SOP 903: HRPP AND NON-COMPLIANCE

PURPOSE

The University of Utah Institutional Review Board (IRB) addresses both allegations and confirmed reports of non-compliance as outlined in this policy. For VA research, the VHA Handbook 1058.01: Research Compliance Reporting Requirements is followed.

SCOPE

This policy applies to the research team, the University of Utah IRB and IRB staff.

DEFINITIONS

A. ***Non-Compliance*** is the failure to abide by the policies, requirements, and determination of the IRB, or federal rules and regulations including the requirements of the VHA Directive 1200.5 governing human subject research.

B. ***Serious Non-Compliance*** is an act or omission to act that resulted in significant harm (physical, psychological, safety, or privacy) or significantly increased the possibility of harm to the rights and welfare of research participants.

C. ***Continuing Non-Compliance*** is a pattern of repeated actions or omissions that suggest a future likelihood of reoccurrence. It demonstrates a deficiency in the ability or willingness to comply with federal regulations, VA Directive 1200.5 or the policy, requirements, and determinations of the IRB governing human subject research.

D. An ***allegation*** is an assertion made by a party that must be proved or supported with evidence.

E. A ***confirmed report*** is alleged non-compliance which in the judgement of the IRB administrator, IRB Chair, or IRB Vice Chair is factual.

Research Misconduct is any fabrication, falsification, or plagiarism that significantly deviates from the commonly accepted standards and practices within the relevant research community for proposing, performing, or reviewing or reporting research.

POLICY

Members of the research community must report apparent non-compliance to the IRB. The determination that non-compliance is serious or continuing rests with the IRB of record.

Instances that meet the definition of research misconduct will be reported to the Office of the Research Integrity Officer (ORIO) by the IRB Director, IRB Chair, or IRB Vice Chair. All investigations and reporting are conducted according to the University of Utah Policy 7-001: Policy for Research Misconduct.

Attempts to intimidate or coerce an IRB member or IRB staff member are not considered research misconduct under federal or University of Utah policy. However, reports of intimidation or attempts to coerce IRB members or IRB staff will be handled according to University of Utah institutional policy. IRB members or IRB staff members who believe that they have been subject to intimidation or coercion must report this to the IRB Director, IRB Chair or Vice Chair, or the VA Facility Director. The IRB Director, IRB Chair or IRB Vice Chair will report all allegations to ORIO, who will coordinate the inquiry, investigation and hearing phases as needed.

PROCEDURES

1. Addressing Allegations of Non-Compliance

1.1. Allegations of non-compliance are investigated by an IRB administrator. The IRB administrator conducts an inquiry for preliminary, informal checking of the facts to determine if there is a reasonable basis for the allegation and if the allegation can be supported or proved by the evidence. The IRB Chair or IRB Vice Chair may also investigate allegations, if necessary.

- If the IRB administrator determines the allegation of non-compliance **not to be** a credible, confirmed report of non-compliance, the inquiry stops and no further action is taken.
- If the IRB administrator determines the allegation of non-compliance **to be** a credible, confirmed report of non-compliance, the inquiry proceeds as outlined in this policy. The allegation of non-compliance is considered a confirmed report of non-compliance according to this policy.

2. Addressing Confirmed Reports of Non-Compliance

2.1. The IRB administrator reviews the confirmed report of non-compliance. The IRB administrator determines whether the confirmed report of non-compliance either 1) **does not** represent serious or continuing non-compliance or 2) **might** represent serious or continuing non-compliance as defined in this policy.

2.1.1. If the IRB administrator determines that the confirmed report of non-compliance is neither serious nor continuing non-compliance, as defined by this policy, the IRB administrator or designee consider, but is not limited to, the following actions:

- Acknowledgement of the problems, requiring no sanctions but with instructions regarding the necessity to establish procedures and policies to avoid further infractions.
- Request the investigator and/or staff complete additional education and training applicable to protecting human subjects in research.
- Request a corrective action plan from the investigator.
- Approve the submitted corrective action plan.
- No further action.

2.1.2. If the IRB administrator determines that the confirmed report of non-compliance might represent either serious or continuing non-compliance, as defined by this policy, the IRB administrator may refer the confirmed report and their review/evaluation of non-compliance to the IRB Chair or IRB Vice Chair. At the discretion of the IRB administrator, the confirmed report of non-compliance and their review/evaluation may be referred directly to the convened IRB. Skip to section 2.3 for procedures to be followed in this case.

2.2. The IRB Chair or IRB Vice Chair reviews the confirmed report of non-compliance.

2.2.1. If more information is needed because the inquiry discloses a reasonable basis for concern that significant infractions have occurred, the IRB Chair or Vice Chair directs further investigation by the IRB administrator. The investigator is notified in writing of the directed investigation by the IRB administrator or designee.

