

Series 405 Expedited Review Process | Institutional Review Board

The Expedited Review Process from Series 405 of the Standard Operating Procedures

I. Expedited Reviews Generally

The Common Rule (45 C.F.R. 46) permits the Secretary of the Department of Health and Human Services to designate certain types of research for Expedited review. The Office for Human Research Protections maintains this list and releases it as guidance by publishing a notice in the Federal Register.

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 and below. Utah State University has not adopted the provisions of the Common Rule regarding Broad Consent. Additionally, Utah State University's IRB does not conduct reviews under FDA regulations. Individuals wishing to conduct FDA-regulated research should contact the HRP Office to learn about options for Reliance.

II. Eligibility for Expedited Review

A protocol is eligible for Expedited Review if it falls under the categories of Expedited Review available in the guidance maintained by the Office for Human Research Protections (OHRP). The Expedited Review process is not available where any of the following are true:

- Identification of participants and/or their responses would reasonably place them at risk of criminal or civil liability, or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- Incarcerated persons are targeted for inclusion in the research.
- The research is classified research.
- The research is greater than minimal risk.

Categories of research activities available for Expedited Review include:

1. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
2. Prospective collection of biological specimens for research purposes by noninvasive means.
Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in

an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

3. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
4. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).
5. Collection of data from voice, video, digital, or image recordings made for research purposes.
6. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Additional areas of Expedited Review are described in SOPs 408 through 409, relating to Continuation Review, Post Approval Monitoring, and Amendments.

III. The Expedited Review Process

The Expedited Review process to gain initial approval is conducted by one or more qualified members of the IRB. At least annually, the IRB Chair reviews the IRB's membership, and designates members of the IRB as qualified, by their scholarly expertise or professional experience, to conduct Expedited Reviews. The IRB Chair or their designee shall make Expedited Review assignments using the areas of expertise outlined on the Scientific Roster, and ensures that each protocol is reviewed by a member with the appropriate, related scientific, scholarly, or professional expertise as related to that protocol.

Initial Expedited Reviews typically undergo review by two members of the IRB: one member qualified to make determinations about the research design and whose expertise permits them to give feedback about the population targeted by the protocol (especially where the participants are a member of population that is vulnerable or disadvantaged), and one member whose primary responsibilities are to ensure technical and legal determinations are appropriately made.

Once a complete protocol submission has been received through Quali Protocols requesting review under the Expedited or Convened IRB process, 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. Once the pre-review is successfully completed, the Expedited 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 Expedited Review Process. Review assignments are made in consideration of the following factors: date of submission, reviewer availability, reviewer expertise, and the need for just-in-time review. This reviewer is the Primary Reviewer.

Primary Review

In order to find and document that the criteria for approval, outlined in Section IV, are present, the Primary Reviewer will complete the Reviewer's Checklist. If the criteria for approval are not met but could be satisfied via revision, the Primary Reviewer shall use the Checklist to detail changes that would be necessary to gain approval.

Review Level Assessment

The Primary Reviewer will assess the criteria for approval, and then determine the eligibility for Expedited Review. If the protocol does not meet the criteria for Expedited Review outlined in Section II, the Primary Reviewer shall use the Reviewer's Checklist to indicate that the protocol should be assigned to the next available meeting of the Convened IRB. The review process will proceed according to the process outlined in SOP 406, in that case.

If the Primary Reviewer indicates in the Reviewer's Checklist that the protocol is appropriate, either as is or with modifications, for Expedited Review, the protocol will then be assigned to the next available HRP expert for the technical and compliance review, called Secondary Review.

Secondary Review

The HRP expert – usually an HRP Coordinator – will complete the Secondary Review of the protocol. The Secondary Reviewer will complete a review of the protocol that incorporates the feedback of the Primary Reviewer from the Reviewer's Checklist, and will ensure that technical and compliance-related aspects of the protocol are appropriately in place. This includes ensuring that there are not aspects of the protocol that require Convened IRB review, such as the involvement of incarcerated persons or a greater than minimal risk designation. The research team will typically work with the Secondary Reviewer for the duration of the protocol's review process, working to incorporate feedback from both rounds of review into the protocol.

