

Addendum B

		Policy and Procedure
Department	Title	Number
Research	Research Approval Criteria, Preliminary Evaluation, and Approval Process	
Board Approval Date	Executive Vice President/COO	Issue Date
Med Staff Approval Date		Review Date

POLICY STATEMENT:

It is the policy of the institution to be notified of and to consistently and confidentially review all human subject research studies (“clinical research”) being conducted at an institution facility or utilizing an institution’s resources or personnel in order to determine if the study is being conducted in alignment with institution’s mission, vision, and ethical guidelines, and meets institution’s clinical research approval criteria.

The purpose of this policy is to outline:

- the approval criteria for research;
- the preliminary evaluation process for new research; and
- the approval/denial process for clinical research studies conducted at INSTITUTION.

SCOPE:

This policy applies to all clinical research conducted at institution.

APPROVAL CRITERIA:

All clinical research studies conducted at INSTITUTION or clinical research studies utilizing INSTITUTION’s resources or personnel must meet the following research criteria.

1. **INSTITUTION Mission and Vision Criteria**

The purpose and design of the clinical research study must be consistent with INSTITUTION’s mission to make a positive difference in the health status and lives of individuals and the community, with special concern for those who are vulnerable, in a manner that is committed to providing high quality, accessible, values-driven programs and services with equal attention to the physical, spiritual, and emotional dimensions of health. This includes, ensuring that all clinical research abides by the Ethical and Religious Directives for Catholic Healthcare Services.

2. Documentation Criteria

All documentation associated with the clinical research study shall be in finalized format, including, but not limited to, the study protocol, informed consent forms, regulatory submissions (IND, IDE), sponsor contract, grant agreements, investigator agreements, financial statements, privacy authorizations, schedule of events, etc.

3. Budget Criteria

The preliminary financial information must indicate that all professional fees, facility expenses, staff costs, and associated fees (i.e. IRB fees, recruitment costs, etc) are fully compensated at a reasonable and customary level, and a final budget must be approved by INSTITUTION's Finance Director.

4. Operational Criteria

A resource utilization plan must demonstrate the availability and commitment of all necessary and competent personnel (i.e. investigator, clinical research coordinator, data manager, pharmacist, nursing staff, etc.) and the accessibility of all necessary facilities and other resources needed to support the conduct of the clinical research study, and be approved by the appropriate INSTITUTION Administrative Executive.

5. Legal/Compliance Criteria

An approval must be obtained from INSTITUTION's Legal Department that the study documents, and operating arrangement between the participating parties comply with all applicable federal and state laws and regulations, and INSTITUTION policies.

6. IRB Criteria

A final, unconditional approval letter from the INSTITUTION authorized institutional review board must be obtained.

PRELIMINARY EVALUATION and INITIAL DETERMINATION of NEW RESEARCH:

1. The Clinical Trials Office (CTO) conducts a preliminary evaluation of all proposed clinical research studies being conducted at INSTITUTION or utilizing INSTITUTION's resources or personnel to determine if the study is in alignment with INSTITUTION's established research criteria. The CTO uses the Preliminary Evaluation of New Research Project checklist and the established research approval criteria (as noted above) to conduct the preliminary evaluation.
2. The CTO identifies and notifies the appropriate Medical Staff member (i.e. Department Chair, Medical Director) of the proposed study.
3. The Principal Investigator (PI) must submit the following to the CTO for preliminary evaluation:
 - 3.1 All documents associated with the clinical research study, specifically the study synopsis, schedule of events, informed consent forms, and contracts; and
 - 3.2 A preliminary budget that indicates the amount the sponsor is willing to pay per

subject and the services the sponsor considers routine/standard care and those services designated as research-related/protocol specific.

4. After preliminary evaluation, the CTO will make the following initial determinations and notify the PI:
 - 4.1 Whether the proposed activity constitutes clinical research in accordance with the policy, “How to Identify Human Subject Research”; or
 - 4.2 Whether the proposed activity meets the criteria for Institutional Review Board exemption; and
 - 4.3 Whether the clinical research study is in alignment with INSTITUTION’s Research Criteria.
5. If the proposed clinical research study is determined to not constitute clinical research, the CTO will notify the PI that no further action is necessary.
6. If the clinical research study is determined to constitute clinical research and be in alignment with INSTITUTION’s research criteria, the study will pass the preliminary evaluation and proceed through the CTO for Detailed Analysis, as described below.
7. If the research study is determined to constitute clinical research, but the PI disagrees with the determination, the PI may request the INSTITUTION Research Oversight Committee to review the determination, as described in Section 9.
8. If the research study is determined to constitute clinical research, but not be in alignment with INSTITUTION’s research criteria, the study will be denied and the CTO will take no further action.
 - 8.1 In circumstances when the PI disagrees with the CTO’s initial determination that the proposed activity is not in alignment with INSTITUTION’s research criteria, except for Budget or Operational Criteria, the PI may request the INSTITUTION Research Oversight Committee to review the determination as described in Section 8.
 - 8.2 In circumstances when the PI disagrees with the CTO’s initial determination that the proposed activity is not in alignment with INSTITUTION’s research Budget or Operational Criteria, the CTO shall instruct the PI to follow the steps outlined in Section 2 of the Detailed Analysis.
9. In circumstances outlined in Section 7 above, when the study proceeds to the Research Oversight Committee for review:
 - 9.1 The Research Oversight Committee may review the initial determination at a special meeting called by the Chair or at the next regularly scheduled meeting.
 - 9.2 The Research Oversight Committee shall make a recommendation based on its review of initial determination.

