Subject: Procedure for IRB Committee Determinations/Motions

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

I. Investigator Responsibilities.
   A. Approved: If approval is granted, the Investigator may begin the research when he/she receives the written letter of approval from the IRB.
   B. Approved Pending Review and Approval by the Chairperson or His/Her Designee:
      1. The Investigator responds to the Committee recommendations in a cover letter outlining the changes and the rationale for any changes not incorporated. Changes not incorporated are referred to full Committee. The Investigator includes in the response a copy of any revised documents in their entirety. The changes to the documents are tracked.
      2. Amendments receiving an approved pending status may not be implemented until a satisfactory response by the Investigator 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 signed a final approval letter.
   C. Deferred:
      1. The Investigator responds to the Committee recommendations 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. The changes to the documents are tracked.
      2. Amendments receiving a deferred status are not implemented until a satisfactory response by the Investigator has been received and final approval has been granted in writing by the IRB.
      3. Deferred studies must go back to the 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 signed a final approval letter.

II. IRB Committee Responsibilities.
   A. 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:
      1. 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.
      2. Approved Pending Review and Approval by the Chairperson or His/Her Designee: An “approved pending” status is stipulated only when the requested modifications are clear and specific in nature and do
not require clarification by the Investigator. Clarifications that are minor and will not change the risk to the participant regardless of the response can also be given an “approved pending” status. Changes not incorporated are referred to full Committee. The recommended modifications are made to the IRB Application, Sponsor’s protocol, informed consent documents, or other pertinent documents before final IRB approval can be granted. The IRB Committee provides a letter to the Investigator stipulating the specific modifications required for approval.

a) New study applications receiving an approved pending status are administratively withdrawn if an adequate response to the Committee recommendations has not been received by the IRB within 11 months of the date of the approved pending letter.

b) Continuing review applications receiving an approved pending status are expired on the date of study expiration if an adequate response has not been received by the IRB prior to the study expiration date.

3. Deferred: A deferral is granted if the study does not meet the criteria for approval as defined in 45 CFR 46.111 or if the IRB Committee recommends substantial revisions to the IRB Application, Sponsor’s Protocol, informed consent document(s), or other pertinent documents. The Investigator’s response is reviewed full Committee.

a) The IRB Committee may invite the Investigator to a Committee to allow the Investigator to address the concerns of the Committee.

b) New study applications receiving a deferral status are administratively withdrawn if adequate responses to the Committee recommendations have not been received by the IRB within 11 months of the date of the deferral letter.

c) Continuing review applications receiving a deferral 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.

4. Tabled: A study that lacks sufficient information to conduct an adequate review at the full Committee review level is tabled pending receipt of the requested information. The study is placed on the next agenda pending receipt of the additional information.

5. Tabled due to Lack of Time: When the Committee lacks sufficient time, at a full Committee meeting, to review a study. The study is placed first on the next week’s agenda.

6. Sponsor-imposed suspension: Notification is reviewed at the level of review for which the study qualifies.

a) If there are no safety issues, the IRB does not change the study status and acknowledges receipt of the Sponsor’s suspension requesting notification of any future correspondence from the sponsor.

b) If safety issues exist and the review determines the suspension is appropriate, the IRB changes the study status to sponsor-imposed suspension and identify 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.

7. Suspension for Cause: A currently approved study is
suspended for cause 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.

8. **Expired:** A currently approved study must expire if continuing review has not been conducted and approved prior to the study’s expiration date. This determination is made and lifted at the level of review for which the study qualifies.

9. **Termination for Cause:** A currently approved study is terminated if the study is not being conducted in accordance with the HRPP policies, is not in compliance with Federal regulations, and/or has been associated with unexpected serious harm to participants.

Terminations for cause are made under full Committee review procedures.

### III. HRPP Regulatory Compliance Analyst (RCA) Responsibilities.

A. The RCA captures in the minutes the determinations and motions as presented during the full IRB Committee meetings.

B. The RCA prepares all Committee Action Letters (CALs) and Final Approval Letters (FALs) corresponding to the Committee’s determinations.

C. The RCA enters into the HRPP database follow-up dates for Investigator responses based on the determinations and send reminders of the impending expiration date to the Investigator.

D. Responses from Investigators for motions of “approved pending” are reviewed and changes are verified. The RCA completes final approval letters and forward to the Chairperson or his/her Designee for review and signature. Upon completion, the FAL is sent to the PI and a copy placed in the HRPP file.

E. Responses from Investigators for motions of “deferral” are prepared for full IRB Committee or the subcommittee for further review and determination.

F. The RCA makes appropriate database entries for motions and responses to Committee Action Letters.

### References

HRPP III.B - IRB Committee Determinations or Motions