and 24 U.S.C 30]
13. U.S. Navy-wide survey research requires additional review  
[SECNA VINST 3900.39D, para. 6e; OPNA VINST 5300.8B]
14. Requirements for reporting unanticipated problems, adverse events, and research-related injury  
[SECNAVINST 3900.39D, para 8d(2), para. 8e(6), and para. 8g(6)]
15. Oversight by the DON HRPP through headquarters-level review of research protocols (including relevant IRB meeting minutes) after local institutional approval and site visit of the institution's HRPP  
  
[DoDD 3216.2, para. 5.3.3; SECNAVINST 3900.39D, para. 6g, 8b, and 8d]  
DON HRPP- Addendum to FW A Add! Requirement List- FINAL- 13 Feb 2007.doc
16. Recordkeeping requirements  
[DoDD 3216.2, para. 5.3.2; SECNAVINST 3900.39D, para. 8c(18)]  
Recordkeeping requirements for DON-supported research with human subjects are longer than the Common Rule's requirement. The DON **HRPP** is developing policy guidance.
17. Addressing and reporting allegations of non-compliance with human research protections  
[DoDD 3216.2, para. 4.10; SECNAVINST 3900.39D, para. 8d(2) and 6k;]
18. Addressing and reporting allegations of research misconduct  
[DoDD 3216.2, para. 4.8; DoDD 3210.7; SECNAVINST 3900.39D, 8d(2)para. 61]
19. Provisions for research with human subjects using investigational test articles (drugs, device, and biologics)  
[DoDD 3216.2, para. 4.9; DoDD 6200.2; SECNA VINST 3900.39D, para. 6h]
20. Prohibition of research with prisoners of war (POW) and detainees  
[DoDD 3216.2, para. 4.4.2; SECNA VINST 3900.39D, para. 6a(8)]
21. Classified Research  
[SECNA VINST 3900.39D, para 6j]

## **National Institute of Justice**

Relevant regulations: [28 CFR 46](#), Judicial Administration Human Subject Protection

The National Institute of Justice Human Subject Protection [website](#) provides detailed information about 28 CFR 26 (which reflects the Common Rule, 45 CFR 46), requirements for a Privacy Certificate, informed consent and other guidance relative to NIJ-supported or conducted research.

Privacy and confidentiality requirements for National Institute of Justice (NIJ) funded research:

- All projects are required to have a [privacy certificate](#) approved by the NIJ Human Subjects Protection Officer.
- All researchers and research staff are required to sign [employee confidentiality statements](#), which are maintained by the responsible researcher.
- The confidentiality statement on the consent form must state that confidentiality can only be broken if the subject reports immediate harm to subjects or others.
- Under a privacy certificate, researchers and research staff do not have to report child abuse unless the subject signs another consent form to allow child abuse reporting.

Data archiving requirement for NIJ-supported or conducted research:

For National Institute of Justice-funded research, 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.

[Frequently Asked Questions Regarding the National Institute of Justice's Confidentiality and Human Subject Protection Requirements](#) are also posted on the NIJ website.

## **Department of Justice: Bureau of Prisons**

Relevant regulations: [28 CFR 512](#), Department of Justice (DOJ) Bureau of Prisons (BOP) Research

The basic DOJ policy for the protection of human subjects (28 CFR 512, Subpart A) is the same as the DHHS basic regulations for the protection of human subjects (45 CFR 46, Subpart A, aka “The Common Rule”).

IRB membership requirement for research supported by the Department of Justice (DOJ) or conducted within the Bureau of Prisons (BOP):

- A majority of the IRB members (exclusive of prisoner members) have no association with the prison involved, apart from their membership on the IRBs.

