Series 404 Exemptions and IRB Review | Institutional Review Board

Exemptions and Limited IRB Review from Series 404 of the Standard Operating Procedures

I. Exemptions & Limited IRB Review Generally

The Common Rule (45 C.F.R. 46) permits the use of Exemptions and Limited IRB Review for certain categories of human subjects research. These categories of review permit some types of human subjects research to move forward without having to comply with many of the regulatory requirements that must be present for Expedited and Convened IRB approvals. Exemption determinations and Limited IRB Review processes can only be carried out by the IRB. Investigators are not permitted to self-determine exemptions.

At Utah State University, both the Belmont Report and the Common Rule provisions guide the review of protocols. Thus, there are certain minimum criteria that must be present in all protocols, regardless of the level of review that protocol receives. Those include: Respect for Persons, Justice, Beneficence, Informed Consent, and Qualified Investigators. Those criteria are outlined and further explained in USU Policy 584. Utah State University has not adopted the provisions of the Common Rule regarding Broad Consent. Accordingly, Limited IRB Review and/or Exemption is not available for projects otherwise meeting the provisions of 45 C.F.R. 46.104(7) or (8).

In order to permit investigators to move forward with maximum flexibility, all Exemptions and Limited IRB Reviews share the Limited IRB Review process. Once a Limited IRB Review is completed, the protocol will be categorized as Exempt in Kuali Protocols and will receive a Certificate of Exemption.

II. Limited IRB Review Process

Limited IRB Review must be performed by a qualified member of the IRB. The Limited IRB Review process may not be used to disapprove (or deny) research; that can only be done by the Convened IRB. However, a qualified member of the IRB can determine that a project does not qualify for Limited IRB Review and must be submitted under a different review level (generally, Expedited or Convened IRB). Qualified IRB reviewers must not have a conflict of interest with the proposed project.

Once a complete protocol submission has been received through Kuali Protocols requesting review under the Exempt or Limited IRB Review categories, a pre-review will occur. The pre-review is a technical check, to ensure that all information necessary to render a determination on a protocol is present; this process is described in greater detail in SOP 403. Once the pre-review is successfully completed, the Limited IRB Review process begins.

Assignment to IRB Member

The complete protocol will be assigned to a qualified and experienced member of the IRB to begin the Limited IRB Review Process. Review assignments are done in order of the date of submission of a completed protocol application (i.e. a protocol that has been deemed to be complete through the pre-review process), except that just-in-time reviews may take precedence over earlier-submitted protocols.

Determine Eligibility

The assigned IRB member will first determine eligibility of the project for Limited IRB Review. This means that the project is minimal risk, it is not being conducted internationally (unless local IRB or REC approval is also obtained or the country has a process for exemption of research), does not target incarcerated individuals, and falls under one of the following categories for exemption:

Category 1

The research is conducted in established or commonly accepted educational settings; the research involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content; the research involves normal educational practices that are not likely to adversely impact the assessment of educators who provide instruction; and the research does not involve incarcerated persons (except for research aimed at a broader population that only incidentally involves incarcerated persons). Examples of work permitted under Category 1 include research on regular and special instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Category 2

The research involves educational tests, survey procedures, interview procedures (including focus groups), and/or observation of public behavior (which includes video or audio recording). Research involving educational tests may involve children. Children may not undergo survey procedures or interview procedures. Observation of public behavior that involves children is acceptable as long as the researchers have no participation or involvement in the activities being observed. When the research is limited to those types of procedures, one of the following must be true:

- The information obtained is recorded in such a manner that participants cannot be identified, directly or indirectly, through identifiers linked to the participants.
- Any disclosure of the participants' responses outside of the research would not reasonably place the participants at risk of criminal or civil liability, or be damaging to participants' financial standing, employability, educational advancement, insurability, or reputation.
- The information obtained is recorded by the investigator in such a manner that the identity of the participants can be readily ascertained, directly or through identifiers linked to the participants, and the IRB member assigned to the review determines that there are adequate provisions to protect the privacy of participants and maintain the confidentiality of the data. No children may be involved in research using Limited IRB Review procedures under this condition.

Category 3

Research involving benign behavioral interventions in conjunction with the collection of information from adult participants through verbal or written responses (including data entry) or audiovisual recording if the participant prospectively agrees to both the intervention and the information collection. A benign behavioral intervention is brief in duration (less than a few hours on a single day), harmless, painless, not physically invasive, and not likely to have a significant adverse lasting impact on the participants. The researcher must have no reason to believe that the participants will find the interventions offensive or embarrassing. When the research falls within this category, one of the following must be true:

- The information obtained is recorded in such a manner that participants cannot be identified, directly or indirectly, through identifiers linked to the participants.
- Any disclosure of the participants' responses outside of the research would not reasonably place the participants at risk of criminal or civil liability, or be damaging to participants' financial standing, employability, educational advancement, insurability, or reputation.
- The information obtained is recorded by the investigator in such a manner that the identity of the participants can be readily ascertained, directly or through identifiers linked to the participants, and the IRB member assigned to the review determines that there are adequate provisions to protect the privacy of participants and maintain the confidentiality of the data.

This category can involve deception (including misinformation or withholding of information) if the participant authorizes the deception by agreeing to be unaware of or misled regarding the nature or purposes of the research.

