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Background

- If research is funded, supported by or otherwise subject to certain federal agencies or agreements, it could be subject to additional requirements to those in the Common Rule.
- Checklists are provided to help ensure that all special considerations are met. IRB Managers, during pre-review, identify these requirements and confirm that they are documented. (See [Resources](#) below)

Scope

This guidance addresses requirements for research supported by or otherwise subject to, the following federal departments and agencies:

- Department of Defense (DoD), including Department of the Navy (DON)
 - Requirements different from or additional to current HRPP policies
 - Other DoD and DON requirements that are congruent with current HRPP policies
- Department of Education (ED)
- Department of Energy (DOE)
- Department of Justice (DOJ)
- Environmental Protection Agency (EPA)
- National Science Foundation (NSF)

For detailed requirements refer to the regulatory links provided in each of these sections.

Resources

Regulations	
Federal Agency Regulations	<ul style="list-style-type: none"> • Department of Defense (DoD) 32 CFR 219; DoD Directive 3216.02; 10 USC 980 • Department of the Navy (DON) SECNAVINST 3900.39D • Department of Education (ED) 34 CFR 99 [FERPA]; 34 CFR 98 • Department of Energy (DOE) DOE 443.1B • Department of Justice (DOJ) 28 CFR 22; 28 CFR 512; Confidentiality & Privacy Protections; • Environmental Protection Agency (EPA) 40 CFR 26 • National Science Foundation (NSF) 40 CFR 26
Other	
Checklists	<ul style="list-style-type: none"> • CHK-42DOD Checklist for Departments of Defense (DoD) and Navy (DON) • CHK-42ED Checklist for Department of Education (ED) • CHK-42DOE Checklist for Department of Energy (DOE) <ul style="list-style-type: none"> ◦ <i>Supplement to eProtocol application for DOE:</i> APP-14 DOE Requirements for the Protection of Personally Identifiable Information (PII) • CHK-42DOJ Checklist for Department of Justice (DOJ) • CHK-42EPA Checklist for Environmental Protection Agency (EPA)

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This section summarizes Department of Defense (DoD) and Department of Navy (DON) requirements different from or additive to our current HRPP policies. See the end of this section for requirements and citations that are congruent with current HRPP DHHS policies.

International Research

Research performed in a foreign country involving participants who are not US citizens or DoD personnel requires permission of the host country.

- [DoD Directive 3216.02](#), 4.c.(2)(e)
- [SECNAVINST 3900.39D](#), para. 6i
[AAHRPP standard I-3]

Reporting – by Researchers, Institution

DoD: Promptly (within 30 days) notify the DoD *Human Research Protection Officer (HRPO)* as follows:
Researcher notifies:

- When significant changes to the research protocol are approved by the IRB.
- The results of the IRB continuing review.
- If the IRB used to review and approve the research changes to a different IRB.

The institution notifies:

- Any unanticipated problems involving risks to participants or others for any DoD-supported research.
- Any determinations of serious or continuing noncompliance of DoD supported research.
- When the institution is notified by any Federal dept or agency or national organization that any part of its HRPP is under investigation for cause involving a DoD-supported research protocol.
- Any suspension or termination of DoD supported research.
 - [DoD Directive 3216.02](#), para. 4.b.4
[AAHRPP element I.5.D, II.2.D, II.2.F, II.2.G]

DON: **The institution** notifies the *DON HRPP Office* of:

- The initiation and results of all investigations of alleged non-compliance with human subject protections of DON-supported research protocols. (Also report *regardless of the findings* to *Surgeon General of the Navy* and appropriate sponsors.)
- All audits, investigations, or inspections of DON-supported research protocols.
- All audits, investigations, or inspections of the institution’s HRPP conducted by outside entities (e.g., the FDA or OHRP), and all restrictions, suspensions, or terminations of institutions’ assurances.
- Significant communication between institutions conducting research and other federal departments and agencies regarding compliance and oversight.
 - [SECNAVINST 3900.39D](#), para. 6k, 8d(2)
[AAHRPP elements I.5.D., II.2.F]

Monitors

For research involving **more than minimal risk** the IRB shall approve an independent research monitor **by name**. The monitor may be an ombudsman **or member of the DSMB**. OSD (Office of the Secretary of Defense) and DoD Component heads may waive the research monitor requirement on a case-by-case basis when inclusion of a monitor is not necessary to provide additional protections for human subjects.

