University of New Mexico Health Sciences Center
Human Research Protections Office

<table>
<thead>
<tr>
<th>Title: Non-Committee Review Conduct</th>
<th>SOP # HRP-032</th>
<th>Revision # 2</th>
<th>Effective Date 03/02/2015</th>
</tr>
</thead>
</table>

Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC

Approved: Richard Larson, MD PhD Vice Chancellor for Research

Date: 7/15

Date: 3/5/15

1 PURPOSE
1.1 This procedure establishes the process for a Designated Reviewer to conduct a Non-Committee Review.
1.2 The process begins when an HRPO staff member assigns a study to review by the Designated Reviewer.
1.3 The process ends when the Designated Reviewer submits his/her designated review.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Section 3: Added clarification about who conducts non-committee review.
2.2 Section 5.2: Added procedure to follow if submission should be reviewed by convened HRRC.
2.3 Updated references to Non-Committee Review Recommendation Checklists.

3 POLICY
3.1 The Designated Reviewer is responsible for conducting Non-Committee Review of eligible submissions.
3.2 The Designated Reviewer may not disapprove research.

4 RESPONSIBILITIES
4.1 The Designated Reviewer and HRPO staff members carry out these procedures.

5 PROCEDURE
5.1 The Designated Reviewer reviews all materials.
5.2 If the Designated Reviewer determines that the submission is not eligible for Non-Committee Review, or is eligible for Non-Committee Review but convened HRRC review is requested, refer to (HRP-040).
5.3 If the request is a continuing review that meets closure criteria, the Designated Reviewer will approve the action to close the study.
5.4 If the request is for study closure that does not meet closure criteria, the Designated Reviewer will instruct the HRPO staff member assigned to the submission to communicate with the investigator. The staff member will explain the issue and offer the opportunity to withdraw or correct the submission.
5.4.1 If the investigator withdraws the submission, stop processing.
5.4.2 If the investigator will not withdraw the submission and does not correct it, the submission requires review by a convened HRRC.
5.4.3 If the investigator corrects the submission, the Designated Reviewer will review the materials and continue to next step.
5.5 If consultation assistance is needed in the review of a study which requires expertise beyond or in addition to that available on the HRRC, follow “SOP: Consultation (HRP-051).”

5.6 The Designated Reviewer will check the accuracy of the Pre-Review in Click. If there are discrepancies, have the HRPO staff member revise the Pre-Review to reflect the accurate information as determined by the Designated Reviewer.

5.7 The Designated Reviewer will complete the appropriate Reviewer Checklist and any other associated checklists to make his/her review determination.

5.8 The Designated Reviewer will use the “Submit Designated Review” activity to document his/her determinations for the submission. Attach completed checklists to the review.

5.8.1 If the Designated Reviewer determines that modifications are required to secure approval, the reviewer will clearly list the comments as they are intended to appear on the communication to the investigator, including the reasons for the modification request, if applicable.

5.8.2 A Designated Reviewer will review PI responses to modifications unless otherwise specified in the “Notes” section of the designated review.

6 MATERIALS

6.1 CHECKLIST: Non-Committee Review Recommendations-NS-Expedited (HRP-402)

6.2 CHECKLIST: Non-Committee Review Recommendations-NS-Exempt (HRP-403)

6.3 CHECKLIST: Non-Committee Review Recommendations-Closure (HRP-404)

6.4 CHECKLIST: Non-Committee Review Recommendations-CR (HRP-405)

6.5 CHECKLIST: Non-Committee Review Recommendations-Mods (HRP-406)

6.6 SOP: Consultation (HRP-051)

7 REFERENCES

7.1 21 CFR §56.110(b)

7.2 45 CFR §46.110(b)