

## **IRB Review Procedure - PHSR**

All projects involving human subjects' research at UMB must undergo internal scientific review (ISR) prior to IRB submission, in accordance with UMB Research policies. The procedure for this review within the PHSR Department will be carried out as follows:

1. The Department Chair serves as the Signature Authority (SA) for the PHSR Department. The submitting faculty member (PI) will designate a faculty member not on the protocol to perform the ISR prior to submission. Both the SA and the ISR reviewer must have reviewer access to the protocol.

2. The ISR will be conducted in accordance with Good Clinical Practice guidelines, and will address each of the following items related to the protocol, including but not limited to:

- Is the research question meritorious?
- Is the study design sound/valid?
- Is the study design able to answer the proposed questions and is it likely to result in significant new information for the field?
- Is the sample size adequate to answer the major scientific questions in the project?
- Have all potential risks been identified?
- Does the protocol incorporate all possible mechanisms for reducing risks?
- Are there adequate resources (i.e., adequate number of qualified staff, adequate facilities, availability of medical or psychological resources that participants may need as a consequence of the research, and adequate access to patients/participants) to carry out the study and ensure the safety and welfare of all participants?
- Are all investigators aware of their individual responsibilities with respect to this study?
- Does the principal investigator have adequate time and expertise to supervise the study appropriately?
- Have the financial implications of the research been considered and deemed acceptable to the department?
- Have ethical principles and/or conflict of interest issues been appropriately addressed?
- Confirmation that the protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility.

3. The ISR Faculty Member will forward recommendations to the Department Chair (SA) for consideration as follows:

- A. Approve – Can be submitted to IRB in current form.
- B. Contingent – Requires modification by PI, and may require second ISR.
- C. Deferred – Requires meeting between the Department Chair and Principal Investigator to discuss weakness of project and develop a contingency plan and/or future resubmission of protocol with second ISR review.

4. The PI will follow-up with Faculty Reviewer and the Department Chair regarding status of IRB review, and appropriate actions will be taken based on the changes made by the PI.