- [DoD Directive 3216.02](#), para. 8
[AAHRPP Element II.3.B]

Provision for research-related injury

DON: Every project involving greater than minimal risk shall include an arrangement for emergency treatment and necessary follow-up of any research-related injury.

- [SECNAVINST 3900.39D](#), para. 6a(5)
[AAHRPP element II.3.F.]

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Research involving surveys

Surveys performed on Department of Defense personnel must be submitted, reviewed, and approved by the Department of Defense after the research protocol is reviewed and approved by the IRB.

- [OPNAVINST 5300.8C](#)
- [SECNAVINST 3900.39D](#), para. 6e
[AAHRPP element II.2.E]

DoD Personnel as participants

U.S. military personnel - minimizing undue influence: Officers and senior noncommissioned officers (NCOs) shall not influence the decisions of their subordinates to participate or not, and shall not be present at the time of research recruitment sessions and consent involving members of units under their command. The IRB shall appoint an ombudsman for research involving Service Members as human subjects that is greater than minimal risk and when recruitment occurs in a group setting.

- [DoD Directive 3216.02](#), 7.e.(1)(b), (d), (2)(d)
- [SECNAVINST 3900.39D](#), para. 6a(6)
[AAHRPP Element II.3.C]

Compensation to Participants (Payment and Limits)

Limitations on dual compensation prohibit US military personnel from receiving payment for research during duty hours, but the participant may be paid for participation during off duty hours. However, federal employees while on duty and non-federal persons may be compensated for research blood draws up to \$50 for each blood draw. Non-federal employees may be compensated for research other than blood draws in a reasonable amount as approved by the IRB.

- [DoD Directive 3216.02](#), 11
- [Dual Compensation Act](#) (Title 5 USC Section 5533), 24 U.S.C 30
[AAHRPP Element II.3.C]

Research Involving a Human Being as an Experimental Subject (*subset of research involving human subjects.*)

An activity, for research purposes, where there is an intervention or interaction with a human being for the primary purpose of obtaining data regarding the effect of the intervention or interaction (32 CFR 219.102(f)).

- [DoD Directive 3216.02](#), Glossary Part II: Definitions
[AAHRPP element II.3.G]

Risk Evaluation; Definition of Minimal Risk

The phrase "ordinarily encountered in daily life or during the performance of routine physical or physiological examinations or tests" in the definition of minimal risk shall not be interpreted to include the inherent risks certain categories of human subjects face in their everyday life.

For example, risks imposed in research 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).

- [DoD Directive 3216.02](#), 6.b.
[AAHRPP element II.3.A]

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Vulnerable subjects

Additional safeguards shall be provided for subjects who may be considered vulnerable to coercion or undue influence because of their age, health, employment, financial status, or other circumstances.

Pregnant women, fetuses and neonates:

- DHHS 45 CFR 46 Subpart B applies, replacing the phrase “biomedical knowledge” with “generalizable knowledge”.
- The applicability of Subpart B is limited to research that is more than minimal risk and includes interventions or invasive procedures to the woman or fetus; *or* research involving fetuses/neonates as human subjects.
- Human subjects research using *fetal tissue* shall comply with [U.S.C. title 42 \(289g-289g-2\)](#).

Prisoners: DHHS 45 CFR 46 Subpart C applies, but note:

All prisoner research must be reviewed and approved at a convened IRB meeting, including research which meets the criteria for exemption.

Epidemiological research is allowable, if the research:

- (1) Describes the prevalence or incidence of a disease by identifying all cases or studies potential risk factor associations for a disease;
- (2) Presents no more than minimal risk;
- (3) Presents no more than an inconvenience to the human subject;
- (4) Does not focus particularly on prisoners.

