



WSU HRPP Policy Guidance Document

Additional Regulations for Research Involving other Federal Agencies

Department of Justice(DOJ), Department of Energy (DOE), & Department of Education (ED)

The following policy guidance is summary to address updates and clarifications to the **HRPP Policy 6-7 Additional Regulations for Research Involving Other Federal Agencies** (current version 11.2024). This policy guidance is also provided to update the WSU IRB processes and procedures to be inline and current with the Federal Agencies named in the policy. The full policy and supporting documents will be released March 2025. Please contact the IRB Administrative Office for assistance with submissions supported by the Federal Agencies named in HRPP Policy 6-7 Additional Regulations for Research Involving Other Federal Agencies.

MAJOR POLICY CHANGES

- Clarifications and additions as follows:

RESEARCH SUPPORTED BY THE DEPARTMENT OF JUSTICE (DOJ):

Principal Investigator Responsibility:

(Addition per AAHRPP Element II.3.E)

In addition to complying with the pre-2018 Common Rule requirements PIs conducting research supported by DOJ/NIJ/OJP have the following responsibilities and the full list of PI responsibilities for conducting research supported by the DOJ, PIs must have a privacy certificate approved by the National Institute of Justice Human Subjects Protection Officer. This is required for all projects.(HRPP Policy 6-7 Additional Regulations for Research Involving Other Federal Agencies, AAHRPP Submission, Document 133, page 275).

RESEARCH SUPPORTED BY THE DEPARTMENT OF ENERGY (DOE):

Protection of Data:

(Clarification per AAHRPP Element III.2.C)

Protocols for research involving PII or PHI must address DOE's specific requirements for the protection of such information, these requirements are currently outlined on DOE's website "[For Researchers.](#)" Additional information on DOE's requirements for the protection of research data is available on DOE's website "[DOE-Specific Requirements](#)".

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

Any breach involving personally identifiable information (PII) must be reported:

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

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

Classified Research:

(Clarified per AAHRPP Element II.3.G)

Per Wayne State University Code University Research policy section 2.41.01.140 (AAHRPP Submission Document 180, page 554): Classified research, that is any research placed under restrictions that prevent it from being freely described and its results openly published in the traditional manner, shall be excluded. This provision may be waived in a national emergency, and then only in circumstances that require University participation. A sponsor, upon request, may have the privilege of reviewing a report of the results of an investigation prior to publication, but publication delays beyond 90 days are not acceptable. Additional details about this process is described in the Wayne State University policy titled: Requesting a Waiver for Restricted and Proprietary Research.

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

Informed Consent:

(Clarified per AAHRPP Element II.3.G & II.3.F)

- When conducting classified research, the IRB may not grant a waiver of the consent process or waiver of documentation of consent.
- Informed consent may only be waived for classified research if the work meets one of the categories of the minimal risk human participant research addressed at 10 CFR 745.104.
- For Classified human subjects research (in whole or in part):
 - Exemptions (as per 10 CFR 745.107) and expedited review cannot be used. If the research meets a particular exemption or expedited category it may be noted, but full IRB review is required.
 - A waiver of informed consent may only be granted by the convened IRB for minimal risk research that qualifies for exemption under 10 CFR 745.104.
- The identity of the sponsoring Federal agency must be disclosed to subjects, unless the Sponsor requests that the information is not disclosed because doing so could compromise intelligence sources or methods, and the research involves no more than minimal risk, and the IRB determines that subjects will not be adversely affected by not disclosing the Sponsor's identity.
- The informed consent document must state that the project is classified and what that means for the purposes of the proposed project and what part of the research that applies to.

- f. The IRB must determine if participants need access to classified information to make a valid decision about whether to provide informed consent.
- g. Consent documents must include additional DOE elements of disclosure.

RESEARCH SUPPORTED BY THE DEPARTMENT OF EDUCATION (ED):

Definition of Children:

(Added per AAHRPP Element III.2.C)

Per Department of Education 34 CFR 97.402(a) children are defined as persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. (HRPP Policy 6-7 Additional Regulations for Research Involving Other Federal Agencies, AAHRPP Submission, Document 133, page 275) .

Family Educational Rights and Privacy Act (FERPA):

(Clarification per AAHRPP Element II.3.G)

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