Title: Non-Committee Review Preparation

SOP #  HRP-031  
Revision # 2  
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Reviewed/Recommended for Approval: Mark Holdsworth, Pharm.D., Executive Chair HRRC  
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Approved: Richard Larson, MD PhD Vice Chancellor for Research  
Date: 3/5/15

1 PURPOSE
1.1 This procedure establishes the process to prepare for a Non-Committee Review.
1.2 The process begins when a HRPO staff member identifies a submission as being possibly eligible for Non-Committee Review.
1.3 The process ends when the HRPO staff member assigns the submission to a Designated Reviewer.

2 REVISIONS FROM PREVIOUS VERSION
2.1 Updated references to Non-Committee Review Recommendation Checklists.

3 POLICY
3.1 Non-Committee Review may be conducted by Designated Reviewers in accordance with HRP-030.
3.2 HRRC rosters are maintained using "DATABASE: HRRC Roster (HRP-601)."

4 RESPONSIBILITIES
4.1 HRPO staff members carry out these procedures.

5 PROCEDURE
5.1 Use the "Assign Designated Reviewer" activity and select a Designated Reviewer.
5.1.1 If a Designated Reviewer is not available, schedule the protocol to be reviewed by the convened HRRC.
5.2 Execute the "Assign Designated Reviewer" activity.
5.2.1 Attach the appropriate Non-Committee Review Recommendations Checklist (HRP-402, HRP-403, HRP-404, HRP-405 or HRP-406).
5.2.2 Attach other relevant checklist(s) and worksheet(s) as indicated by Pre-Review.
5.2.3 Attach any relevant minutes or correspondence.
5.2.4 WORKSHEET: Review Materials (HRP-301) may be used as an optional resource to provide support for HRPO staff that prepare materials for non-committee review.

6 MATERIALS
6.1 DATABASE: IRB Roster (HRP-601)
6.2 WORKSHEET: Review Materials (HRP-301)
6.3 CHECKLIST: Non-Committee Review Recommendations-NS-Expeditied (HRP-402)
6.4 CHECKLIST: Non-Committee Review Recommendations-NS-Exempt (HRP-403)
6.5 CHECKLIST: Non-Committee Review Recommendations-Closure (HRP-404)
6.6 CHECKLIST: Non-Committee Review Recommendations-CR (HRP-405)
6.7 CHECKLIST: Non-Committee Review Recommendations-Mods (HRP-406)

7 REFERENCES
7.1 21 CFR §56.110(b)
7.2 45 CFR §46.110(b)
7.3 HRP-030 Designated Reviewers SOP