

SOP: 305	DOCUMENTATION OF IRB DISCUSSIONS, DECISIONS AND FINDINGS
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Approved by IRB Executive Committee: November 12, 2008
Supersedes Document Dated: N/A (originally approved under SOP 304: IRB Meeting Administration)
AAHRPP Element II.3.C.

POLICY

The University of Utah IRB documents discussions, decisions and findings through IRB minutes. Minutes will not be altered by anyone including a higher authority once approved by a convened IRB at a subsequent IRB meeting. 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.

For approval of research which involves the VA and when approval is contingent upon minor conditions by the IRB Chair or designee, the minor conditions are documented in the minutes of the first IRB meeting following the final approval date by the IRB Chair or designee.

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.
 - 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 and reason for recusal 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).
- Justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample consent document.
- For initial and continuing review, the approval period.
- Determinations required by regulation and protocol specific findings justifying those determinations for: waiver or alteration of informed consent, waiver of documentation of consent, vulnerable populations (i.e. pregnant women, human fetuses and neonates, children, prisoners).
- The rationale for significant risk/non-significant risk device determinations.

2. Procedures of Approval of Minutes

- 2.1. The IRB coordinator is responsible for preparing the draft minutes and making the draft minutes available within three weeks of the meeting date. 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. The IRB Chair or IRB Vice-Chair electronically signs the final, approved minutes. The date of the electronic approval is recorded in the ERICA online system.
- 2.4. 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 (7) 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 notification includes the date of approval and the expiration of approval.
- 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.