- 9.3 The CTO will notify the PI of the recommendation of the INSTITUTION Research Oversight Committee.
- 9.4 Unless the CTO or PI disagrees with the recommendation, the CTO will follow the recommendation of the INSTITUTION Research Oversight Committee.
- 9.5 If either the CTO or PI disagrees with the recommendation of the INSTITUTION Research Oversight Committee, either party may request the Signatory Institutional Official to review the initial determination and recommendation. The decision of the Signatory Institutional Official shall be final.

DETAILED ANALYSIS and FINAL DETERMINATION of NEW RESEARCH:

1. If the proposed research study (i) passes the initial determination, (ii) is otherwise approved by the recommendation of the INSTITUTION Research Oversight Committee, or (iii) is approved by the Signatory Institutional Official, the CTO begins processing the research study in detail.
2. If during the detailed analysis (i.e. budget development, contract negotiation, reimbursement analysis, regulatory processing), the CTO determines that the research study no longer meets INSTITUTION's research criteria, then the Detailed Analysis stops. In that situation, the CTO immediately notifies the PI to try to rectify the situation.
 - 2.1 At this time, the PI will be advised to contact the Sponsor to discuss issues and make necessary changes to the study.
 - 2.2 If the study fails to meet INSTITUTION's Research Criteria, except for the Budget and Operational Criteria, and the Sponsor is unwilling to make necessary changes, the PI may request the INSTITUTION Research Oversight Committee to review the CTO's Detailed Analysis determination in accordance with Section 9 of the Preliminary Evaluation Section of this Policy.
 - 2.3 If the study does not meet the Budget criteria, and the Sponsor is unwilling to make necessary changes, the PI may consider seeking alternate funding sources, obtaining approval from a third-party payor to bill portions of the services, or making adjustments to the cost structure of the study. If funds are obtained, and/or changes are made to meet the Budget Criteria, the CTO will allow the study to proceed to the IRB for review.
 - 2.4 If all attempts to meet the Budget Criteria are exhausted, or the proposed research study does not meet the Operational Criteria, the PI may request INSTITUTION's Operations Council to review the CTO's initial determination or Detailed Analysis determination. INSTITUTION's

Operations Council may approve or deny that the study meets the Budget and/or Operational Criteria, and its decision on these criteria will be final. The CTO will notify the PI of the INSTITUTION Operations Council decision,

- 2.4.1 In circumstances when the study proceeds to the INSTITUTION Operations Council, the CTO provides a study summary to the INSTITUTION Operations Council in advance of their meeting to discuss the study.
 - 2.4.2 If the INSTITUTION Operations Council has any concerns regarding the study after review, those concerns must be presented to the Research Oversight Committee.
3. At the conclusion of the Detailed Analysis processing, if the clinical research study meets the Research Criteria, or is otherwise approved by the INSTITUTION Operations Council, or Signatory Institutional Official, the CTO shall then grant INSTITUTION Operational approval and allow the study to proceed to the IRB for review and approval.
 4. Once IRB approval is granted, the CTO will be prepared to make a final determination approving the study.
 5. If the study fails to meet IRB approval, and the Sponsor is unwilling to make the necessary changes to meet IRB requirements, no further action will be taken. The CTO will notify the PI of the IRB's decision to deny the study and instruct the PI to NOT enroll any human subjects.
 6. The final determination approving or denying a study shall be recorded on the INSTITUTION Administrative Approval Form for Research Protocols.

FINAL DETERMINATION of APPROVAL:

1. The INSTITUTION Operational approval and the IRB approval must both be granted in order to receive a final determination approving the study.
2. Once the CTO is prepared to make a final determination, the CTO shall grant a final determination approving the study. Thereafter, the study may commence to enroll human subjects.
3. In order for a study to receive a final determination of approval, the study must receive INSTITUTION Operational approval and IRB approval. Operational or IRB approval alone does not constitute a final determination of approval. The operational approval shall be granted prior to obtaining IRB approval. If the PI would like the study to proceed to the IRB prior to receiving operational approval, the CTO notifies the PI that if the study does not receive operational approval, the PI remains responsible for any IRB fees associated with the IRB review.

END POLICY