

Series 406 Convened Review Process | Institutional Review Board

The Convened IRB Review Process from Series 406 of the Standard Operating Procedures

I. Reviews Generally

The Common Rule (45 C.F.R. 46) tasks the Convened IRB with the review of proposed human subjects research. While many of those review processes can be delegated as outlined in SOP 402, the undelegated review processes occur via a meeting of the Convened IRB. For a detailed description of procedures for conducting a meeting of the Convened IRB, please see SOP 407.

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, in addition to the Common Rule criteria that must be present in all approved studies. 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. Convened IRB Review Categories – Initial and Continuing Review

The Common Rule assumes a Convened IRB review standard will apply for all non-exempt human subjects research. It permits the IRB to remove certain categories of review from that level, as outlined in SOPs 402-405. All other proposed human subjects research will receive review via the Convened IRB. Generally speaking, a protocol will be reviewed by the Convened IRB under the following circumstances:

1. The protocol includes procedures that are greater than minimal risk
2. The protocol is ineligible for review under the Exempt, Limited IRB, or Expedited Review processes
3. The assigned reviewer has documented a reason why the review should be done via the Convened IRB Review process
4. The protocol targets participants who are incarcerated or who are otherwise wards of the state;
5. There is a conflict of interest that impacts the risk determination of the protocol; or
6. The assigned reviewers are unable to agree regarding criteria for approval

III. The Convened IRB Review Process

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 required determinations on a protocol is present. Once the pre-review is successfully completed, the Convened IRB Review process begins.

Assignment to IRB Member

The complete protocol will be assigned to a qualified and experienced member of the IRB or a Consultant Reviewer to begin the Convened IRB 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. This completed checklist shall form the basis for discussion, and the documentation of findings, by the Convened IRB once the protocol is assigned to a meeting.

Review Level Assessment

The Primary Reviewer will assess the criteria for approval, and then determine the level of review required. 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.

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; SOP 405 shall govern the review process, in that case.

Convened IRB Review

An HRP expert – usually an HRP Coordinator – will complete a Secondary Review of the protocol, if that secondary review would not delay assignment to the Convened IRB. The Secondary Reviewer will complete a review of the protocol that incorporates some of 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 in order to allow the Convened IRB to focus on substantive items related to the Criteria for Approval, below. In some cases, this Secondary Review will take place after the Convened IRB meeting, in order to more expeditiously complete the protocol's review.

Once Step C is completed, the protocol will be assigned to the next available meeting of the Convened IRB. The next available meeting is the meeting on which there is adequate agenda space to complete a thorough review, and where the Primary Reviewer is able to attend the meeting. The Primary Reviewer will present the protocol to the Board. The Reviewer's Checklist will be made available to the members of the IRB in line with the procedures outlined in SOP 407, and will form the basis of the discussion of the protocol. Any member disagreeing with any finding or determination on the Checklist shall submit that disagreement as an item for discussion. The IRB shall reach agreement (via consensus or vote) on all determinations material to the Criteria for Approval in Section IV, below, and will vote on an action to be taken. The IRB may take the following actions on a protocol seeking initial review and approval:

1. Approve
2. Approve with minor specified modifications
3. Table
4. Disapprove

An approved protocol shall receive final approval and permission to begin once the Secondary Review for technical and compliance has been completed, if it was not completed before the meeting. A protocol that has been approved with minor specified modifications will be delegated to a qualified member or group of members to ensure the specified changes have been made; those minor modifications will be communicated to the research team along with any changes needed during the Secondary Review. It shall receive final approval once the Secondary Review and minor specified changes have been made. Final approval occurs on the date that the research team is given permission to begin the research. A protocol that has been tabled will be scheduled to return to a future meeting of the Convened IRB. The reasons the protocol was tabled will be delivered to the research team for action. A disapproved protocol will be disapproved in *Kuali Protocols*, and a reason for the disapproval will be delivered to the research team in writing. Investigators disagreeing with any of the actions the IRB takes on a protocol are able to appeal using the procedures specified in SOP 411.

Delegation of Further Review Activities

From time to time, it may be appropriate for the Convened IRB to delegate future review activities, such as where a protocol was approved by the Convened IRB to resolve an issue with the Conflict of Interest Management Plan, but the protocol would otherwise be approvable under the Expedited Review process. When a protocol reviewed and approved by the Convened IRB does not require Convened IRB Review, the Board may delegate future reviews to the Expedited Review process. This should be documented by a motion and a vote at a meeting of the Convened IRB.

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 IRB.

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

Unless the IRB finds and documents a need for more frequent review, protocols approved by the Convened IRB shall expire 364 days after the date of final approval. To extend the project beyond the approval period of 364 days, timely renewal of the protocol must be sought in accordance with the procedures outlined in SOP 409. Failure to seek timely renewal will result in the expiration of the protocol. When a protocol expires, all research activities must stop. All interventions and interactions on current participants must stop, unless the IRB finds an overriding safety concern or ethical issue involved such that it is in the best interests of individual participants to continue participating. New enrollment of participants shall not occur.