

University of California, San Diego  
Human Research Protections Program  
Institutional Review Board  
Standard Operating Policies and Procedures

Section 4.2  
Categories of Action

***Policy***

The IRB has the authority to take one of the actions outlined below after reviewing a research proposal. Except when the expedited review process is used, these actions will be taken by a vote of a majority of the regular and alternate members present, except for those members present but unable to vote in accordance with IRB's conflict of interest policies.

***Categories of Action***

1. Approved
  - a) Action taken if majority of the IRB votes to approve the study.
2. Approval Pending with Conditions
  - a) Action taken when minor additional information and/or modifications are required or the IRB is unable to judge the application adequately with the information provided. The PI is informed of the additional information/modifications that are required before approval can be granted. The response provided by the PI to the IRB's conditions will be reviewed as follows:
    1. Response to conditions that require review at a convened IRB meeting.
      - a) Action taken if the response is directly relevant to the determinations required by the IRB under 45 CFR 46.111 and/or 21 CFR 56.111 or;
      - b) Action taken if the IRB requests the response be reviewed at a convened IRB meeting. If the IRB requests that the same IRB review the response, the response will be assigned for review by that IRB at a subsequent, convened IRB meeting, or under exigent circumstances, may be assigned for review by a different IRB with the approval of the Chair of the IRB that requested the same IRB review the response, the Chair of the IRB accepting the review, and the HRPP Director.
    2. Response to conditions that can be reviewed by the IRB Chair, Primary or Secondary IRB Reviewer, or the IRB Chair's designee under expedited procedures ("Out-of-Committee review").
      - a) Action taken if the response is not directly relevant to the determinations required by the IRB under 45 CFR 46.111 and/or 21 CFR 56.111, AND the IRB requires minor additional information and/or specific modification(s). The needed information/revisions are agreed upon at the meeting. The additional information may include confirmation of specific assumptions or understandings on the part of the IRB regarding how the research will be conducted. The specific modifications may include precise language changes to the protocol or consent. The investigator is required to concur and provide the additional information and/or written revision of the document(s).
3. Deferral
  - a) Action taken if substantial modification is required, the IRB is unable to judge the application sufficiently because insufficient information was provided, or the IRB was unable to provide

specific changes to the protocol that if made would allow the IRB to make the required determinations regarding project approval. The study is deferred and the PI is informed of the reason(s) for the action. In order to receive approval for a deferred protocol, the study must be submitted to the same IRB for review at a subsequent, convened IRB meeting, or under exigent circumstances, may be assigned for review by a different IRB with the approval of the Chair of the IRB that deferred the study, the Chair of the IRB accepting the review, and the HRPP Director.

#### 4. Disapproval

- a) Action taken if the risks to the participants outweighs possible benefits or the proposed research does not meet federal criteria for IRB approval even after substantial modifications. A project may be disapproved if a majority of IRB members cast a vote of disapproval. The study is disapproved and the PI is informed of the reason(s) for the action. In order to receive approval for a disapproved protocol, the study must be re-written and submitted to the same IRB, if possible, for review at a subsequent, convened IRB meeting. The PI may also be given the opportunity to respond in person at the discretion of the IRB and IRB Chair.

#### ***Approval and Continuing Review Dates***

IRB approval is effective as of the date of the convened meeting of the IRB at which the action to approve was taken, indicating that all modifications requested during initial review, if any, have been made. Because investigators may take time to submit modifications or information needed to satisfy the approval pending stipulations, the release date of the approval letter may occur later than the date of the IRB meeting, and both dates will be included in the approval letter. No subjects can be enrolled prior to the IRB approval date. Approval of other appropriate institutional committees may also be required before the research can actually begin.

The approval period will expire exactly 365 days from the date of the most recent convened IRB meeting at which the project was reviewed (not 365 days from the approval release date), unless a shorter period is specified by the IRB during its review of the application. If the project was reviewed at several meetings, the date of the last convened meeting at which the project was reviewed may be used. Beyond this date, study approval expires. If the IRB has not reviewed and approved a research study by the study's current expiration date, i.e., IRB approval has expired, research activities should stop including recruitment, screening and enrollment of new subjects; continuation of research interventions or interactions with currently participating subjects; and data analysis. The PI will immediately submit to the IRB Chair a list of research subjects who could be harmed by stopping study procedures. The IRB Chair will determine if subjects on the list may continue participating in the research interventions or interactions.

When a project undergoes annual continuing review and is approved for continuation, the approval is for 365 days after the date of the most recent review of the study at a convened IRB meeting (not 365 days from the continuing review approval release date). However, OHRP permits the IRB to re-approve the research up to 30 days prior to the continuing review expiration and still maintain the same date for the Continuing Review approval.

