



TITLE: **Conduct of Non Committee Reviews**

PURPOSE: Administrative/Designated Reviewer conduct of a Non-Committee Review.

RESPONSIBILTIES: Administrative/Designated Reviewer
HSPP Staff

PROCEDURES:

The Administrative/Designated Reviewer reviews all relevant materials, using “W311: Criteria for Approval and Additional Considerations,” as appropriate and determines the required level of review:

- Not Human Research,
- Exempt Human Research
- Human Research approved using the expedited procedure,
- Verification that the conditions required by the IRB for approval of Human Research are met,
or
- Human Research that requires review by a convened IRB.

If the Administrative/Designated Reviewer cannot determine that the Human Research can be approved through non-committee review, the project must be referred to the convened IRB following SOP-022.

Should the Administrative/Designated Reviewer request the assistance of a consultant, following SOP-021, Consultations to the IRB.

Administrative reviewers designated by the IRB Chairs may review items not requiring review by the convened IRB.

Complete the HSPP Correspondence Form.

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: Included that, as designated by the convened IRB, a Designated Reviewer or Administrative Reviewer may verify that the conditions for approval as set out by the convened IRB have been met; Added reference to P&P-040, W311, OHRP's Guidance on Continuing Review and clarified the HSPP Correspondence Form as T106.

From 08/01/2011 version: Revised administrative reviewers' scope to be consistent with letter of designation; Removed reference to the VA; Referenced Operations Manual.

From 01/2014 version: Renumbered from P&P-032; References to P&P-040 and P&P-051 revised to SOP-022 and SOP-021, respectively, to reflect new numbering system.