

CATEGORIES OF ACTION

SOP #:	407	Version #:	1	EFFECTIVE DATE:	5/1/09	SUPERSEDES DOCUMENT:	/ /
THIS POLICY PERTAINS TO:		ALL RESEARCH SUBMITTED TO THE IRB					
RESPONSIBILITY FOR EXECUTING POLICY:		ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB MEMBERS					
LAST REVIEWED ON:		/ /		RESULTS:	REVISED		
APPROVAL AUTHORITY:		Associate Vice President for Research and Economic Development					
APPROVED BY:						DATE:	/ /

1. POLICY

As a result of its review, the IRB may determine to approve, disapprove, defer, or table the discussion of the proposed research activity, or to require modifications to the proposed research in order to secure IRB approval of the research activity. Except when expedited or exempt review procedures are used, these actions will be taken by a vote of a majority of the regular and alternate members present. When reviewed via expedited or exempt review, the IRB Chairperson, IRB Vice Chairperson, or designee (experienced) IRB member can take any of the following actions except to table or disapprove a study.

2. SPECIFIC POLICY

2.1 Determinations

Determinations of the IRB will be reported to Investigators using the Report of Action form. The IRB may make one of the following determinations as a result of its review of research submitted for initial review or for continuing review:

Approval: The protocol and accompanying documents are approved as submitted. Final approval will commence on the day the study is approved by an action of the convened IRB or the IRB Chairperson, IRB Vice Chairperson, or designee, and will expire within (1) year of the approval date, but not later than the day preceding the date of review.

Approvals are always conditional. The conditions for continued approval and the time frame (if any) within which they must be met will be clearly stated in the approval letter. If the conditions of the approval are not met, approval may be withdrawn.

Minor Modifications: The IRB will stipulate specific revisions that require simple agreement by the Investigator, or when the IRB Chairperson or designee may subsequently approve the revised protocol on behalf of the IRB under an expedited procedure. Changes required will be discussed and will be voted upon during the IRB meeting, as well as the terms of approval, duration of approval, and the risk level, as necessary. The Investigator will be informed in writing of the required changes, and must provide the IRB with the changes or information in writing.

The IRB Chairperson, IRB Vice Chairperson, or his or her designee, or the Primary Reviewer of the proposal will be assigned to review the information provided by the Investigator. If the designated IRB reviewer determines that the Investigator has not made the appropriate responses to the IRB's request, he or she may request additional information or request re-review of the response by the Full IRB at a convened meeting. Upon satisfactory review, approval will be issued.

Approval Date: is issued as of the date that the requested information or materials are approved.

Expiration Date: is the last day the research is approved. For a proposal that was reviewed by the Full IRB, the expiration date will be no longer than one year from the last time the proposal was reviewed at the IRB meeting. Approval is usually one year, but may be given for a lesser period of time (less than one year) based on the relative perceived high level of risk to the subject population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study subject population. Participants must not be recruited into the study until final approval has been issued.

Deferred: The IRB requests any additional information, any clarifications, or any modifications that cannot be described as specific revisions that require simple concurrence by the Investigator. The Investigator will be informed in writing of the required changes, and must provide the IRB with the changes or information in writing. If a proposal that was reviewed by the Full IRB is deferred, the convened IRB must review the responsive materials. Upon satisfactory review, the convened IRB may approve the research.

Approval Date: is issued as the date of the IRB meeting in which the study was approved.

Expiration Date: is the last day the research is approved. Approval is usually one year, but may be given for a lesser period of time based on the relative perceived high level of risk to the subject population, previously reported issues with the drug, biologic or device, previous issues with the PI, nature and location of the study, or the vulnerability of the study subject population. Participants must not be recruited into the study until final approval has been issued.

Tabled: Significant questions are raised by the proposal requiring its reconsideration after additional information is received from the Investigator and/or Sponsor. Tabling cannot be given through the expedited review mechanism and may only be given by a majority vote at a convened meeting of the IRB.

Disapproved: The proposal fails to meet one or more criteria used by the IRB for approval of research. Disapproval cannot be given through the exempt or expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB.

3. RESPONSIBILITY

The IRB Chairperson is responsible for ensuring that all IRB decisions and actions are based on institutional and regulatory requirements.

The IRB Chairperson or IRB Vice Chairperson is responsible for ensuring the appropriateness of all IRB decisions and actions.

4. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 56.109, 56.111, 56.113

45 CFR 46.109

5. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task
<i>IRB Secretary</i>	Document and distribute IRB decisions in the minutes.
<i>IRB Chairperson, IRB Vice Chairperson or designee</i>	Review and sign all IRB decision letters.