For research conducted within the Bureau of Prisons:

- Implementation of Bureau or operational initiatives made through pilot projects is not considered to be research.
- When submitting a research proposal, the applicant shall provide the following information:
  - o A summary statement, which includes:
    - Names and current affiliations of the researchers.
    - Title of the study.
    - Purpose of the study.
    - Location of the study.
    - Methods to be employed.
    - Anticipated results.
    - Duration of the study.
    - Number of subjects (staff or inmates) required and amount of time required from each.
    - Indication of risk or discomfort involved as a result of participation.
  - o A comprehensive statement, which 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 subjects or a class of subjects, and a discussion of the likelihood that the risks and discomforts will actually occur.
    - Description of steps taken to minimize any risks.
    - Description of physical or administrative procedures to be followed to:

- o Ensure the security of any individually identifiable data that are being collected for the study.
  - o Destroy research records or remove individual identifiers from those records when the research has been completed.
- o Description of any anticipated effects of the research study on organizational programs and operations.
- o Relevant research materials such as vitae, endorsements, sample consent statements, questionnaires, and interview schedules.
- o A statement regarding assurances and certification required by 28 CFR 46, if applicable.
- The researcher must have academic preparation or experience in the area of study of the proposed research.
- 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.
- The university, IRBs, and researchers and research staff must follow the requirements of 28 CFR 512, including:
  - o The project must not involve medical experimentation, cosmetic research, or pharmaceutical testing.
  - o The research design must be compatible with both the operation of prison facilities and protection of human subjects. The researcher must observe the rules of the institution or office in which the research is conducted.
  - o Any researcher who is a non-employee of the Bureau must sign a statement in which the researcher agrees to adhere to the provisions of 28 CFR 512.
  - o All research proposals will be reviewed by the Bureau Research Review Board.
- The project must have an adequate research design and contribute to the advancement of knowledge about corrections.
- In regards to selection and compensation of subjects:
  - o The selection of subjects within any one university must be equitable.
  - o Incentives may not be offered to help persuade inmate subjects to participate. However, soft drinks and snacks to be consumed at the test setting may be offered.
  - o Reasonable accommodations such as nominal monetary recompense for time and effort may be offered to non-confined research subjects who are both:
    - No longer in Bureau of Prisons custody;
    - Participating in authorized research being conducted by Bureau employees or contractors.
- In regards to informed consent, required elements of disclosure include:
  - o Identification of the researchers.
  - o Anticipated uses of the results of the research.

- o A statement that participation is completely voluntary and that the subject 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).
  - o A statement regarding the confidentiality of the research information and exceptions to any guarantees of confidentiality required by federal or state law. For example, a researcher may not guarantee confidentiality when the subject indicates intent to commit future criminal conduct or harm himself or herself or someone else, or, if the subject is an inmate, indicates intent to leave the facility without authorization.
  - o A statement that participation in the research project will have no effect on the inmate subject's release date or parole eligibility.
- In regards to BOP records:
    - o A non-employee of the Bureau may receive records in a form not individually identifiable when advance adequate written assurance that the record will be used solely as a statistical research or reporting record is provided to the agency.
    - o Except as noted in the consent statement to the subject, the researcher must not provide research information that identifies a subject to any person without that subject's prior written consent to release the information. For example, research information identifiable to a particular individual cannot be admitted as evidence or used for any purpose in any action, suit, or other judicial, administrative, or legislative proceeding without the written consent of the individual to whom the data pertain.
    - o 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.
    - o If the researcher is conducting a study of special interest to the Office of Research and Evaluation (ORE) but the study is not a joint project involving ORE, the researcher may be asked to provide ORE with the computerized research data, not identifiable to individual subjects, accompanied by detailed documentation. These arrangements must be negotiated prior to the beginning of the data collection phase of the project.
- In regards to data, results, and reports:
    - o At least once a year, the researcher shall provide the chief, Office of Research and Evaluation, with a report on the progress of the research.
    - o At least 12 working days before any report of findings is to be released, the researcher shall distribute one copy of the report to each of the following: the chairperson of the Bureau Research Review Board, the regional director, and the warden of each institution that provided data or assistance. The researcher shall include an abstract in the report of findings.
    - o In any publication of results, the researcher shall acknowledge the Bureau's participation in the research project.
    - o The researcher shall expressly disclaim approval or endorsement of the published material as an expression of the policies or views of the Bureau.
    - o 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.

## **Department of Energy**

Relevant regulations: [10 CFR 745](#), Department of Energy (DOEn).

