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 Full Board Review including all types of submissions or reports, the IRB Chairperson or designee will determine if outside consultation is needed.
3.2. For Non-Full Board Review including all types of submissions or reports, the Executive Reviewer will contact the IRB Chairperson to discuss obtaining outside consultation. If it is agreed that outside consultation is needed, this will be carried out under the guidance of the IRB Chair with the assistance of the Assistant Director of IRBs, if needed.

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 Conflict of Interest.
   4.3.1. If so, inform the Meeting Chair or the Executive Reviewer.
4.4. Determine if the consultant wants to remain anonymous to the study staff
4.5. When appropriate, obtain a written agreement of the consultant to maintain confidentiality of information provided.
4.6. Provide the protocol and any other relevant material to the consultant for review. For Full Board 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, either invite the consultant to the IRB meeting or the IRB chair or designee will summarize the findings of the consultant for the Board.
   4.6.3. If requested by an IRB, invite the consultant to the IRB meeting.
   4.6.4. Document within myIRB the information received with the name of the consultant.
4.7. For Non-Full Board Review:
   4.7.1. Directly obtain the information (oral or written) from the consultant.
   4.7.2. Document within myIRB the 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