Detainees and POWs: Research involving prisoners of war (POW) and detainees is prohibited.

- [DoD Directive 3216.02](#), 7
- [SECNAVINST 3900.39D](#), para. 6a(3), para. 6a(6), para. 6a(8)
- [10 USC 980](#)
[AAHRPP element II.4.A]

Limitations on research where consent by legally authorized representatives is proposed

In such cases, the determination that research is intended to be beneficial to the subject must be made by the IRB.

- [DoD Directive 3216.02](#), para. 4.2.1
[AAHRPP element II.4.A]

Waivers of Informed Consent

DON: Exception from consent in emergency medicine research is prohibited unless a waiver is obtained from the Secretary of the Navy.

DoD: For *research involving a human being as an experimental subject*, waivers of the consent process are prohibited unless granted by Assistant Secretary of Defense for Research and Engineering (or for DON, the Secretary of the Navy).

- [DoD Directive 3216.02](#), 9
- [SECNAVINST 3900.39D](#), para. 6a(3) and 7a(1)
- [10 USC 980](#) (b)
[AAHRPP element II.3.G, II.4.C]

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Other DoD and DON Requirements that are Congruent with Current HRPP Policies

Training

- [DoD Directive 3216.02](#), 5.d
- [SECNAVINST 3900.39D](#) para. 6a(2)
[AAHRPP element I.1.E.]

Scientific Review

- [DoD Directive 3216.02](#), 4.b.2
[AAHRPP element I.1.F.]

Conflict of Interest

- [SECNAVINST 3900.39D](#), para. 6b
[AAHRPP Element I.6.B]

Exempt research

- [SECNAVINST 3900.39D](#), para. 6c
[AAHRPP Element II.2.A]

Definition: Human Subject Research

- [DoD Directive 3216.02](#), Glossary Part II: Definitions
[AAHRPP element II.3.G]

Children: DHHS 45 CFR 46 Subpart D applies

- [DoD Directive 3216.02](#), 7b.(3)
- [32 CFR 219.101\(i\) footnote #1](#)
[AAHRPP element II.4.A]

When a subject becomes a prisoner see:

- [DoD Directive 3216.02](#), 7d.
- [SECNAVINST 3900.39D](#), para. 6a(3), para. 6a(6), para. 6a(8)
- [10 USC 980](#)
[AAHRPP element II.4.A]

Record Keeping and Retention

- [DoD Directive 3216.02](#), 15.a., d.
[AAHRPP element II.5.A, II.5.B]

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Obtaining Student Records or Personal Education Information

When researchers obtain student records or personal education information from an education program (as defined in [34 CFR 99.3](#)), such activity is subject to the Family Educational Rights and Privacy Act (FERPA).

- [34 CFR 99.3](#) [FERPA Definitions]
[AAHRPP element II.3.G.]

Releasing Records Without Consent

An educational institution may disclose personally identifiable information from an education record of a student *without consent* under certain conditions as listed in FERPA.

- [34 CFR 99 \[FERPA\]](#)
[AAHRPP element II.3.G.]

Protection of Students

No student shall be required, as part of any program specified in §98.1 (a) or (b), to submit without prior consent to psychiatric examination, testing, or treatment, or psychological examination, testing, or treatment, in which the primary purpose is to reveal information concerning certain topics.

- [34 CFR 98.4](#)
[AAHRPP element II.4.B.]

Protection Of Pupil Rights

Inspection of instructional materials by parents or guardians;
Limits on survey, analysis, or evaluations;
Local policies concerning student privacy, parental access to information, and administration of certain physical examinations to minors.

- [20 U.S.C. Ch.31, Subchapter III, Part 4, § 1232h](#) especially (a),(b),(c)(1) (as was amended by PUBLIC LAW 107-110—JAN. 8, 2002 115 STAT. 2083)
[AAHRPP element II.4.B.]

