

Department of Pharmaceutical Sciences Procedure for IRB Protocol Submission Review

Procedure for Review of all Submitted Protocols

All new submission of IRB protocols will be submitted to the Vice Chair for Research (VCR), the Research Coordinator, and the Department Chair. The VCR will assign a faculty member who is NOT on the protocol to review the protocol for

1. The protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility,
2. There is a clinical and scientific justification for conducting the study
3. The department has made the appropriate space, personnel, and time commitment necessary to carry out the project
4. The financial implications of the research have been considered and deemed acceptable to the department,
5. Ethical principles AND CONFLICT OF INTEREST ISSUES have been appropriately addressed.

Comments and suggestions from the reviewer will be sent to the VCR and the Research Coordinator via email confirming that they have reviewed the protocol and have found it in compliance with the criteria. If however, there are concerns regarding the submission the VCR will inform the PI and ask that they address the concerns and return the revised protocol to the VCR and the Research Coordinator.

The VCR will forward all fully committee reviewed and approved submissions to the Department Chair for final departmental review and approval.

Criteria for Review of all Submitted Protocols

For the purpose of Scientific and feasibility review, Reviewer(s) should confirm that each protocol meets the following criteria

- A. At a minimum, the review should address the following questions/issues:
 - a. Is the research question meritorious?
 - b. Is the study design sound/valid?
 - c. Is the study design able to answer the proposed questions and is it likely to result in significant new information for the field?
 - d. Is the sample size adequate to answer the major scientific questions in the project?
 - e. Have all potential risks been identified?
 - f. Does the protocol incorporate all possible mechanisms for reducing risks?
 - g. 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?

- h. Are all investigators aware of their individual responsibilities with respect to this study?
- i. Does the principal investigator have adequate time and expertise to supervise the study appropriately?
- j. Have the financial implications of the research been considered and deemed acceptable to the department?
- k. Have ethical principles AND CONFLICT OF INTEREST ISSUES been appropriately addressed?
- l. Confirmation that the protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility.

Procedure for Submission to CRIES

Each submitted protocol is required to have the following prior to it being submitted to CICERO (formally BRAAN) showing Scientific and Feasibility Review

- B. The electronic signature of the designated individual on the CICERO (formally BRAAN) protocol will indicate that:
 - a. To ensure that the responsible entity has endorsed the study and agrees to take full oversight responsibility for the study if it is implemented each approved protocol should include the following statement of assurance signed by the Chair
 - i. My signature indicates that this protocol has been reviewed by the appropriate departmental REPRESENTATIVES, who have DETERMINED AND ADVISED ME that 1) the protocol has been reviewed and approved at the unit level for scientific value, validity of study design, and feasibility, 2) there is a clinical and scientific justification for conducting the study 3) the department has made the appropriate space, personnel, and time commitment necessary to carry out the project 4) the financial implications of the research have been considered and deemed acceptable to the department, 5) ethical principles AND CONFLICT OF INTEREST ISSUES have been appropriately addressed.
 - b. The protocol has passed entity-level review.
 - c. The protocol can be submitted to the IRB via CICERO for review and determination by the IRB.