	SOP: Consultation		
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1 PURPOSE

- 1.1 This SOP establishes the process for the IRB to obtain consultants.
- 1.2 The process begins when the IRB/HRPP staff or IRB member has identified the need for consultation for review of any research submission through:
 - 1.2.1 Convened Meetings
 - 1.2.2 Expedited Procedures
 - 1.2.3 Reportable New Information Process
- 1.3 The process ends when the consultant has provided additional expertise to the IRB.

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 Revised from the 5/30/2017 version
- 2.2 Revised from the 5/1/2022 version

3 SOP Statement


- 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 are to disclose to the IRB/HRPP when the consultant, or their immediate family have a financial interest in the sponsor, product, or service being tested or are involved in the design, conduct, or reporting of the research.
- 3.3 Consultants with a Conflicting Interest may not perform reviews for the IRB.

4 RESPONSIBILITIES

- 4.1 For review by a convened IRB, IRB/HRPP staff members carry out these procedures.
- 4.2 For Non-Committee Review, the Designated Reviewer or IRB/HRPP staff 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 [15.01.03 - Financial Conflicts of Interest in Sponsored Research \(tamus.edu\)](#) and University Rule [15.01.03.MI - Financial Conflicts of Interest in Sponsored Research](#) or as described in 3.2 above. If so, obtain another consultant.
- 5.4 Use HRP-301 - WORKSHEET - Review Materials to determine which documents to make available to the consultant so the IRB can obtain the additional expertise needed, and make these documents available to the consultant.
- 5.5 If the consultant has a user account in the IRB electronic system, use the 'Ad hoc" review function.
- 5.6 If the additional expertise needed does not require review of any materials, no materials need be provided.
- 5.7 For review by the convened IRB:
 - 5.7.1 Make the consultant's written comments, if any, available to the IRB members attending the meeting.
 - 5.7.1.1 IRB members have access to any consultant comments posted through the Ad hoc activity.

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5.7.1.2 The consultants comments may be obtained through other means of communication outside of the electronic system (i.e. email, teleconference, etc.).

5.7.2 If the consultant did not provide a written report or if requested by an IRB member, invite the consultant to the IRB meeting.

5.8 For Non-Committee Review:

5.8.1 Directly obtain the information (oral or written) from the consultant or access any consultant comments through the Ad hoc review activity.

5.8.2 Verify documentation of the information and the name of the consultant.

6 MATERIALS

6.1 HRP-001 - SOP - Definitions

6.2 HRP-301 - WORKSHEET - Review Materials

6.3 Texas A&M University System Regulation 15.01.03 Financial Conflicts of Interest in Sponsored Research

6.4 University Rule 15.01.03.M1 Financial Conflicts of Interest in Sponsored Research

7 REFERENCES

7.1 21 CFR §56.107(f)

7.2 45 CFR §46.107(f)

7.3 AAHRPP elements I.1.F, I-9, II.1.D, II.1.E, II.2.E-II.2.E.2