The basic DOEn policy for the protection of human subjects (10 CFR 745, Subpart A) is the same as the DHHS basic regulations for the protection of human subjects (45 CFR 46, Subpart A, aka “The Common Rule”). Research involving fetuses, pregnant women, and in vitro fertilization, prisoners, or children shall be conducted in accordance with 45 CFR Part 46 Subparts B, C, and D. Any IRB member can appeal a vote to approve research to the Institutional Official, Secretary of Energy, and Director of the Office of Science and Technology, in that order.

Assessment of compliance at Columbia:

- When following DOEn regulations and as an essential component of its program for protection of human subjects, Columbia will periodically conduct self-assessments to ensure compliance with the HRPP procedures and other requirements.
- Researchers will be asked to complete and submit the “Checklist for IRBs to Use in Verifying That HHS Research Protocols Are in Compliance with Department of Energy Requirements”.
- The IRBs will review and approve the “Checklist for IRBs to Use in Verifying That HHS Research Protocols Are in Compliance with Department of Energy Requirements” submitted by the researchers to verify compliance with the DOE requirements for the protection of personally Identifiable Information.
- Employees and contractors are considered vulnerable subjects.
- A description of additional protections that must be considered by the IRB if additional protections are required for research involving employees and contractors.

Reporting requirements when following Department of Energy regulations:

- Researchers must promptly report the following to the DOE Human Subject Protection Program Manager:
  - o Any significant adverse events, unanticipated risks, and complaints about the research, with a description of any corrective actions taken or to be taken, within 48 hours.
  - o Any suspension or termination of IRB approval of research, within 48 hours.
  - o Any significant non-compliance with HRPP procedures or other requirements, within 48 hours.
  - o Any compromise of personally identifiable information must be reported immediately, i.e., as soon as possible but no later than 48 hours after discovery or notification.

### Resources:

- DOfEn Human Subject Protection website:  
<http://humansubjects.energy.gov/research/default.htm>
- DOfEn Human Subject Regulations, Orders, and Policies:  
<http://humansubjects.energy.gov/regulations/default.htm>
- The [Human Subjects Protection Resource Book](#) is an attempt to synthesize the information currently available on the protection of human subjects in research, the continuing application of such information to new areas of endeavor, and the ever-changing rules, regulations, and guidance involved in the hope that it might provide useful information for investigators, Institutional Review Boards (IRBs), research organizations, research subjects, and others.
  - The book contains chapters that provide background information on the history and development of the federal regulations, chapters that discuss procedural and substantive issues regarding the review and conduct of human subjects research, and chapters that are specific to one type of research (e.g., genetics, biological samples) or research in specific populations (e.g., international settings, children, and workers).
  - The resource book was a joint project of several agencies: DOE, the U.S. Department of Defense, and the U.S. Department of Veterans Affairs. However, this manual does not represent the official views or policies of any of these or any other agencies.



## Department of Education

Relevant regulations:

[34 CFR Part 97, Protection of Human Subjects](#). Includes Subpart A (Basic Policy) and Subpart D (Additional Protections for Children).

For research supported by the Department of Education (DOE):

- 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 must be available for inspection by the parents or guardians of the children engaged in such research.
- 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.
- Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

See also, later in this document, specific DOE requirements pursuant to the [Family Rights and Educational Privacy Act](#), the [Protection of Pupil Rights Amendment](#), and the [National Institute on Disability and Rehabilitation Research](#).

### Resources:

- Information About the Protection of Human Subjects in Research Supported by the Department of Education - Overview: <http://www2.ed.gov/policy/fund/guid/humansub/overview.html>
- The U.S. Department of Education (DOE) [website](#) provides details about the process for funding of research as well as the requirements for protection of human subjects.
- Family Policy Compliance Office (FPCO): <http://www2.ed.gov/policy/gen/guid/fpc/index.html>. The mission of the Family Policy Compliance Office (FPCO) is to meet the needs of the Department's primary customers--learners of all ages--by effectively implementing two laws that seek to ensure student and parental rights in education: the Family Educational Rights and Privacy Act (FERPA) and the Protection of Pupil Rights Amendment (PPRA).

