

**Policy Number: 11**

**Title: IRB Committee Determinations/Motion**

**Date of Last Revision: 11/30/2009, 06/01/2010, 06/05/2013, 08/16/2017**

**Policy:**

It is the policy of the UC Irvine (UCI) Institutional Review Board (IRB) to render motions/determinations according to the Federal regulations.

**I. Approved**

An approval is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable) and no changes to the research application are required. Investigators are notified that the official IRB approval letter is available within 10 working days. Actual commencement of the study may have to wait until other (non-IRB) approvals have been obtained.

**II. Minor Changes**

Minor Changes status is granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable) and the changes required by the full Committee or subcommittee, if research qualifies as expedited, are specific, non-substantive changes or are changes that only require simple concurrence by the Lead Researcher (LR). An official IRB communication will be sent via e-mail to the LR within 10 working days. The specified changes can be reviewed via an expedited procedure (i.e., by the Chair or another member designated by the Chair) without going back to the full committee. The application is approved if, on review, the changes have been made by the Investigator and confirmed by the Chair or his/her Designee. If any required changes have not been made, or additional changes have been made that were not requested, the Chair or his/her designee may refer the study for re-review.

**III. Tabled for Re-review**

A study that lacks sufficient information to conduct an adequate review may be tabled for re-review pending receipt of the requested information. In addition, a study may be tabled for re-review if the study does not meet the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable), the subcommittee requires full Committee review of an expedited submission; or the IRB Committee recommends substantial changes to the IRB Application, Protocol Narrative, informed consent document(s), or other pertinent documents rendering it unable to assess the risk/benefit ratio without the completed changes. An official IRB communication will be sent via e-mail to the LR within 10 working days. A completely revised protocol/consent package must be reviewed by the IRB. Meeting deadlines apply to full committee protocols.

**IV. Disapproved**

A study that does not meet the criteria for approval as defined in 45 CFR 46.111 (and 21 CFR 56.111, if applicable). Disapproval of a protocol is generally only considered after multiple attempts have been made to resolve the issues (i.e., Tabled for Re-review) including, at the discretion of the IRB, discussing the issues with the LR or inviting the LR to the Committee meeting. A study can only be disapproved by the full IRB Committee. An official IRB communication will be sent via e-mail to the LR within 10 working days. The memo includes the rationale for the Committee's decision to disapprove and gives the LR an opportunity to respond in writing. If the LR chooses to

respond, a completely revised protocol/consent package must be reviewed by the IRB. Meeting deadlines apply to full committee protocols.

V. **Administrative Hold**

The IRB Committee or IRB Chairperson or designated Committee member may request the Investigator place some or all research activities of a currently approved study on hold when more information is needed. The determination may be requested and lifted at the level of review for which the study qualifies.

VI. **Sponsor-Imposed Suspension**

A sponsor-imposed suspension is when the IRB receives written notification that the sponsor has suspended the research study. This will be acknowledged by the IRB Committee, Chairperson or his/her Designee when the appropriate level of review determines the suspension is appropriate. The IRB may impose additional criteria for suspension, if needed, to protect the participants from potential harm.

VII. **Suspension**

A currently approved study may be suspended when evidence of a possible increase in risk to participants or non-compliance by the Investigator has been determined by the IRB. Suspensions are made by the IRB under full Committee review procedures.

VIII. **Expiration**

A currently approved study is expired when continuing review has not been conducted and approved prior to the study's expiration date. The study expires at midnight of the date specified on the approval letter and the informed consent document. No research activities can occur after the expiration date.

IX. **Termination**

A currently approved study may be terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with Federal regulations, and/or has been associated with unexpected serious harm to participants. Terminations are made under full Committee review procedures.

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**Procedure Number: 11.A**

**Title: Procedure for IRB Committee Determinations/Motion**

**Procedure:**

This procedure describes the process for the rendering of the IRB Committee determinations/motions following the review of proposed research activities.

**I. Lead Researcher (LR) Responsibilities**

- A. **Approved:** If approval is granted, the LR may begin the research when he/she receives the approval letter and approved documents from the IRB. The LR will be notified by the HRP staff via e-mail when these documents are available at the IRB Document Depot.
- B. **Minor Modifications:**
  - 1. The LR responds to the Committee requirements in a cover letter outlining the changes and the rationale for any changes not incorporated. Changes not incorporated are referred to the Committee. The LR includes in the response a copy of any revised documents in their entirety. The changes to the documents are highlighted or underlined.
  - 2. Amendments receiving a minor modification status may not be implemented until a satisfactory response by the LR has been received and final approval has been granted in writing by the IRB.
  - 3. Research activities may not start until all conditions have been met and the IRB Chairperson or his/her designee has approved the study and the approval documents have been processed.
- C. **Tabled for Re-review:**
  - 1. The Investigator responds to the Committee requirements in a cover letter outlining the changes and the rationale for any changes not incorporated. The Investigator includes in the response a copy of any revised documents in their entirety.
  - 2. Amendments receiving a "tabled for re-review" status are not implemented until a satisfactory response by the LR has been received and approval has been granted in writing by the IRB.
  - 3. Tabled for re-review studies must go back to the original IRB Committee for review once a response is received.
  - 4. Research activities may not begin until all conditions have been met and the IRB Chairperson or his/her designee has approved the study and the approval documents have been processed.

