UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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| **Procedure #:** | HRPP-037 |
| **AAHRPP:** | Element I.1.F. |
| **Date Adopted:** | |
| **Last Updated:** | March 22, 2021 |
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| **Reviewed By:** | IRB Chair; IRB; ORIO |
| **Procedure Title:** | Scientific Review |

## 1.0 Objective

**1.1.** To describe policies, procedures and expectations for the Institutional Review Board (IRB) to assess the scientific importance and methodologic validity of proposed research, whether and how this importance justifies exposing research participants to risk of harms, and whether and how such risks could be minimized.

## 2.0 General Considerations

**2.1.** Under 45 CFR 46.111(a) and 21 CFR 56.111(a). IRBs are required to assess:

2.1.1. Whether or not the promise of a research project (potential direct benefits and value of knowledge gained) justifies the risks to participants, and

2.1.2. Whether the study is designed to achieve this promise with the minimum exposure of individuals to risk.

**2.2.** In order to properly protect the rights and welfare of the human subjects in each protocol it reviews, the IRB must understand the implications of the "knowledge to be gained" and the possible direct benefits of participation. This shall occur through:

2.2.1. The background section of the protocol should provide an argument for conducting the study and the IRB must be knowledgeable enough to assess the merits of that argument.

2.2.1.1. It is not the responsibility of the IRB to create such an argument itself, or even to reframe it if it feels the argument as presented is inadequate.

2.2.2. The IRB must be knowledgeable enough to understand the risks faced by participants, and to recognize when those risks can be further reduced. This will require expertise in areas such as the practice of medicine or the conduct of social science, in addition to general expertise in experimental statistics and study design.

2.2.2.1. For most protocols, which apply established methods and techniques to novel problems, a general level of expertise will be sufficient, but where general expertise is not sufficient, the IRB must call on additional resources.

**2.3.** In addition to the material presented in the protocol, the IRB will sometimes have additional external sources of information to assist in assessing the science of proposed research. These may include:

2.3.1. Food and Drug Administration (FDA) review in the context of an Investigational New Drug (IND) application

2.3.2. FDA review in the context of an Investigational Device Exemption (IDE) application

2.3.3. Review by Institutional Scientific Review Committees (SRCs)

2.3.3.1 If an SRC is in place, it should review a research proposal before it is submitted to the IRB. Wherever possible, the basis for this approval should be shared with the IRB.

2.3.4. Grant review committees

2.3.5. Investment decisions by commercial sponsors

2.4. Once a research proposal reaches the IRB, the board must rely on the expertise of the presenter, members of the review board or consultants. Both the Common Rule and the FDA regulations require that:

2.4.1. Each IRB shall have at least five members, with varying backgrounds to promote **complete and adequate review** of research activities commonly conducted by the institution;

2.4.2. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence); and

2.4.3. The diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. (24 CFR 46.107(a), 21 CFR 56.107(a)).

2.4.4.. Elements of complete and adequate review

2.4.4.1. USM follows a generalist IRB model with a small number of IRBs handling all of the institution's research reviews. When needed, specialized scientific knowledge can be provided by:

2.4.4.1.1.. Institutional SCRs, which can be established for different research specialties as required; or

2.4.4.1.2.. Consultants, per 45 CFR 46.107(e) "An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals will not vote with the IRB." Consultants may come from inside or outside the institution, and their qualifications to assist in review will be documented in the meeting minutes.

## 3.0. Research that presents no more than minimal risk

**3.1.** The USM IRB will follow three principles when reviewing research studies that present no more than minimal risk. The IRB will take all three of these considerations (maintaining respect, taking benefit to student researchers into account, and respecting the contributions of participants) into account when reviewing minimal risk research. The three principles are:

3.1.1. It will strive to maintain respect for its deliberations, and such respect would be undermined by the routine approval of poorly conceived or executed studies;

3.1.2. It will also take into consideration when research is conducted by students, part of the "importance of the knowledge that may reasonably be expected to result" is the learning of the student researchers themselves. When it presents no more than minimal risk to participants, the IRB will consider the learning process as one of the benefits of research and should not require research proposed by students to be perfect.

3.1.3. Lastly, when individuals are asked to participate in research, they likely do so in the expectation that they are making a contribution to others. Approving research that an IRB can foresee is without value robs participants of the meaning of their participation.

## 4.0 Specific Considerations

**4.1.** The University of Southern Maine (USM) IRB conducts reviews both for USM researchers and for researchers from other institutions that have contracted with USM through reliance agreements or other contractual mechanisms. The IRB needs formal mechanisms to assess its performance and the quality of its decisions, both with the USM community and with contracting institutions and investigators.

**4.2.** The USM IRB follows the generalist model, with social/behavioral and biomedical boards. Consequently, the IRB needs mechanisms to (a) assure that prior scientific reviews, where they have occurred, are communicated to the board; (b) assess whether

existing expertise on the board is sufficient for the review of specific protocols; (c) engage consultants where additional expertise is needed.

## 5.0 Responsibility

**5.1.** 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.

## 6.0 Procedures

**6.1.** ORIO staff will determine, at the time of receipt of a protocol for initial review, whether the board has the requisite expertise to provide adequate and complete review.

**6.2.** IRB staff will maintain a list of the specific areas of expertise of each board member and alternate.

**6.3.** IRB staff will take a submission's area of research and the expertise into consideration when assigning reviewers.

**6.4.** Board members assigned as reviewers will be asked if they have appropriate experience and knowledge to conduct a review.

**6.5.** If either the IRB staff or the assigned board member does not feel that they have the qualifications necessary for review, staff will identify and engage a consultant who can assist with review.

**6.6.** IRB staff will maintain a list of consultants for specific research domains.

**6.7.** Consultants will either submit their assessment of the protocol in writing in advance of the board meeting or be allowed to present at a convened meeting.

**6.8.** Consultants will not be allowed to vote in convened meetings.

**6.9.** The qualifications of consultants will be recorded in the minutes for the review of items to which they contribute.

**6.10.** When applicable IRB meeting minutes will explicitly reflect the board's assessment of the scientific or scholarly validity of proposed research.

**6.11.** If and when USM conducts scientific review of the proposed research, ORIO will communicate any such review to the IRB at the time of protocol submission, including both an assessment of scientific merit and the rationale for that assessment. Such procedures are coordinated with the ethics review process.

**6.12.** For research conducted at other institutions, reliance agreements or other contracts will require similar communication of scientific or scholarly review to the USM IRB at the time of protocol submission, if such review has occurred.

**6.13.** The IRB will meet at least annually with various USM departments that use its services, as well as with outside institutions, to conduct an assessment of the IRB's performance and to gather feedback on the quality of its decisions regarding scientific review.