

Guidance for Reporting Non-compliance/Protocol Deviation

As detailed in the UNA Human Subject Research Program Policy, investigators and other study personnel involved in human subjects research are required to comply with all laws and regulations governing their research activities, as well as with requirements and determinations of the HSC as indicated in an approved protocol. Study personnel include the principal investigator and any staff members directly involved with participants or the informed consent process.

Non-compliance is the deliberate or inadvertent violation, or failure to comply with, federal regulations, UNA policies, or HSC requirements for the protection of human subjects in research. Anyone may submit a report of non-compliance and should do so immediately upon becoming aware of the occurrence. A report of non-compliance may be submitted to the HSC in person or via a letter, email, or telephone call.

Protocol deviation is the deliberate or inadvertent departure from HSC-approved protocol procedures, assent/consent forms and scripts, and supporting documents such as the data security plan, hazardous material handling plan, medical/safety monitoring plan or any other supporting documentation outlining procedures to be followed.

Changes to the protocol or any supporting documentation are to be approved prior to any execution of those changes. (See Protocol Modifications section of the UNA Human Subject Research Program Policy). If **any** protocol deviation occurs it must be reported to the HSC **within five days** of the occurrence. A protocol deviation could be:

- A change intended to eliminate apparent immediate hazards to research subjects;
- A change that does not impact the level of risk to subjects; or
- A change that does impact the level of risk to subjects.

Non-compliance/Protocol Deviation Report Form

For purposes of the following guidelines, regulation/policy violation and protocol deviation are considered “non-compliance.”

Serious Non-compliance

Serious non-compliance is an act or omission that resulted in increased risk to subjects or others that compromised the subjects’ rights, safety, or welfare. Examples are:

- Deliberate or repeated violation of federal regulations or UNA policy.
- Deliberate or repeated failure to obtain prior review and approval by the HSC before initiating or continuing human subject research.
- Deliberate or repeated failure to obtain or document informed consent from human subjects.
- Deliberate or repeated omission of a serious risk when obtaining informed consent.
- Deliberate or repeated failure to maintain accurate research protocol records, report protocol changes to the HSC, or report unanticipated problems to the HSC.
- Deliberate falsification of HSC documents.

Continued Non-compliance

Continued non-compliance is a pattern of repeated acts or omissions that indicate an inability or unwillingness to comply with the federal regulations governing human subject research.

Examples are:

- Consistently late submissions of continuing review protocols or other items that require prompt reporting to the HSC.
- Repeated failure to comply with the UNA education and training requirements for investigators conducting studies that meet the definition of human subject research.
- Repeated failure to submit required documents to the HSC.
- Repeated refusal to comply with an HSC request.

Review Procedures

An alleged incident of non-compliance will be reviewed by the HSC Chair to determine if it had significant effect on subjects' rights, safety, or welfare and/or the integrity of the resultant data.

If the alleged non-compliance is determined by the HSC Chair to be potentially serious or continued non-compliance, the incident will be referred to the Director, Office of Sponsored Programs (OSP) for further evaluation and fact-finding. Findings and recommendations of the Director, OSP are forwarded to the HSC for review at a convened meeting of the full committee, with the PI invited to attend. If the HSC determines the non-compliance to be serious or continued, the HSC reports its findings to UNA's Signatory Official (Vice President for Academic Affairs, designated in the Federalwide Assurance). The Signatory Official then reports the finding to other appropriate institutional officials and external agencies including the sponsor (e.g., UNA personnel, HHA, NIH). All such determinations and requested corrective actions are communicated in writing to the PI.

After Chair or full HSC review, actions taken may include, but are not limited to, the following:

- The non-compliance is acknowledged as submitted and no further action is necessary.
- The PI is given a warning with instructions on how to avoid further infractions.
- The non-compliance is considered an unanticipated problem and/or adverse event, and the PI is instructed to submit a report.
- The PI and/or the research team members are required to participate in additional training/education for the protection of human subjects in research.
- The protocol is subject to an audit by the Office of Sponsored Programs.
- The PI is required to submit a corrective action plan addressing how the rights, safety, or welfare of the research participants will be protected, and how the research data will be overseen to protect its integrity.
- The PI is required to submit a protocol modification.
- The PI is required to develop and submit for HSC approval a data security, hazardous material handling, or medical/safety monitoring plan.
- The PI is required to submit periodic status reports.
- The protocol requires HSC review more frequently than once per year.
- The PI is required to notify current subjects if the information about the non-compliance might affect their decision to continue participation in the research.
- The PI is required to provide relevant information to previously enrolled subjects.

- Some or all of the research protocol must be suspended or terminated.
- The data must be destroyed and may not be used when reporting the research results.
- The PI is suspended or disqualified from conducting human subject research.

Monitoring Research Protocols

All protocols reviewed by the HSC are subject to regulatory monitoring by the HSC personnel. Studies can be selected at random for review to ensure compliance with human subjects regulations or HSC requirements or determinations.

After a protocol has been selected for monitoring and usually two to four days before the planned visit, the HSC Chair or designee contacts the investigator, and study coordinator if applicable, to schedule the monitoring appointment. A written follow-up message from the HSC confirms the appointment and lists materials that should be available for the reviewer, as well as any issues that need to be specifically addressed.

The monitor inspects the general maintenance of study records, including the following specific documents as applicable:

- Original HSC protocol approval and supporting documents (e.g., data security plan)
- Approved modifications
- Assent/consent forms
- HSC Continuing Review materials
- Completion/Termination Report
- Unanticipated Problems/Adverse Events Report(s)
- Sponsor correspondence
- Investigator Brochure
- FDA Form 1572, if applicable
- Participant Screening and Enrollment Logs
- Monitoring Report

Within 2 weeks of completing the monitoring visit, the HSC designee completes the monitoring report and provides a copy to the HSC Chair and to the principal investigator. The HSC puts a copy of the report in the protocol file and schedules the report for review by the convened HSC. After the review is completed, the HSC sends the principal investigator a copy of the HSC's determinations and puts a copy in the protocol file.

References

45 CFR 46.103(b)(5)(i)
 45 CFR 46.116(b)(5)
 21 CFR 50.25(b)(5)
 21 CFR 56.108(b)(2)
 10 CFR 745
 DOE O 443.1A
 DOE P 443.1A
 32 CFR 219
 DODD 3216.2
 SECNAVINST 3900