



SOP 305: DOCUMENTATION OF IRB DISCUSSIONS, DECISIONS AND FINDINGS

POLICY

The University of Utah IRB documents discussions, decisions, and findings through IRB minutes. Copies of the minutes, as well as the agenda and pertinent materials are maintained within the ERICA online system.

When the expedited procedure for review is used, documentation is made in the IRB reviewer checklist. Reviewer checklists are maintained in the ERICA online system.

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

PROCEDURES

1. Procedures for Recording Minutes

- 1.1. IRB coordinators are responsible for preparing a draft outline of meeting minutes prior to a convened meeting based upon the IRB Agenda/Minutes Template.
- 1.2. The IRB administrator and IRB coordinator are responsible for documenting discussions, decisions and findings during the IRB meeting 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.
 - Each action (new studies, continuing review, and review of amendments, etc.) 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 in the room at the time vote is called. These votes along with notation of those members who recused themselves for a conflicting interest will be recorded. The names of the members absent for the vote will be documented.
 - 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;

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



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. Procedures of Approval of Minutes

- 2.1. The IRB coordinator is responsible for preparing the draft minutes. Draft minutes are made available via the electronic agenda for the subsequent meeting of that panel. The draft minutes are available to all panel members for review and approval at the subsequent meeting of that panel.
- 2.2. The convened IRB reviews and approves the minutes.
 - 2.2.1. Corrections requested by the convened IRB are made by the IRB coordinator. Corrected minutes are made available to members at the subsequent meeting of that panel via the electronic agenda in the ERICA online system.
- 2.3. Copies of approved minutes are provided to the VASLCHCS R&D Committee via the ERICA online system.

3. Procedure for Investigator Notification of IRB Decisions and Findings

- 3.1. The IRB coordinator is responsible for notifying the investigator of the IRB's decision within seven business days after the meeting or expedited review. Notifications are sent via the ERICA system. As required, notifications will be sent to other offices according to SOP 905 (Institutional Reporting Procedures).
- 3.2. If the IRB approves the research, the approval notification includes the date of approval, the expiration of approval, and the effective date. The date of approval is the date the board voted to approve the study. The date of the expiration is explained in SOP 307 (Approval Period and Determination of Expiration). The approval is effective as of the day the approval notification is issued.
- 3.3. If the IRB disapproves the research, the notification includes the reason(s) for disapproval and instructions to the investigator for appeal of the decision.
- 3.4. 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.

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