

Approved by IRB Executive Committee: January 14, 2009
Supersedes Document Dated: May 1, 2004
AAHRPP Element I.3.B.

POLICY

Except when the expedited review procedure is used, the following actions will be taken by a vote of a majority of the regular and alternate members present at a convened board meeting. When an application is reviewed using expedited procedures, the IRB Chair or designee may take any of the following actions except to table or to disapprove a study.

The IRB Chair or designee is responsible for ensuring the appropriateness of all IRB decisions and actions. The IRB Chair may confer with the IRB administrator or coordinator to verify that all IRB decisions and actions are based on institutional and regulatory requirements.

IRB decisions and actions are documented by way of board reviewer checklists and official minutes of the convened meeting approved by the IRB Chair or designee.

The IRB reports decisions and actions to the VASLCHSC within four weeks after each convened board meeting by way of IRB minutes accessible within ERICA to an authorized representative of the VA. Other ancillary committees and institutional offices (e.g., the Office of Sponsored Projects, Clinical Cancer Investigations Committee, Radiological Health Committee, Conflict of Interest Committee, Primary Children's Medical Center, Center for Clinical and Translational Sciences, etc.) are provided decisions and actions upon request by way of IRB minutes. Appropriate institutional officials (i.e. IRB Executive Committee, Associate Vice President for Research Integrity, Vice President for Research, etc.) receive IRB reports of decisions and actions upon request or as needed by way of IRB minutes. IRB minutes are either made available to authorized members of the parties listed within ERICA or are provided via e-mail or hard copy by any IRB staff member.

The Clinical Cancer Investigations Committee, Radiological Health Committee, Conflict of Interest Committee, VASLCHSC, Center for Clinical and Translational Sciences, Office of Sponsored Projects, and other designated committees are responsible for additional review and approval or disapproval of research approved by the IRB. IRB approval is contingent upon approval by ancillary committees.

PROCEDURES

1. IRB Actions

The IRB may take one of the following actions as a result of its review of research submitted for initial review or for continuing review, including review of amendments. Actions are recorded in the minutes when reviewed by a full convened board. When an IRB Chair or designee takes one of the following actions as a result of his/her expedited review of research, it is recorded in the reviewer checklist.

- 1.1. **Approval as Submitted.** If the IRB approves an application as submitted, approval commences on that day. The application and accompanying documents are approved as submitted.

The IRB may issue approval pending the receipt of administrative changes (e.g. verification of training, etc.). In such cases, the IRB staff withholds the release of the approval letter and approved documents until the administrative changes are completed as requested.

- 1.2. **Approval upon Receipt of Required Modifications.** The IRB may stipulate minor modifications of, or additions to, a protocol or accompanying document(s) are required. These changes or modifications must stipulate specific revisions that require simple concurrence by the investigator. The Investigator will be informed in writing of the required changes or requested information and must provide the IRB with the changes or information.

The IRB Chair or designee has the authority to review the requested revisions or information via expedited review unless the IRB specifies that the material or information must be reviewed by a convened IRB, the primary reviewer or another individual delegated by the IRB to review the response.

Any response from the Investigator which is pertinent and relevant to judgments required by a convened IRB will be returned to a convened IRB for review and approval.

- 1.3. **Tabled.** If the convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under the regulations, the study is tabled pending subsequent review by the convened IRB of responsive material.

If a designated expedited reviewer believes a study should be tabled, the reviewer documents the recommendation in the reviewer checklist and contacts the IRB coordinator. The IRB coordinator moves the item to the agenda for discussion by the convened board.

- 1.4. **Disapproval.** If the proposal fails to meet one or more criteria used by the IRB for approval of research, the IRB may disapprove the application. Disapproval cannot be given through the expedited review mechanism and may only be given by majority vote at a convened meeting of the IRB. If a designated expedited reviewer believes a study should be disapproved, the reviewer documents the recommendation in the reviewer checklist and contacts the IRB coordinator. The IRB coordinator moves the item to the agenda for discussion by the convened board.

Criteria for disapproval may include but is not limited to the following:

- The study violates any laws or regulations of the United States, the state of Utah, or the University of Utah.
- Risks to subjects outweigh the benefits to them or society.
- Unnecessary risks are created.
- Selection of subjects is inequitable.

- Procedures for obtaining and documenting informed consent are inadequate.
- Payment or other offered inducements are likely to influence subjects' judgment.
- The study is poorly or improperly designed such that meaningful conclusions cannot be derived.
- The study is promotional (seeding), and not scientific in nature.