# SOP 305: DOCUMENTATION OF IRB DISCUSSIONS, DECISIONS AND FINDINGS

**PURPOSE**
This SOP outlines the procedure for documenting University of Utah Institutional Review Board (IRB) review of research applications, and the related discussion, decisions or actions, and findings.

**SCOPE**
This SOP applies to the University of Utah IRB.

**POLICY**
The University of Utah IRB documents discussions, decisions or actions, and findings through minutes of convened meetings. Copies of the minutes and pertinent materials are maintained within the Electronic Research Integrity and Compliance Administration system (ERICA).

When the expedited procedure for review is used, documentation of decisions or actions, and findings are made in the IRB reviewer checklist. Reviewer checklists and pertinent materials are maintained in ERICA.

Investigators are notified of IRB decisions and findings by email through ERICA.

**PROCEDURES**

**1. Recording Minutes**

1.1. Minutes document discussions, decisions, and findings made during convened IRB meetings. IRB coordinators prepare minutes with support from IRB administrators and are responsible to record the following:

- Meeting attendance.
- When an alternate member replaces a regular member.
- Attendance of members or alternate members who participate through teleconference or videoconference. It should be noted whether the meeting was conducted in-person or virtually.
- The presentation and discussion of each agenda item (new studies, continuing review, and review of amendments, etc.). Eash item will be discussed and voted individually, including a description for the basis of requiring changes in or disapproving the research.
- Summary of the discussion of controverted issues and resolution.

- Recommendations documented in the IRB reviewer checklists submitted prior to the meeting may deviate from board decisions after a discussion at a convened meeting. In the event that recommendations in the IRB checklist are not consistent with the conclusions resulting from the board discussion, the minutes will document the final decisions and determinations.

- Voting results include number for, opposed, and abstaining. This will include only voting members present at the meeting when the vote is called. The names of the members absent for the vote will be documented. Members who recused themselves for a conflicting interest will be recorded in the minutes.

- Determination of the level of risk (minimal, greater than minimal).

- For initial and continuing review, the approval period.

- If applicable, determinations required by regulation and protocol specific findings justifying those determinations for: waiver or alteration of informed consent and/or authorization; waiver of documentation of consent; research involving pregnant women, human fetuses, and neonates; research involving children, research involving prisoners; research involving participants with diminished capacity to consent.

- If applicable, the rationale for significant risk/non-significant risk device determinations.

- If applicable, the rationale for conducting continuing review on research that otherwise would not require continuing review.

- If applicable, the rationale for an expedited reviewer's determination that research appearing on the expedited review list is more than minimal risk.

**2. Distribution of Minutes**

2.1. IRB coordinators are responsible for preparing the meeting minutes. Finalized meeting minutes are made available at the subsequent meeting of that panel via ERICA. Meeting minutes are retained in ERICA and are also retained for each item in the electronic file of its respective study.

2.2. Items approved using expedited procedures are also accessible in the electronic meeting minutes.

2.3. The R&D Committee of the VA Salt Lake City Healthcare System (VASLCHCS) may access finalized meeting minutes via ERICA.

## 3. Results of Reviews, Actions, and Decisions

3.1. The results of reviews and actions taken by the convened IRB that grant or may appear to grant investigators with initial or continuing approval of research involving human subjects, are signed off by the IRB Chair or IRB Vice Chair except when the convened IRB votes to approve research as submitted. All results and actions taken by the IRB are reflected and recorded in ERICA.

3.2. If the convened IRB approves research as submitted, documentation of the board's determination in the minutes is sufficient and subsequent electronic approval by an IRB Chair or IRB Vice Chair is not required.

3.3. The results of reviews and actions taken by the IRB via expedited review that grant or may appear to grant investigators with initial or continuing approval of research projects involving human subjects, must be signed off by the IRB Chair, IRB Vice Chair, or IRB member designated by the IRB Chair (i.e., designated expedited reviewer). All results and actions taken by the IRB are reflected and recorded in ERICA.

3.4. For research involving veterans, the IRB notifies the VASLCHCS R&D Committee of its decision to approve or disapprove a proposed research activity, or of modifications required to secure IRB approval via notification from ERICA. Notification is a copy of the investigator's approval letter, or a copy of the IRB minutes with the actions of the IRB. Approval letters are sent via ERICA and received by the VASLCHCS Research Compliance Officer or designee. IRB minutes are made available within 4 weeks of the meeting date and accessible by the VASLCHCS Research Compliance Officer or designee.

3.5. Projects which are classified as exempt from IRB review and involve veterans must be reviewed by the VASLCHCS R&D Committee prior to initiation. The exempt status must be approved by the IRB Chair, IRB Vice Chair, or IRB member designated by the IRB Chair.

## 4. Notification of IRB Decisions and Findings

4.1. IRB coordinators are responsible for notifying the investigator of the IRB's decision within seven business days after the convened meeting or expedited review. Notifications are sent via ERICA. As required, notifications will be sent to other offices according to IRB SOP 905: Institutional Reporting Procedures.

4.2. If the IRB approves the application, the approval notification includes the date of approval, the expiration of approval (as appliable), and the effective date. The date of approval is the date the board voted to approve the application or the expedited reviewer electronically approved the application. The date of the expiration is explained in IRB SOP 307: Approval Period and Determination of Expiration. The approval is effective as of the day the approval notification is issued.

4.3. If the IRB disapproves the application, the notification includes the reason(s) for disapproval and instructions to the investigator for appeal of the decision.

4.4. If the IRB requires additional materials or a response from the investigator or sponsor, the notification describes the request(s) of the IRB in detail. The notification also states the IRB must receive the response within 30 days of the date of notification; however, this period may be extended if the investigator or sponsor communicates a need for an extension.