



| <b>SOP: Consultation</b> |            |          |             |        |
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| NUMBER                   | DATE       | AUTHOR   | APPROVED BY | PAGE   |
| HRP-051                  | 07.23.2013 | L. Smith | C.Gates     | 1 of 1 |

## 1. PURPOSE

- 1.1 This procedure establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the HSRO staff or IRB member has identified the need for consultation.
- 1.3 The process ends when the consultant has provided additional expertise to the IRB.

## 2. REVISIONS FROM PREVIOUS VERSION

- 2.1 None

## 3. GUIDING PRINCIPLES

- 3.1 The IRB invites consultants with competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 3.2 Consultants with a Conflict of Interest must disclose the conflict in their consultation notes.

## 4. RESPONSIBILITIES

- 4.1 For review by a convened IRB, HSRO staff members carry out these procedures.
- 4.2 For Non-Committee Review, the Designated Reviewer carries out these procedures.

## 5. PROCEDURE

- 5.1 Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
  - 5.1.1 IRB members from other committees
  - 5.1.2 Other employees of the organization
  - 5.1.3 External consultants
- 5.2 Contact the consultant and determine availability for review.
- 5.3 Determine whether the consultant has a Conflicting Interest as defined in "SOP: Definitions (HRP-001)." If so, ensure that conflict is disclosed to IRB.
- 5.4 Use "WORKSHEET: Review Materials (HRP-301)" to determine which documents to make available to the consultant such that the IRB can obtain the additional expertise needed, and make these documents available to the consultant. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.5 For review by the convened IRB:
  - 5.5.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.
  - 5.5.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.
- 5.6 For Non-Committee Review:
  - 5.6.1 Directly obtain the information (oral or written) from the consultant.
  - 5.6.2 Document information received with the name of the consultant.

## 6. MATERIALS

- 6.1 SOP: Definitions (HRP-001)
- 6.2 WORKSHEET: Review Materials (HRP-301)

## 7. REFERENCES

- 7.1 21 CFR §56.107(f)
- 7.2 45 CFR §46.107(f)