



SOP 105: NON-FEDERALLY FUNDED RESEARCH

PURPOSE

The University of Utah Institutional Review Board (IRB) applies applicable U.S. federal regulations for protecting research participants when research is sponsored or supported by a federal agency. Generally, those same regulations are followed by the University of Utah IRB for non-federally funded research. Exceptions are outlined in this policy.

SCOPE

This policy applies to human subject research conducted at the University of Utah.

DEFINITIONS

- A.** The **Federalwide Assurance (FWA)** is an assurance of compliance with the U.S. federal regulations for the protection of human subjects in research.

POLICY

The University of Utah IRB follows the applicable U.S. federal regulations for protecting research participants when research is sponsored by a federal agency. Regulations on research involving drugs, biological products, and medical devices that fall under the jurisdiction of the Food and Drug Administration (FDA) are also applied by the University of Utah IRB when applicable (21 CFR 50, 56, 312, and 812). The University of Utah generally applies the regulations in 45 CFR 46 subparts, A, B, C, and D to research that is not federally funded except as outlined in this policy or other University of Utah IRB SOPs, as indicated.

Specifically, non-federally funded research is not subject to the same requirements for the following:

Continuing Review (see IRB SOP 404: Continuing Review)

For studies with no federal oversight or federal funding, the University of Utah IRB permitted continuing review to occur within two (2) years of approval. Granting two-year approval for new studies was discontinued in 2023 but the ongoing use of the two-year approval for studies undergoing continuing review is still allowed.

Unless the IRB determines otherwise, continuing review of research is not required for research eligible for expedited review, including studies with no federal oversight or federal funding.

Exemption from IRB Review (see IRB SOP 401b: Research Activities Exempt from IRB Review)

For studies with no federal oversight or federal funding, the University of Utah IRB designated additional exemption categories (A-E) allowing minimal risk research that fits into one or more of the additional exemption categories to be exempt from IRB review.

Please contact the IRB Office at (801) 581-3655 or irb@hsc.utah.edu for additional guidance.

**Informed Consent Requirements** (see IRB SOP 701: General Requirements of Informed Consent)

For studies with no federal oversight or federal funding, the pre-2018 Common Rule requirements for informed consent are required. The informed consent requirements related to the content, organization, and presentation of information included in the consent form and process as well as the basic and additional elements of informed consent in the Final Common Rule are not required but may be included.

Institutional Reporting Procedures (see IRB SOP 905: Institutional Reporting Procedures)

For studies with no federal oversight or federal funding, the IRB will not reporting to OHRP if the IRB takes any of the following actions:

- Determines that an event represents an unanticipated problem involving risks to participants or others.
- Determines that non-compliance was serious or continuing.
- Suspends or terminates approval of research.

Certification of Prisoner Research (see Investigator Guidance Series: Research Involving Prisoners)

The IRB will apply the criteria and additional duties outlined in Subpart C, Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects, with the exception that the IRB will not provide written certification to the Secretary that the duties of the Board have been fulfilled (outlined in §305(7)(c)).

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