2.2.2. The IRB Chair or IRB Vice Chair determines whether the confirmed report of non-compliance either does not represent serious or continuing non-compliance or might represent serious or continuing non-compliance as defined in this policy.

2.2.3. If the IRB Chair or IRB Vice Chair determines that the confirmed report of non-compliance is neither serious non-compliance nor continuing non-compliance, as defined by this policy, the IRB Chair or IRB Vice Chair considers but is not limited to the following actions:

- Acknowledgement of the problems, requiring no sanctions but with instructions regarding the necessity to establish procedures and policies to avoid further infractions.
- Request the investigator and/or staff complete additional education and training applicable to protecting human subjects in research.
- Request a corrective action plan from the Investigator.
- Approve the submitted corrective action plan.
- No further action.

2.2.4. If the IRB Chair or IRB Vice Chair determines that the confirmed report of non-compliance might represent serious non-compliance and/or continuing non-compliance, as defined by this policy, the IRB Chair or IRB Vice Chair refers the confirmed report of non-compliance and their review/evaluation to the convened IRB.

2.3. When issues of non-compliance are reviewed by the convened IRB, the IRB staff prepares the documents listed below, if they apply, and makes them available to all members of the convened IRB for review three working days prior to the meeting. Documents may be made available using University of Utah Electronic Research Integrity and Compliance Administration system (ERICA) or in paper. All IRB members are expected to review the information and be prepared to discuss it at the meeting.

- The current ERICA application including the informed consent document, company protocol, and investigator brochure;
- The confirmed report of non-compliance;

- The audit report (investigation report) including a list of witnesses and documents reviewed;
- Previous reports of non-compliance and the past record of the investigator and/or study staff;
- The review/evaluation of the confirmed report of non-compliance by IRB Chair or IRB Vice Chair;
- All additional pertinent documents or portions thereof (e.g., primary data).

2.4. An IRB staff member assigns a primary reviewer based on scientific expertise to perform an in-depth review of the documents. The primary reviewer presents their findings. The primary reviewer and the IRB Chair or IRB Vice Chair lead the discussion during the convened IRB meeting.

2.5. **For VA Research:** The IRB Chair or designee must consult the relevant Office of Research Oversight (ORO) Regional Office (RO) if the significance of a reported event is not clear.

2.6. The convened IRB votes on whether the confirmed report of non-compliance represents serious non-compliance and/or continuing non-compliance as defined by this policy. IRB staff records the discussion, rationale for any action and vote in the minutes.

2.7. If the convened IRB determines that the confirmed report of non-compliance is neither serious non-compliance nor continuing non-compliance, as defined by this policy, the IRB considers but is not limited to the following actions:

- Acknowledgement of the problems, requiring no sanctions but with instructions regarding the necessity to establish procedures and policies to avoid further infractions.
- Request the investigator and/or staff complete additional education and training applicable to protecting human subjects in research.
- Request a corrective action plan from the investigator.
- Approve the submitted corrective action plan.
- No further action.

2.8. If the convened IRB determines the confirmed report of non-compliance represents serious non-compliance and/or continuing non-compliance, as defined by this policy, the IRB considers but is not limited to the following actions:

- Verification that participant selection is appropriate.
- Observation of the research and the informed consent process by an IRB administrator.
- Modifications of the protocol.
- Request an increase in monitoring of the research activity via an independent data safety monitor or board.

- Safety intervention as necessary such as visits to the activity site and continuing evaluation of the site by an IRB administrator.
- Request audit and progress reports from the sponsor monitor or contract research organization (CRO).
- Request a directed audit of targeted areas of concern by an IRB administrator.
- Request a status report after each participant receives intervention from the investigator.
- Modify the frequency of the continuing review cycle.
- Request additional investigator and staff education focused on human subject research protections from appropriate available sources (e.g., GCP Training, OHRP conferences, NIH tutorial, human subject research protections seminars).
- Notify current subjects, if the information about the non-compliance might affect their willingness to continue participation.
- Provide additional information to past participants.
- Suspend IRB approval of the respective study pending a written plan for the correction and /or prevention of the non-compliance.
- Remove the principal investigator of the research study.
- Suspend or terminate some or all of the research study and possibly other studies being conducted by the investigator. See IRB SOP 904: Administrative Hold, Suspension and Termination of Approved Research for suspension and termination procedures.

2.9. If the IRB determines that the confirmed report of non-compliance was either serious non-compliance or continuing non-compliance, as defined by this policy, the matter is referred to the IRB staff to conduct reporting according to SOP 905: Reporting Procedures.