Access to Instructional Material Used In Research

All instructional material—including teachers' manuals, films, tapes, or other supplementary instructional material—which will be used in connection with any research or experimentation program or project shall be available for inspection by the parents or guardians of the children engaged in such program or project.

- [34 CFR 98.3](#)
[AAHRPP element III.2.C.]

Other Department of Education Requirements that are Congruent with Current HRPP Policies

Representation for Vulnerable Subjects on the IRB

When an IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research subjects, the IRB must include at least one person primarily concerned with the welfare of these research subjects.

- [34 CFR 356.3](#)
[AAHRPP element II.1.E.]

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Contractor Requirements

Regardless of the performer of the work, the contractor is responsible for compliance with the requirements of the Contractor Requirements Document (CRD), including periodically conducting self-assessments to ensure compliance with the Human Subject Research Program procedures and other requirements.

There is required prompt reporting to the DOE Human Subjects Research Program Manager for specified events.

- [DOE 443.1B](#) [Contractor Requirements Document: *Protection of Human Research Subjects*] [AAHRPP elements I.5.A., III.2.D.]

Required Checklist for Researchers

Researchers submit a checklist for IRBs to use in verifying that HS research protocols comply with DOE requirements, including those for protection of Personally Identifiable Information

- [DOE Checklist to Verify Compliance with DOE Requirements](#) [AAHRPP elements II.3.E., III.2.C.]

Reporting – by Researchers

Researchers must report the following to the DOE Human Subjects Protection Program Manager (or as appropriate, the National Nuclear Security Administration (NNSA) HSP Program Manager):

Promptly (within 48 hours):

- Any significant adverse events, unanticipated risks; and complaints about the research, with a description of any corrective actions taken or to be taken.
- Any suspension or termination of IRB approval of research.
- Any significant non-compliance with HRPP procedures or other requirements.

Immediately, and report to the DOE-Cyber Incident Response Capability:

- Any finding of a suspected or confirmed data breach involving personally identifiable information in printed or electronic form,
- And provide a description of corrective actions to be taken within 48 hours for concurrence by the appropriate HSP Program Manager.

(*'Immediately' means as soon as breach is discovered*)

- [DOE 443.1B](#) [Attachment 1: Contractor Requirements Document: *Protection of Human Research Subjects*] [AAHRPP elements III.2.D.]

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Pilot Projects not Considered Research

For research conducted within the Bureau of Prisons, the implementation of Bureau programmatic or operational initiatives made through pilot projects is *not* considered to be research.

- [28 CFR 512.10](#)
[AAHRPP element I.1.A.]

28 CFR 512 - Judicial Administration Regulations

Research supported by DOJ shall comply with the Judicial Administration regulations covering research, 28 CFR 512 ("Subpart B").

- [28 CFR 512](#)
[AAHRPP element I.1.D.]

Research Design

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

- [28 CFR 512.11\(a\)\(2\)](#)
[AAHRPP element I.1.F.]

Participant Protections and Payment

Risk to subjects minimized and reasonable in relation to anticipated benefits.

Selection of subjects *within any one institution* must be equitable.

When applicable, informed consent must be sought and documented.

There may be no incentives to persuade inmate subjects to participate (soft drinks and snacks to be consumed at the test setting allowed): Reasonable accommodations may be offered to non-confined research subjects when certain criteria are met.

- [28 CFR 512.11\(a\)\(4,5\)](#)
[AAHRPP element II.3.C.]

National Institute of Justice (NIJ) funded research

All projects are required to have a Privacy Certificate approved by the NIJ Human Subjects Protection Officer, and all researchers and research staff are required to sign Employee Confidentiality Statements, which are maintained by the responsible researcher (PD).

Research conducted with the Bureau of Prisons must follow regulations for the receipt, use, and storage of individually identifiable information.

Regulations prohibit the use of electronic storage/retrieval systems under certain circumstances.

- [28 CFR 22](#), [28 CFR 512.8,11,12,13,15](#)
[AAHRPP element II.3.E.]