**II. IRB Committee Responsibilities**

The IRB Committee Chairperson or his/her designee, or the full IRB Committee rendering decisions on reviewed research activities may make the following determinations and/or motions:

- A. **Approved:** Approval may be granted if the research activity meets the criteria for approval as defined in 45 CFR 46.111 and no changes to the research application are recommended.
- B. **Minor Changes:** A "minor changes required" status is stipulated only when the requested changes are clear and specific in nature and do not require clarification by the LR. Clarifications that are minor and will not change the risk to the participant regardless of the response can also be given a "minor changes" status. Changes not incorporated are referred back to the original Committee. The recommended changes are made to the IRB Application, Protocol Narrative, informed consent documents, or other pertinent documents before IRB approval can be granted. The IRB Committee provides a letter to

the Investigator outlining the specific changes required for approval.

1. New IRB applications receiving a “minor changes” required status are administratively withdrawn if an adequate response to the Committee requirements has not been received by the IRB within 6 months of the date of the “minor changes” required letter.
  2. Continuing review applications receiving a “minor changes” required status expire on the date of study expiration if an adequate response has not been received by the IRB prior to the study expiration date.
- C. **Tabled for Re-Review:** Tabled for re-review is granted if the study lacks sufficient information to conduct an adequate review at the full Committee review level; the study does not meet the criteria for approval as defined in 45 CFR 46.111; the Committee requires full Committee review of an expedited submission; or if the IRB Committee recommends substantial changes to the IRB Application, Protocol Narrative, informed consent document(s), or other pertinent documents.
1. New IRB applications receiving a “tabled for re-review” status are administratively withdrawn if an adequate response to the Committee requirements has not been received by the IRB within 6 months of the date of the “tabled for re-review” letter.
  2. Continuing review applications receiving a “tabled for re-review” status expire on the date of study expiration if an adequate response has not been received by the IRB prior to the study expiration date.
  3. The IRB reviewers may contact the Investigator directly or the IRB may invite the Investigator to a Committee meeting to allow the LR the opportunity to address the Committee’s concerns.
- D. **Disapproved:** A study that does not meet the criteria for approval as defined in 45 CFR 46.111. Disapproval of a protocol is only considered after multiple attempts have been made to resolve the issues with the Investigator (i.e., Tabled for Re-review status). A study can only be disapproved under full Committee review procedures.
- E. **Administrative Hold:** The IRB Committee or IRB Chairperson or designated Committee member may request that an Investigator voluntarily place some or all research activities on hold when additional information is needed by the IRB. This request is made and lifted at the level of review for which the study qualifies.
- F. **Sponsor-Imposed Suspensions:** A sponsor-imposed suspension notification is reviewed at the level of review for which the study qualifies. If there are no safety issues (e.g., for interim analysis of data), the IRB does not change the study status. If safety issues exist and the review determines the suspension is appropriate, the IRB changes the study status to sponsor-imposed suspension and identifies the criteria for the suspension. The IRB may impose additional criteria for suspension, if needed, to protect the participants from potential harm. Sponsor-imposed suspensions are lifted at the level of review for which the study qualifies.
- G. **Suspension:** A currently approved study is suspended when evidence of a possible increase in risk to participants or non-compliance by the Investigator has been determined by the IRB. Suspension is conducted at the level of review for which the study qualifies.
- H. **Expired:** A currently approved study must expire if continuing review has not been conducted and approved prior to the study’s expiration date.
- I. **Termination:** A currently approved study is terminated if the study is not being conducted in accordance with the IRB policies, is not in compliance with Federal regulations, and/or has been associated unexpected serious harm to participants. Terminations for cause are made under full Committee review procedures.

### III. IRB Analyst or Administrator Responsibilities

- A. The Analyst or higher captures in the minutes the determinations and motions as presented during the full IRB Committee meetings.
- B. The HRP team under the direction of the Analyst or higher prepares all Committee review letters and approval letters corresponding to the Committee's determinations. Administrative Contacts are copied on all Committee correspondence. Department Chairs and Faculty Sponsors (when applicable) are copied on IRB Tabled for Re-review, Disapproval, Administrative Hold and Suspension and Termination correspondence. School Deans are copied on Suspension and Termination correspondence.
- C. Responses from LRs for motions of "minor changes" required are reviewed and changes are verified. The HRP team will meet with the Chairperson or his/her Designee for review of the response and final approval. Upon completion, approval documents are processed and a copy is placed in the IRB file. The HRP staff will notify the LR when the Approval Letter and approved documentation (e.g., Protocol Narrative, informed consent document(s)) are available for downloading.
- D. Responses from the LR for motions of "tabled for re-review" are prepared for full IRB Committee or the subcommittee for further review and determination.
- E. The Analyst or higher and/or HRP staff makes appropriate database entries for motions and responses to Committee actions and review correspondence.