



TITLE: Consultation to the IRB

PURPOSE: The IRB invites consultants with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

RESPONSIBILITIES: For review by a convened IRB, HSPP staff
For Non-Committee Review, the Designated Reviewer

PROCEDURES:

The HSPP staff or IRB chair identify a consultant with the required expertise needed to review the submitted information. Determine whether the consultant has a Conflicting Interest as defined in SOP-001: Definitions. If so, get a different consultant.

Contact the consultant and determine availability for review.

Using the “HRP-301 - WORKSHEET: Agenda Packet Contents”, prepare the necessary information for the consultant. The information may be limited to that needed by the consultant to review in order provide the expertise needed. If the consultant does not need to review any materials in order to provide a knowledgeable review, no materials need be provided.

For consultation to the convened IRB:

- Invite the consultant to the IRB meeting.
- If the consultant cannot attend the IRB meeting in person, provide the consultant’s written comments to the IRB members attending the meeting.

For consultation on a matter for Non-Committee Review:

- Obtain written information from the consultant, or
- For information received orally, document with the name of the consultant.

MATERIALS:

- SOP-001: Definitions
- HRP-301 - WORKSHEET: Agenda Packet Contents

REFERENCES:

- 21 CFR §56.107(f)
- 45 CFR §46.107(f)

REVIEW/REVISIONS: From 10/01/2010 version: Renumbered from P&P-051; references to P&P-001 revised to SOP-001 to reflect new numbering system.