Informed Consent Requirements

The researcher, in addition to presenting the statement of informed consent to the subject, shall obtain the subject's signature on the statement of informed consent prior to initiating the research activity. **The researcher may not be required to obtain the signature if** the researcher can demonstrate that the only link to the subject's identity is the signed statement of informed consent or that there is significantly more risk to the subject if the statement is signed. **The signed statement shall be submitted to the chairperson of the appropriate local research review board.**

Required elements for the written consent document *include*:

- A statement that participation is completely voluntary and that the participant may withdraw consent and end participation in the project at any time without penalty or prejudice (the inmate will be returned to regular assignment or activity by staff as soon as practicable);
- Anticipated uses of the results of the research
- 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, if the subject is an inmate, indicates an intent to leave the facility without authorization.

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

Other DOJ requirements for informed consent are congruent with current HRPP policies. See:

- [28 CFR 512.16](#)
[AAHRPP element II.3.F.]

Researcher Experience

For research conducted within the Bureau of Prisons, the researcher must have academic preparation or experience in the area of study of the proposed research.

- [28 CFR 512.11\(a\)\(6\)](#)
[AAHRPP element III.1.C.]

Content of research proposal

For research conducted within the Bureau of Prisons, when submitting a research proposal, certain specified items of information must be provided by the applicant, including a statement regarding assurances and certification required by [28 CFR 46](#), if applicable.

- [28 CFR 512.12](#)
[AAHRPP element III.1.C.]

PD Responsibilities

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.

- [28 CFR 512.11\(a\)\(7\)](#)
[AAHRPP element III.2.B.]

Progress Reports and Publication

Requirements for reports of progress, and (at least annually) of findings;
Publication of research results; Copyright provisions.

- [28 CFR 512.19](#) (Reports)
- [28 CFR 512.20](#) (Publication of results of research project)
[AAHRPP element III.2.D.]

Exposure to Substances; Protections for Pregnant Women, Children, and Others

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

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

Before the research can begin IRB determinations and approval must be submitted to the EPA Human Subjects Research Review official for final review and approval.

For research not conducted or supported by any federal agency that has regulations for protecting human research participants and for which the intention of the research is submission to the EPA, the EPA regulations protecting human research participants apply, including:

- The provisions of 40 CFR 26 are extended to human research involving the intentional exposure of non-pregnant, non-nursing adults to any substance,
 - The intentional exposure of pregnant women, nursing women, or children to any substance is prohibited.
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- [40 CFR 26](#), 40 CFR 26.201-203, 40 CFR 26.304, 404-405,
 - [40 CFR 26.1101-1125](#) (Subpart K—Basic Ethical Requirements for Third-Party Human Research for Pesticides Involving Intentional Exposure of Non-pregnant, Non-nursing Adults)
 - [40 CFR 26.1201-1203](#) (Subpart L—Prohibition of Third-Party Research for Pesticides Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women) [AAHRPP element I.1.D.]

Children in Observational Research Greater than Minimal Risk but with Prospect of Direct Benefit

Such research is allowable if:

- The intervention or procedure holds out the prospect of direct benefit to the individual participant or is likely to contribute to the participant's well-being.
 - The risk is justified by the anticipated benefit to the participants.
 - The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.
 - Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §26.406. 40 CFR 26.304, 40 CFR 26.404-405
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- [40 CFR 26](#), [40 CFR 26.201-203](#) (Subpart B—Prohibition of Research Conducted or Supported by EPA Involving Intentional Exposure of Human Subjects who are Children or Pregnant or Nursing Women)
 - [40 CFR 26.304](#) (Additional protections for pregnant women and fetuses involved in observational research) [AAHRPP element II.4.A.]

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Financial Disclosures

In addition to requirements for an institutional policy on conflict of interest, several federal agencies have their own requirements for disclosures related to their sponsored research projects.

The Stanford Research Policy Handbook provides guidance related to the requirements of those agencies.

- Stanford University Research Policy Handbook: [RPH 4.2](#)
PHS and NSF Requirements Regarding Financial Disclosures and Agency Notifications
[AAHRPP element I.6.B]