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

2 REVISIONS FROM PREVIOUS VERSION
   2.1 Section 3.3: Added policy clarification that consultants may not vote as a member of the HRRC.

3 POLICY
   3.1 The HRRC or HRPO 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 HRRC.
   3.2 Consultants with a Conflict of Interest may not provide information to the HRRC.
   3.3 Consultants may not vote as a member of the HRRC.

4 RESPONSIBILITIES
   4.1 For review by a convened HRRC, HRPO staff members carry out these procedures.
   4.2 For Non-Committee Review, the Designated Reviewer or designated HRPO staff member 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 HRRC 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 Conflict of Interest as defined in "SOP: Definitions (HRP-001)." If so, obtain another consultant.
   5.4 If the consultant does not have access to the study materials in Click, use "WORKSHEET: Review Materials (HRP-301)" or equivalent to determine which documents to make available to the consultant so the HRRC 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 HRRC:

5.5.1 Make the consultant’s written comments, if any, available to the HRRC members attending the meeting.

5.5.2 If the consultant did not provide a written report or if requested by an HRRC member, invite the consultant to the HRRC meeting and sign a confidentiality agreement for non-disclosure of the discussion topics under review.

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 and attach to the study record, if applicable.

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)