

SOP: CONSULTATION

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1. PURPOSE

- 1.1. This procedure establishes the process to obtain consultation.
- 1.2. This procedure begins when the IRB requires competence in special areas to assist in the review of issues which require expertise beyond or in addition to that available on the IRB.
- 1.3. This procedure ends when the IRB is informed of the consultation.

2. POLICY

- 2.1. None

3. RESPONSIBILITY

- 3.1. For <Committee Review>, HRPP staff members carry out these procedures.
- 3.2. For <Non-Committee Review>, the <Designated Reviewer> carries out these procedures.

4. PROCEDURE

- 4.1. Identify a consultant with the required expertise who can provide a review. Identify individuals as follows:
 - 4.1.1. IRB members
 - 4.1.2. Employees
 - 4.1.3. External consultants
- 4.2. Contact the consultant and determine availability for review.
- 4.3. Determine whether the consultant has a <Conflicting Interest>.
 - 4.3.1. If so, inform the <Meeting Chair> or the <Designated Reviewer>.
- 4.4. Obtain the agreement of the consultant to maintain confidentiality of information provided.
- 4.5. Use "POLICY: IRB Member Review Expectations (CM-004)" and "POLICY: IRB Member Review Expectations HUD (CM-009)" 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. If the additional expertise needed does not require review of any materials, no materials need be provided.
- 4.6. For review <Committee Review>:
 - 4.6.1. If the consultant provided a written report, make the report available to the IRB members attending the meeting.
 - 4.6.2. If the consultant did not provide a written report, invite the consultant to the IRB meeting.
 - 4.6.3. If requested by an IRB, invite the consultant to the IRB meeting.
- 4.7. For <Non-Committee Review>:
 - 4.7.1. Directly obtain the information (oral or written) from the consultant.
 - 4.7.2. Document information received with the name of the consultant.

5. REFERENCES

- 5.1. 21 CFR §50.54
- 5.2. 45 CFR §46.207 and §46.407