



VERIFICATION FROM OTHER SOURCES

Description

The IRB determines which clinical investigations need verification from sources other than the clinical investigator that no material changes in the research have occurred since the previous IRB review.

When making this determination, the IRB should consider:

- Whether the study involves new or novel therapeutic modalities, drugs, biologics, or significant risk medical devices.
- The degree of uncertainty regarding the risks involved
- The vulnerability of the subject population.
- The experience of the investigators in conducting the research (e.g., compliance history, previous problems with the researcher obtaining informed consent, prior complaints from participants about the researcher).
- The IRB's previous history with the investigators.
- The projected rate of enrollment.
- Other situations where the IRB determines it is appropriate to request verification that no material changes in the research have occurred since the previous IRB review.

Verification from other sources other than the investigator that no material changes have occurred since the last review may be requested during the continuing review and may be requested by the convened IRB board, the assigned IRB reviewer, or the assigned IRB expedited reviewer. The convened board, or the IRB reviewer should specify the specific reason for the request, and the information to be verified.

The IRB staff will assist in coordinating the verification process. The following options are available to verify that no material changes have occurred include, but are not limited to:

- An audit of research records conducted by an IRB administrator.
- Assistance from the University of Utah's Research Participant Advocate (i.e., observation of consent procedure).
- Review of investigational product records (e.g. investigational pharmacy records).
- Review of grant applications.

Points to Address

Reviewer Checklist, Continuing Review:

1. **Verification from Other Sources:** The reviewer checklist will document whether the reviewer feels that verification from other sources should be requested. The question, "May the study proceed without verification from sources other than the investigators that no

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material changes have occurred since previous IRB review?" will document whether the verification from other sources is necessary.

References & Links

*SOP 908: Routine and
For-Cause Audits*

<https://irb.utah.edu/guidelines/irb-sops.php>

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