SOP 903: HRPP AND NON-COMPLIANCE

DEFINITIONS

a)	**Non-Compliance**	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**	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**	A pattern of repeated actions or omissions to act that suggest a future likelihood of reoccurrence and that indicate 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)	**Allegation**	An assertion made by a party that must be proved or supported with evidence.
e)	**Confirmed Report**	Alleged non–compliance which in the judgment of the IRB administrator, IRB Chair or IRB Vice-Chair is factual.
f)	**Research Misconduct**	Any fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or reporting research results. Instances meeting the definition of research misconduct will be reported to the Associate Vice President for Research Integrity by the IRB Director, IRB Chair, or IRB Vice-Chair. Attempts to unduly influence an IRB member or IRB staff is not considered research misconduct under federal or University of Utah policy. However, this is considered a violation of University of Utah IRB policy. IRB members or staff members who believe that they have been subject to undue influence must report this to the Associate Vice President of Research Integrity or 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 of undue influence to the Vice President for Research Integrity, who will coordinate the inquiry, investigation and hearing phases as needed.

All investigations and reporting will be conducted according to the University of Utah Policy for Research Misconduct *http://www.admin.utah.edu/ppmanual/6/6-1-1.html*.

POLICY

It is the policy of the University of Utah to address both allegations and confirmed reports of any non-compliance in accordance with 45 CFR Part 46 and 21 CFR Part 50 the policies, requirements and determinations of the IRB and the VHA Handbook 1058.01: Research Compliance Reporting Requirements. This policy applies to the research investigative team, the IRB and IRB staff.

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.

PROCEDURES

1. Procedures for Addressing Allegations of Non-Compliance

Allegations of non-compliance are investigated by an IRB administrator, the IRB Chair, or a designated IRB Vice-Chair.

1.1. The IRB administrator conducts a pre-inquiry review 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.

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

2. Procedures for Addressing Confirmed Reports of Non-Compliance

The IRB administrator reviews the confirmed report of non-compliance.

2.1. The IRB administrator 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.

2.1.1. 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.
- Require additional education and training applicable to human research participant protections of the Investigator and/or staff.
- 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 of non-compliance to the IRB Chair or IRB Vice-Chair with his/her evaluation. At the discretion of the IRB administrator, he/she may also refer the confirmed report of non-compliance to the convened IRB with his/her evaluation (skip to 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 the IRB Chair or IRB Vice-Chair determines that more information is needed because the inquiry discloses a reasonable basis for concern that significant infractions have occurred, he/she 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 determine 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.
- Require additional education and training applicable to human research participant protections of the Investigator and/or staff.
- 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 to the convened IRB with his/her evaluation.

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, either in ERICA or in paper form. All IRB members are expected to review the information and be prepared to discuss it at the meeting.

- The current ERICA application;
- The Informed Consent Document;
- The 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 his/her team;
- The 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 will present his/her findings. The primary reviewer and the IRB Chair or IRB Vice-Chair will 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.
- Require additional education and training applicable to human research participant protections of the Investigator and/or staff.
- 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 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 research protections from appropriate available sources (e.g., GCP Training, OHRP conferences, NIH tutorial, human 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 Principal Investigator as well (See IRB SOP 904 for suspension and termination procedures and IRB SOP 905 for reporting 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 handle according to SOP 905 (Reporting Procedures).