



SOP 905: INSTITUTIONAL REPORTING PROCEDURES

POLICY

It is the policy of the University of Utah IRB to comply with all applicable local, state, and federal regulations in the conduct of research studies and to communicate certain actions to entities that may have an interest in the status of the research being conducted. The IRB will notify institutional officials, funding sources, regulatory agencies, as appropriate, once the IRB takes any of the following actions:

- Determines that an event represents an unanticipated problem involving risks to participants or others
- Determines that non-compliance was serious or continuing
- Suspends or terminates approval of research

For research conducted at the VASLCHCS, reporting will be performed according to the VHA Handbook 1058.01.

The IRB must report to the Association for the Accreditation of Human Research Protection Programs (AAHRPP) within 48 hours after the University of Utah or any researchers (if the researcher is notified rather than the University of Utah) becomes aware of:

- Any negative actions taken by a government oversight office, including, but not limited to, OHRP determination letters, FDA warning letters, FDA 483 Inspection Reports with official action indicated, FDA restrictions placed on IRBs or researchers.
- Any litigation, arbitration, or settlements initiated related to human research protections.
- Any press coverage (including but not limited to radio, TV, newspaper, online publications) of a negative nature regarding the University of Utah HRPP

Allegations of **research misconduct** will be reported by the IRB Director, IRB Chair or Co-/Vice-Chair to the Associate Vice President for Research Integrity, who will coordinate the inquiry, investigation and hearing phases as needed. All investigations and reporting to appropriate officials will be conducted according to the University of Utah Policy for Research Misconduct.

PROCEDURES

1. An IRB administrator or designee prepares a letter that contains the following information:
 - The nature of the event (unanticipated problem involving risks to participants or others, serious or continuing non-compliance, suspension or termination of approval of research);
 - Name of the institution conducting the research;
 - Title of the research project and/or grant proposal in which the problem occurred;
 - Name of the principal investigator on the protocol;
 - Number of the research project assigned by the IRB and the number of any applicable federal award(s) (grant, contract, or cooperative agreement);

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



- A detailed description of the problem including the findings of the organization and the reasons for the IRB decision;
 - Corrective actions and/or sanctions the institution is taking or plans to take to address the problem (e.g., revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, etc.);
 - Plans, if any, to send a follow-up or final report by a specific date or when an investigation has been completed or a corrective action plan has been implemented.
 - For suspensions or terminations of IRB approval of FDA-regulated studies, the letter will also include:
 - The name of the drug, biologic, or device
 - The IND number; or the IDE number/non-significant risk (NSR) status of the device
 - The address(es) of the clinical investigator(s)
2. The IRB Chair reviews the letter and modifies the letter as needed.
 3. The IRB Chair electronically approves the letter.
 4. The IRB administrator or designee sends a copy of the report to the following as applicable. Reporting to a regulatory agency is not required if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
 - Principal investigator;
 - Sponsor, if the study is sponsored;
 - The Institutional Official at the University of Utah and when appropriate, Officials of the institutions that have a Memorandum of Understanding (MOU) with the University of Utah IRB
 - Chairman or supervisor of the principal investigator and/or offending investigator;
 - The IRB, by providing the determination letter;
 - The Institutional Representative(s) identified in a relevant IRB reliance agreement if the University of Utah IRB is responsible for review and oversight of the study;
 - The Privacy Officer of a covered entity, if the event involved unauthorized use, loss, or disclosure of individually-identifiable patient information from that covered entity;
 - The Information Security Officer of an organization if the event involved violations of information security requirements of that organization;
 - University of Utah Office of Risk Management;
 - University of Utah Clinical Research Compliance & Education (CRCE) FDA Compliance Officer;
 - OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federal Wide Assurance;
 - Other federal agencies when the research is overseen by those agencies, if they require reporting separate from that to OHRP;
 - FDA, if the study is subject to FDA regulations;
 - For VA research
 - Local Research and Development Committee;
 - Associate Chief of Staff for Research;
 - Local Medical Center (Facility) Director;
 - Regional Office of Research Oversight;

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- VA Privacy Office, when the report involves unauthorized use, loss, or disclosure of individually identifiable patient information;
 - VHA Information Security Officer when the report involves violations of VA information security requirements;
 - VA Central Office, if an unanticipated problem involving risks to participants or others is an adverse event;
 - The Department of Defense, if the research is conducted under the terms of the Department of Defense Addendum Federal-Wide Assurance
 - The IRB administrator or designee can provide copies to others as deemed appropriate by the Institutional Official or IRB chair.
5. The IRB administrator or designee will ensure that all steps of this policy will be completed within 30 days of the initiating action. For more serious actions, the IRB administrator or designee will expedite reporting.

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