## Department of Education: Protection of Pupil Rights Amendment

Relevant regulations:

[34 CFR Part 98, the Protection of Pupil Rights Amendment \(PPRA\)](#)

PPRA is designed to protect the rights of parents and students in programs that receive funding from the Department.

Applicability is to any research that is funded by the DOE, with the exception of the following funded programs:

Name of program	Authorizing statute	Implementing regulations
1. High School Equivalency Program and College Assistance Migrant Program	Section 418A of the Higher Education Act of 1965 as amended by the Education Amendments of 1980 (Pub. L. 96–374) <a href="#">20 U.S.C. 1070d–2</a> )	part 206.
2. Programs administered by the Commissioner of the Rehabilitative Services Administration	The Rehabilitation Act of 1973 as amended by Pub. L. 95–602 ( <a href="#">29 U.S.C. 700</a> , et seq.)	parts 351–356, 361, 362, 365, 366, 369–375, 378, 379, 385–390, and 395.
3. College housing	Title IV of the Housing Act of 1950 as amended ( <a href="#">12 U.S.C. 1749</a> , et seq.)	part 614.

- When following Department of Education regulations, researchers and the IRBs will comply with the Protection of Pupil Rights Amendment:
  - o 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:
    - Political affiliations.
    - Mental and psychological problems potentially embarrassing to the student or his or her family.
    - Sex behavior and attitudes.
    - Illegal, anti-social, self-incriminating and demeaning behavior.
    - Critical appraisals of other individuals with whom the student has close family relationships.
    - Legally recognized privileged and analogous relationships, such as those of lawyers, physicians, and ministers.
    - Religious practices, affiliations, or beliefs of the student or student’s parent.
    - 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:
  - 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 an un-emancipated minor. Schools and contractors obtain prior written parental consent before minor students are required to participate in any ED-funded survey, analysis, or evaluation.
- For research not funded by the US Department of Education, the IRB must verify compliance with DOE regulations that schools are required to develop and adopt policies in conjunction with parents regarding the following:
  - 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.
  - 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.
  - 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):
    - Political affiliations or beliefs of the student or the student’s parent.
    - 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 and analogous relationships, such as those of lawyers, physicians, and ministers.
    - Religious practices, affiliations, or beliefs of the student or the student’s parent.
    - Income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
  - 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.
  - Any applicable procedures for granting a request by a parent for reasonable access to instructional material received.
  - The administration of physical examinations or screenings that the school or agency may administer to a student.
  - 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.
  - 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.
  - 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.

## **Department of Education: Family Educational Rights and Privacy Act**

Relevant regulations:

[34 CFR Part 99, the Family Educational Rights and Privacy Act \(FERPA\)](#)

FERPA is designed to protect the privacy of a student's education records at all public elementary and secondary schools and virtually all public and private postsecondary institutions.

When following Department of Education regulations, researchers and the IRBs will comply with the Family Educational Rights and Privacy Act (FERPA).

- An educational agency or institution may disclose personally identifiable information from an education record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
  - Develop, validate, or administer predictive tests.
  - Administer student aid programs.
  - Improve instruction.
- The IRB will determine, after consultation when necessary with the Office of the General Counsel, the Office for Institutional Research (for Columbia student records), and/or representatives of the DOE, when exceptions to parental/student consent to release student records for research are acceptable.
- A school district or postsecondary institution that uses this exception is required to enter into a written agreement with the university or researcher conducting the research that specifies:
  - The determination of the exception.
  - The purpose, scope, and duration of the study.
  - The information to be disclosed.
  - 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 34 CFR 99.31(a) (6) on re-disclosure and destruction of information.
  - 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 university legitimate interests.
  - That the university is required to destroy or return all personally identifiable information when no longer needed for the purposes of the study.
  - The time period during which the university 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:

- 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 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; 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.

**Department of Education: National Institute on Disability and Rehabilitation Research**

Relevant regulations:

[Excerpts from 34 CFR Part 350 and 34 CFR Part 356, Disability and Rehabilitation Research](#)

Additional Institutional Review Board membership requirements in certain research projects.

Requirement for IRB expertise:

- When an IRB reviews research funded by the National Institute on Disability and Rehabilitation Research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.