Approval or Assignment to Convened IRB

A protocol cannot be disapproved using the Expedited Review process. Only the Convened IRB may disapprove a protocol. If the Primary or Secondary Reviewers wish to disapprove a protocol, it must be brought to the next available Convened IRB meeting for such action. If the research team is able to meet the criteria for approval to the satisfaction of the Primary and Secondary Reviewers, the Secondary Reviewer will issue an approval under the appropriate Expedited categories.

IV. Criteria for Approval

In order for a protocol to be eligible for approval, the following criteria, along with the criteria outlined in SOP 502, Informed Consent, must be found and documented by the assigned reviewer(s).

1. Risks to subjects are minimized by:
 - a. Using procedures that are consistent with sound research design
 - b. Using procedures that do not unnecessarily expose subjects to risk
 - c. Using procedures that are already being performed on the subjects for diagnostic or treatment purposes, whenever possible.
2. Risks to the subjects are reasonable in relation to any anticipated benefits
3. Risks to the subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.
4. Calculations of risks do not consider risks and benefits of procedures the participants will engage with if they choose not to participate in the research.
5. Calculations of risks do not consider possible long-term knowledge as a risk (can be considered as a benefit)
6. Selection of subjects is equitable considering the purpose of the research
7. Selection of subjects is equitable considering the setting in which the research will be conducted

8. Selection of subjects is equitable giving special consideration to populations that are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, economically disadvantaged persons, and educationally disadvantaged persons
9. Informed consent will be sought from prospective participants or their legally authorized representatives in line with the 500 Series of these SOPs
10. Informed consent will be documented or waived in accordance with the criteria outlined in SOP 502
11. Safety of subjects will be monitored via the data, as appropriate, in addition to any contemporaneous procedures
12. For greater than minimal risk research, data & safety monitoring plans are clear and provide adequate protections to participants
13. Safety of subjects is maximized by the involvement of qualified investigators in the research project
14. Privacy of the participants is adequately protected, when appropriate
15. Confidentiality of the data/specimens/information is adequately protected when appropriate
16. Adequate resources (including time, staffing, facilities, equipment, and/or supports to participants) exist for the safe and ethical conduct of the research
17. Additional safeguards are included in the study to protect the rights and welfare of subjects likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, economically disadvantaged persons, and educationally disadvantaged persons
18. Local laws, regulations, and norms have been explored by the research team and are represented in the overall design of the research
19. The structure of the project is in line with the Belmont Report principles of Respect for Persons, Justice, and Beneficence
20. If the procedures fall within the Expedited Review categories but are designated to be greater than minimal risk, a documentation for the rationale behind the greater than minimal risk finding

V. 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 the protocol that impact the accuracy of the information on file with the IRB must be filed as an amendment to the protocol before the change is implemented, except in the case where a change is required immediately to prevent or mitigate imminent harms to participants. In that case, a Reportable Event should be filed within five business days of implementing the change.

Only minor modifications are permitted via the amendment process. Changes that are more than minor modifications require a new protocol. Activities that have already occurred cannot be approved via the amendment process, unless accompanied by a Reportable Event to document the activities that have already taken place. Details regarding minor modifications and other amendment-specific determinations are available in SOP 407. Details regarding Reportable Events are available in the 600 Series of these SOPs.

Amendments to protocols reviewed and approved via the Expedited Review process are reviewed by one or more qualified members of the IRB, except in the case of administrative changes, which can be approved by appropriately qualified HRP staff.

VI. Expiration

For protocols approved after January 21, 2019: Unless timely renewal has occurred under SOP 409, protocols approved using the Expedited Review process shall expire in five years or on the date the research team indicates anticipated study completion – whichever is sooner. If a protocol is active for longer than five years, Continuation Review is required in order to ensure appropriate oversight of long-term human subjects research projects. While continuation review is not needed within that five year period, the protocol may be selected for post-approval monitoring during its initial approval period. Failure to complete post-approval monitoring activities will result in suspension of the protocol until such activities are complete, or until a finding of noncompliance has been determined under the 800 Series of these SOPs.

For protocols approved before January 21, 2019: Protocols shall be approved for a period of 364 days. Renewal must be obtained annually via the Continuation Review process, outlined in greater detail in SOP 409.