Category 4

Secondary research for which consent is not required using identifiable private information or identifiable biospecimens, if one of the following criteria are met:

- The identifiable private information or identifiable biospecimens are publicly available.
- Information, including information about biospecimens, is recorded by the investigator in such a manner that the identity of the participants cannot be readily ascertained directly or through identifiers linked to the subjects; the investigator does not contact participants, and the investigator will not re-identify the participants.
- The research involves only information collection and analysis involving the investigator's use of identifiable health information regulated under HIPAA for the purposes of health care operations, research, or public health activities as defined in HIPAA.
- The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 or Privacy Act of 1974, 5 U.S.C. 552a., and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501
- The information is obtained by the investigator in a manner that complies with the requirements for accessing education records under FERPA. This criterion is specific to Utah State University, and may not be utilized where the investigator will seek reliance by another institution.

Category 5

The project is a research or demonstration project conducted by or subject to the approval of a U.S. federal government department or agency head. The research must be designed to study, evaluate, improve, or otherwise examine a program that delivers a public benefit or service. The research must be conducted pursuant to specific statutory authority of the U.S. government, and that authority must have no other requirement that the research be reviewed by an IRB. Such research must include one of the following:

- Examination of procedures for obtaining benefits or services under such program;
- Investigation of possible changes in or alternatives to those programs or procedures; or
- Investigation of possible changes in methods or levels of payment for benefits or services under those programs.

The U.S. agency or department must publish a list of research and/or demonstration projects they will conduct or approve in a publicly-accessible format on a federal website prior to the involvement of human participants in the research, and it cannot involve any significant physical invasions or intrusion on the privacy of participants.

Category 6

Taste and food quality evaluation or consumer acceptance studies where either i) wholesome foods without additives are consumed; or ii) if a food is consumed that contains a food ingredient or an agricultural chemical/environmental contaminant, the food ingredient or agricultural chemical/environmental contaminant is at or below the level and for a use found to be safe by either the FDA, EPA, or USDA's Food Safety and Inspection Service.

Ensure Minimum Review Standards

Once the IRB member has determined that the project falls under one of the categories articulated above, the IRB member must also ensure that the minimum review standards in USU Policy 584.2.2 are met. These criteria include the following:

Respect for Persons

The circumstances of recruitment shall be disclosed, and will not be coercive or present undue influence or inducement for participation. When appropriate, participants will receive all relevant information about the study in advance and in a manner that is clear to them. Questions from prospective participants and participants shall be answered truthfully, and information cannot be withheld simply to enhance recruitment efforts. Participants will be fully aware of their rights. Vulnerable and underrepresented populations will receive advanced consideration and protection.

Beneficence

Research will not expose participants to unreasonable risk of harm, including social, legal, economic, psychological, or physical harm. Sound research design will be used to ensure risks are minimized and benefits are maximized. Both the probability and magnitude of harm will be reasonable in relation to the anticipated direct or indirect benefits of participation.

Justice

Selection of subjects will be equitable, with the overall goal of ensuring that the benefits and burdens of research participation are fairly distributed. Subjects should be selected based on the research questions, rather than ease of access or vulnerability. Subjects must not be unduly induced to participate in research, and no procedures should be used that undermine the completely voluntary nature of research participation. Enrollment into a study must never be the product of coercion or undue influence.

Qualified Investigators

Research must be performed or closely supervised by individuals who have the expertise, experience, and training to minimize risks and ensure, as much as possible, that no harm comes to human participants in research. The PI maintains primary responsibility for the conduct of the research, and must ensure that all study team members are appropriately trained in human subjects research protections, the relevant study procedures, and all applicable laws and regulations impacting the research.

Informed Consent

All participants will be given the opportunity to receive complete information about the research and its risks, procedures, and benefits before freely giving their consent to participate. Participants should provide informed consent prior to participation; in cases where a participant cannot render legally effective informed consent, they should still be given a separate opportunity to assent to the research procedures. Coercion or undue influence must be minimized in a participant's decision-making process. All information should be made available in a manner easily understood to the participants. Informed consent is an ongoing process, and investigators are responsible for ensuring comprehension and continued consent throughout the life of a research project. In Limited IRB Review processes, this can be effectuated by including the following minimum information to participants with whom there is prospective interaction: that the activity involves research, a description of the research procedures, that participation is voluntary, risks and benefits of participation, the name and contact information for the researchers and the IRB, and a disclosure of the provisions made to maintain the privacy of participants and confidentiality of their information.

Clarifications regarding the criteria for Limited IRB Review for both Subsections Beneficence and Justice might need to be obtained via a review process with the research team.

Exemption Determined

Once Subsections A-C's criteria are demonstrated through the protocol materials submitted to the IRB, the IRB member will complete the Limited IRB Review process. A Certificate of Exemption will be issued, which will clearly state the Category/ies under Subsection B that apply to this research. The Exemption will be valid for five years from the date of issue, unless a lesser period is requested by the research team.

III. Amendments

As outlined in SOP 301, it is the research team's responsibility to ensure that the materials on file with the IRB are accurate and up-to-date. Any changes to materials, procedures, or processes that are material to the Limited IRB Review process should be filed as amendments to the protocol. This permits qualified IRB members to ensure that the changes permit the research to continue to move forward under Exemption and/or Limited IRB Review categories of review. If a change in the project requires review under a different level of review, that review is required to take place before the change can be implemented. However, while that review process is occurring, the research team may continue to operate under the terms of the Exemption and/or Limited IRB Review that was in place before the amendment was filed.

Amendments to Exempt protocols are reviewed using the Limited IRB Review procedure.

IV. Expiration

Once the Limited IRB Review process culminates in an Exemption, the project will retain its Exemption for five years, unless a lesser period is requested by the research team. No continuation review is required, though the protocol may be selected for post-approval monitoring. At the end of the five year period, a new protocol submission is required if the research is ongoing. Investigators should request closure of the protocol if the project is completed sooner than the expiration date assigned to the protocol.