UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-022
AAHRPP:	Element II.1.D. & Element II.1.E.
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Reviewed By:	IRB Chair; IRB; ORIO
Procedure Title:	IRB Use of Additional Expertise

1.0 Objective

1.1. To describe the policies and procedures associated with the IRB's request for additional assistance by consultants to aid an in-depth review of a human subject research study.

2.0 General Description

2.1. The University of Southern Maine (USM) Institutional Review Board (IRB) Chair, IRB members, or the convened IRB may determine that additional expertise from outside the USM IRB is needed in order to conduct an in-depth review of a human subject research study.

2.2. In some circumstances, the IRB may request informal input from individuals not associated with the IRBs or even the university. 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, although they must be documented in the IRB records.

2.3. If the IRB requires additional expertise from individuals outside the USM IRB and will provide any identifiable details about the study, the procedures described in Section 5.0 below must be followed.

3.0 Definitions

3.1. Consultants: Subject matter experts who are employed, retained or otherwise engaged to give their opinion on a specific subject matter.

3.2. Conflict of Interest: "Situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's judgment in conducting or reporting research." *See Association of American Medical Colleges (AAMC), 1990*

3.2.1. "A conflict of interest in research exists when the individual has interests in the outcome of the research that may lead to a personal advantage and that might, therefore, in actuality or appearance, compromise the integrity of the research." *See National Academy of Sciences (NAS), Integrity in Scientific Research*

4.0 Responsibility

4.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

5.0 Procedure

5.1. ORIO staff and the RCA consider the need for consultants during the screening process.

5.2. Alternatively, an IRB member assigned to review a study may determine that they do not have the expertise needed to conduct an in-depth review of the study. The member notifies the RCA of this determination.

5.3. The Chair may be consulted to find another member on the USM IRB who has the required expertise. If it is found that no member of the USM IRB 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.

5.4. Depending on the field in which the additional expertise is needed, a consultant affiliated with USM may be used. A USM consultant may be identified through recommendations from the USM community (e.g., administrators, researchers or IRB members).

5.5. If USM lacks such expertise or is unable to obtain the expertise from a USM individual, consultants not affiliated with USM may also be used. An external to USM consultant may be identified through recommendations from the USM community (e.g., administrators, researchers, IRB members) or recommendations from associates at other institutes or organizations.

5.6. Once an individual is identified, the IRB Chair or IRB staff will contact the individual to determine if the individual is interested. Consultants will be queried as to whether they have a conflict of interest. (IRB Member Conflict of Interest).

5.7. The individual's background and experience in a particular field will be examined to determine if they have the appropriate expertise. Examples of ways to determine if the individual has the needed expertise include:

5.7.1. Recommendation(s) from administrators; and

5.7.2. Curriculum vitae including relevant expertise.

5.8. Prior to serving as an expert, the IRB will require the consultant to disclose any real or potential conflict of interest by him/her, a member of his/her family or any business partner/associate. If no such conflict of interest is present, the IRB Chair will confirm the engagement of the consultant for the specific review of the study. If the individual or a member of his/her immediate family, or business partner/associate, has a conflict of interest, he/she will be excluded from consideration as a consultant on the study.

5.9. Documentation will be maintained that assures that the consultant:

5.9.1. Has the needed expertise;

5.9.2. Does not have any conflicts of interest that would inhibit his/her ability to make fair and impartial judgments when reviewing the study;

5.9.3. Accepts the terms for confidentiality; and

5.9.4. Was provided an explanation that only IRB members may approve or disapprove the research. Appropriate documentation will be maintained as required by IRB policies.

5.10. 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.

5.11. 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 a 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 IRB record.

5.12. 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's presence will not count towards a quorum. Once the consultant presents his/her information, the IRB Chair will ask the consultant to leave the meeting, and the final discussion and vote will then occur. The consultant cannot vote at the convened IRB meeting. Any information or discussion provided by the consultant at the meeting will be recorded in the IRB minutes.

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

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

6.0 References

6.1. Association of American Medical Colleges (AAMC), 1990;

6.2. National Academy of Science (NAS), Integrity in Scientific Research;

6.3. 45 CFR 46.107(e);

6.4. Korenman, Stanley G. MD. Annotated between 2000 and February 2006. Chapter 4: Conflicts of Interest (COI). Teaching the Responsible Conduct of Research utilizing a Case Study Approach URL: https://ori.hhs.gov/education/products/ucla/chapter4/default.htm;

6.5. 21 CFR 56.107(e)