



TITLE: **Non-Committee Review Preparation**
PURPOSE: Establish process for non-committee review.
RESPONSIBILITIES: Administrative/Designated Reviewer

PROCEDURES:

When incoming material is identified as eligible for Non-Committee review, choose the appropriate reviewer:

- **Designated Reviewer:** Using the IRB Roster, select a Designated Reviewer. If a designated reviewer is not available, schedule the protocol to be reviewed by the convened IRB.
- **Administrative Reviewer:** Refer to the appropriate administrative reviewer designated for non-committee review.

Prepare the review materials following the guidelines outlined in *Operations Manual: Pre-Review* and *Operations Manual: Non-Committee Review*

When the complete application materials are received and the review materials are prepared, send to the Administrative/Designated Reviewer. The Administrative/Designated Reviewer reviews the material according to SOP-042: Conduct of Non-Committee Review.

Follow *Operations Manual: IRB Records*.

MATERIALS:

- SOP-022: IRB Meeting Preparation
- SOP-021: Consultation to the IRB
- Operations Manual
- T106: HSPP Correspondence Form
- W311: Criteria for Approval and Additional Considerations

REFERENCES:

- 45 CFR §46.110(b).
- 21 CFR §56.110(b).
- OHRP's "Guidance on IRB Continuing Review of Research," dated November 10, 2010.



REVIEW/REVISIONS: From 10/01/2010 version: Referenced preparation of materials to appropriate SOPs instead of including them in this policy; Included reference to P&P-032: Conduct of Non-Committee Review.

From 08/01/2011 version: Revised SOP references to Operations Manual

From 01/2014 version: Renumbered from P&P-031; References to P&P-040 and P&P-051 revised to SOP-022 and SOP-021, respectively, to reflect new numbering system.