The Institutional Review Board (IRB) chairs, IRB members, or the convened IRB may determine additional expertise from outside the Michigan State University (MSU) IRBs is needed in order to conduct an in-depth review of a human subject research study. See the Human Research Protection Program (HRPP) Manual 8-2 “Expedited Review Procedure” and 8-3 “Full Board Review Procedure” for assessment of needed expertise.

In some circumstances, the IRB may request informal input from individuals not associated with the IRBs. This informal input is limited to providing general information and the individual is not provided the IRB application, materials, or identifying information about the study. These informal requests do not require a formal agreement and are not subject to the requirements described below. Such requests are documented in accordance with HRPP Manual 4-7 “Recordkeeping.”

IRB members from other MSU IRBs may also be contacted (e.g., if the study is being reviewed by the Social Science / Behavioral / Education IRB, a Biomedical and Health IRB member is contacted) to provide additional expertise. IRB review will be conducted in accordance with HRPP Manual policies and procedures (e.g. access of materials through MSU IRB online system, review comments). The IRB member can provide recommendations regarding the study, including a recommendation for approval. However, the IRB member cannot approve or disapprove the research or vote at a convened IRB meeting of the MSU IRB of which they are not a member.

If the IRB requires additional expertise from individuals outside the MSU IRBs and will provide any identifiable details about the study, the procedures described below must be followed.

If an IRB member assigned to review a study determines that he/she does not have the expertise needed to conduct an in-depth review of the study or determines that additional expertise is needed, IRB staff is notified. The chair may be consulted to find another member on the IRBs for expertise. If it is found that no member on the IRBs has the particular expertise needed, additional expertise will be sought. When reviewing studies at a convened IRB meeting, the IRB may also make the determination that additional expertise is needed.
Depending on the field in which the additional expertise is needed, a consultant affiliated with MSU may be used. Examples of ways to locate an MSU consultant include:

- Recommendations from the MSU community (e.g., administrators, IRB members)
- Searches via the Community of Science website

If MSU lacks such expertise or is unable to obtain the expertise from an MSU individual, consultants not affiliated with MSU may also be used. Examples of ways to locate consultants not affiliated with MSU include:

- Recommendations from the MSU community (e.g. administrators, IRB members)
- Recommendations from associates at other universities
- Searches the Community of Science website

Once an individual is identified, the IRB chair or IRB staff will contact the individual to determine if the individual is interested. If the individual is interested, the individual will then be evaluated to assure they have appropriate expertise and that there is no conflict of interest.

The individual’s background and experience in the particular field will be examined to determine if he/she has the appropriate expertise. Examples of ways to determine if the individual has the needed expertise include:

- Recommendation(s) from research dean’s or chair’s of appropriate departments
- Curriculum vitae includes relevant expertise
- The individual’s profile on the Community of Science website, if available, demonstrates relevant expertise:

See HRPP Manual 10-1 “Conflict of Interest” for policies and procedures on conflict of interest. The definitions for conflict of interest apply to consultants. HRPP Manual 10-1 “Conflict of Interest” is provided to the individual prior to serving as an expert and the IRB chair confirms that the individual or their immediate family has no conflict of interest. If the individual or a member of his/her immediate family has a conflict of interest, he/she will be excluded from consideration as a consultant on the study.

If it is determined that the individual has the appropriate expertise and there is no conflict of interest, the individual will be asked to sign a consultant agreement. This agreement includes provisions for confidentiality. Requirements for confidentiality may include, but is not limited to, holding his/her review of the research study in confidence and not using any information gleaned from such review for his/her own gain. If the consultant will be attending the convened IRB meeting to provide his/her review, he/she is also required to hold the contents of the meeting in confidence and may not use any information gleaned from the meetings for his/her own gain. The agreement will also explain that while the consultant will be providing additional expertise and assisting in the review of the study, only members of the IRB may approve or disapprove research.
A fee arrangement, if applicable, will be made when it is determined that the consultant is appropriate to review the research study. Fee arrangements are typically limited to situations in which the individual is not affiliated with MSU, whose expertise is needed, and a fee for service is required to engage the individual in the review.

Documentation will be maintained that assures that the consultant:
- Has the needed expertise
- Does not have any conflicts of interest that would inhibit his/her ability to make fair and impartial judgments when reviewing the study
- Accepts the terms for confidentiality
- Was provided an explanation that only IRB members may approve or disapprove the research

Appropriate documentation will be maintained as required by HRPP Manual 4-7 “Recordkeeping.”

The consultant is provided with the needed information and a timeline for review. The type of information provided will vary depending on the type of review taking place (i.e., the scientific design of the entire study vs. the appropriateness of a particular procedure). The timeline will be based on the volume of material to review.

The consultant will review the provided information and make recommendations to the IRB members via a written report. For expedited review, the written report will be provided to members assigned to review the study. For full review, the written report will be provided to all IRB members. The report should include recommendations, such as whether the proposed conduct of the research is appropriate for the discipline, and if there are any changes that should be recommended to the investigator. Any report or information provided by the consultant will be kept in the corresponding IRB file.

The consultant may also be asked to make a presentation at the convened IRB meeting, if appropriate. Information presented by the consultant at the convened IRB meeting will be recorded in the IRB minutes. The consultant may not vote at the convened IRB meeting.

The IRB will take into account the recommendations and discuss the study and determine the course of action to take (i.e., approval, modification, disapproval). All criteria for approval need to be met before approval may be granted.

The decision will be communicated to the appropriate parties.

Follow-up with the consultant may be arranged on an as needed basis (i.e. evaluation of investigator’s response to requested modifications).