Study modifications are effective as of the date of signature of the approval memo after either expedited or full committee review.

### ***Approval and Documentation***

The IRB will document that the criteria for approval of the project and the informed consent documents have been discussed at the meeting and that the criteria have been met. This will be documented in the meeting minutes, reviewer worksheets, and other sources. The results of IRB review and actions taken by the IRB will be communicated to the investigator, and to other offices, where appropriate, in a timely manner.

### ***Procedures***

1. The IRB reviews and determines the appropriate action, noted above, regarding the project under review.
2. The IRB Chair, HRPP Director and/or an Associate Director will review the response provided by the PI regarding projects determined to have approval pending conditions.
  - a) If the response is directly relevant to the determinations required by the IRB under 45 CFR 46.111 and/or 21 CFR 56.111 or the IRB requests the response be reviewed at a convened IRB meeting, the response will be placed on the agenda for review at the next appropriate IRB meeting. If the IRB requests that the same IRB review the response, the response will be assigned for review by that IRB at a subsequent, convened IRB meeting, or under exigent circumstances, may be assigned for review by a different IRB with the approval of the Chair of the IRB that requested the same IRB review the response, the Chair of the IRB accepting the review, and the HRPP Director.
    1. If the response is assigned to the same IRB that performed the initial review, the response will be assigned to either the previous Primary Reviewer/Discussant, Secondary Reviewer or IRB Chair who will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials.
    2. If the response is assigned to an IRB that did not perform the initial review, the IRB Chair is assigned as the reviewer of the response. The Chair will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials. The IRB Chair or a member of the IRB that performed the initial review of the project will be asked to provide a review of the response.
  - b) If the IRB requests that the response be reviewed by a convened IRB, the response will be placed on the agenda for review at the next appropriate IRB meeting. The response will be assigned to either the previous Primary Reviewer/Discussant, Secondary Reviewer or IRB Chair who will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials.
  - c) If the response provides the specific modifications and/or information requested by the IRB and the response is not directly relevant to the determinations required by the IRB under 45 CFR 46.111 and/or 21 CFR 56.111, the response is assigned for review by an IRB Chair, the Primary or Secondary reviewer or the IRB Chair's designee, and the response may be reviewed using expedited procedures.
3. The IRB Chair, HRPP Director and/or an Associate Director will review the response provided by the PI regarding projects determined to be deferred.
  - a) The response will assigned to the same IRB that determined the project be deferred unless under exigent circumstances, when the response may be assigned to a different IRB, if the Chair of the IRB that deferred the project, the Chair of the IRB accepting the review, and the HRPP Director have approved review by a different IRB. If the response is assigned to the same IRB, the

response will be assigned to the previous Primary Reviewer/Discussant and/or Secondary Reviewer and/or IRB Chair if the Primary Reviewer/Discussant and/or Secondary Reviewer are not able to review the response. The Primary Reviewer/Discussant, Secondary Reviewer or IRB Chair will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials. If the response is assigned to a different IRB for review, the response will be assigned by expertise to the appropriate Primary Reviewer/Discussant and/or Secondary Reviewer. The IRB Chair or a member of the IRB that deferred the project will be asked to provide a review of the response. The Primary Reviewer/Discussant, Secondary Reviewer or and/or IRB Chair will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials.

4. The IRB Chair, HRPP Director and/or an Associate Director will review the response provided by the PI regarding projects determined to be disapproved.
  - a) The response will assigned to the same IRB that disapproved the study, if possible. If the response is assigned to the same IRB, the response will be assigned to the previous Primary Reviewer/Discussant and/or Secondary Reviewer and/or IRB Chair if the Primary Reviewer/Discussant and/or Secondary Reviewer are not able to review the response. The Primary Reviewer/Discussant, Secondary Reviewer or IRB Chair will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials. If the response is assigned to a different IRB for review, the response will be assigned by expertise to the appropriate Primary Reviewer/Discussant and/or Secondary Reviewer. The IRB Chair or a member of the IRB that disapproved the project will be asked to provide a review of the response. The Primary Reviewer/Discussant, Secondary Reviewer or and/or IRB Chair will lead the discussion by presenting his/her findings and recommendations resulting from the review of the response materials. The PI may also be given the opportunity to respond in person at the discretion of the IRB and IRB Chair.

***Applicable Regulations***

[21 CFR 56.110\(b\)](#)

[21 CFR 56.111](#)

[45 CFR 46.110\(b\)](#)

[45 CFR 46.111](#)

[ICH 3.1.1](#)

[ICH 3.3.9](#)