



## **SOP 407: IRB ACTIONS TO APPROVE OR DISAPPROVE RESEARCH**

### **PURPOSE**

This SOP outlines the actions to approve or disapprove research by the University of Utah Institutional Review Board (IRB) and the method of communicating those actions.

### **SCOPE**

This SOP applies to the University of Utah IRB.

### **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 IRB members present at a convened board meeting. Majority means more than half of the total number of voting members attending the meeting at which the vote takes place. 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 an IRB administrator to verify that all IRB decisions and actions are based on institutional and regulatory requirements.

IRB decisions and actions are documented by board reviewer checklists and minutes of the convened meeting.

The University of Utah IRB makes reports of decisions and actions to available to the VA Salt Lake City Healthcare System (VASLCHSC) within four weeks of each convened board meeting, through IRB minutes accessible in the University of Utah Electronic Research Integrity and Compliance Administration system (ERICA) to an authorized VA representative. Other ancillary committees and institutional offices including the Office of Sponsored Projects (OSP), Huntsman Cancer Institute Protocol Review and Monitoring Committee (HCI PRMC), Human Use Subcommittee of the Radiation Safety Committee (HUS-RSC), Conflict of Interest Committee (COI), Primary Children's Hospital (PCH), Clinical and Translational Science Institute, (CTSI) etc., may access reports of IRB decisions and actions upon request through IRB minutes. Appropriate institutional officials (i.e. IRB Executive Committee, Associate Vice President for Research Integrity and Compliance, Vice President for Research, etc.) may access reports of IRB decisions and actions upon request or as needed through 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 Huntsman Cancer Institute Protocol Review and Monitoring Committee, Human Use Subcommittee of the Radiation Safety Committee, Conflict of Interest Committee, VASLCHSC, Clinical and Translational Science Institute, Office of Sponsored Projects, and other designated committees are responsible for additional review and approval or disapproval of research approved by the IRB. University of Utah IRB approval is contingent upon approval by ancillary committees.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



The IRB may approve, table, or disapprove research submitted for initial or continuing review, including amendments. Actions are recorded in the minutes when reviewed by a full convened board. When an IRB Chair or a designated expedited reviewer takes one of the following actions after their expedited review of research, it is recorded in the reviewer checklist.

## PROCEDURES

### 1. Approval as Submitted

- 1.1. If the IRB approves an application as submitted, approval commences on that day. The application and accompanying documents are approved as submitted.
- 1.2. 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.
- 1.3. The approval is effective as of the day the approval notification is sent to the investigator (see IRB SOP 305: Documentation of IRB Discussions, Decisions, and Findings).

### 2. Approval upon Receipt of Required Modifications

- 2.1. 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.
- 2.2. 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.
- 2.3. 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.

### 3. Tabled

- 3.1. 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 administrator. The IRB administrator moves the item to the agenda for discussion by the convened board.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.



- 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 procedure. A study proposal may only be disapproved 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 administrator. The IRB administrator 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.

Please contact the IRB Office at (801) 581-3655 or [irb@hsc.utah.edu](mailto:irb@hsc.utah.edu) for additional guidance.