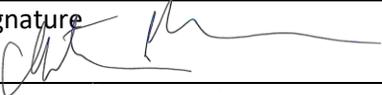


| Standard Operating Procedures | | |
|--------------------------------------|--|------------------------------|
| SOP #406.2 Revision 2 | TITLE: Directed Audits and Full Assessments | Effective Date: 7/18/2018 |
| Approved By: OIRB Director | Signature  | Date 7/18/2018 |
| Approved By: IRB Chair | Signature  | Date 7/18/2018 |

PURPOSE

The purpose of conducting audits and full assessments is to ensure adequate protection of research participants. Audits are used for monitoring the implementation of approved projects, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuing improvement of OIRB processes.

REVISIONS FROM PREVIOUS VERSION

Revised title and clarified communication of findings

POLICY

Principal Investigators (PIs) of human research projects approved by the UNM IRB are obligated to participate in post approval monitoring activities. Audits of approved projects may be conducted either for cause or randomly at any time. Audit authority includes but is not limited to the following:

- Observation of the informed consent process;
- Observation of research procedures including interactions and/or interventions with participants;
- Surveying participants enrolled in the project about the informed consent process and their experience as a participant;
- Review of all documents and materials pertaining to the permission for or conduct of research activities.

When research procedures or interactions with participants are observed as part of an audit, the authorized observer shall acquire prior permission from participants being observed. If the participant is a minor or an adult who did not directly provide informed consent to enroll in the research, audit permission shall be acquired from the parent, guardian, or legally authorized representative who previously provided permission for the minor or adult to enroll in the research.

PROCEDURE

Types of audits

Audits for cause: If a concern or complaint about the conduct of a project is discovered or reported to the OIRB staff, any member of the IRB, or other administrative official, an audit for cause may be initiated. The determination of the need for an audit for cause shall be made by the IRB Chair in consultation with the OIRB Director. Audits for cause may occur at any time. An audit may be project-oriented (focused on a specific project) or researcher-oriented (focused on all the projects of a particular

researcher). Audits may include all project documents or be limited to consent forms only or other limited scope.

Full On-Site Assessment: Full assessments of any active project may occur at any time for the purposes of quality assurance oversight with a specific focus on the following criteria:

- Recruitment of vulnerable populations;
- Federal funding;
- Large numbers of participants;
- PI with large number of active projects and history or pattern of noncompliance;
- Procedures that are greater than minimal risk to participants;
- IRB Reviewer recommendation.

Conducting an Audit or Assessment

1. The OIRB has the primary responsibility for conducting audits and assessments of projects involving human participants. At the discretion of the OIRB, assistance conducting an audit or assessment may be requested from the IRB chair, Research Integrity Officer, IT staff, or other experts.
2. The PI must be present for the opening interview but is not required to be present for the entire conduct of the audit/assessment. In instances when the PI will not be present for the entire audit/assessment, another project team member must be available to answer questions and assist with accessing files.
3. In order to determine the facts surrounding the conduct of the project and if the project is in compliance with written procedures and regulations, OIRB staff may review the researcher's files, participant research records, signed consent/assent forms, and other documents that could serve to provide factual information.
4. All on-site records may be reviewed and compared to OIRB office records to ensure compliance.
5. Any written SOPs or procedures and plans followed by the research staff may be reviewed to ensure appropriate conduct of the research.
6. Interviews with the PI, members of the project team, or research participants may be conducted.
7. Findings will be recorded and, when feasible, the summary of findings will be reviewed with the research staff at the close of each assessment day to allow clarifications or additional information to be communicated as appropriate.
8. External sponsors of human research may conduct research compliance audits, investigations, site visits, or evaluations as detailed in the sponsor contract. Audits initiated by research sponsors, internal or external to UNM, normally do not include audit of OIRB files, records, meetings, or interviews with IRB members except as required by a federal agency or with prior written agreement by the IRB Chair. Such audits, investigations, site visits, and evaluations may be random or for cause and must be coordinated in advance through the OIRB under the direction of the OIRB Director.

Confidentiality

Knowledge of audit/assessment procedures and the content of any findings shall be kept appropriately confidential by all parties involved in the audit. A signed confidentiality agreement may be requested of participating parties at the discretion of the OIRB.

Notification to Researchers

The PI of a project randomly selected for full assessment shall be notified at least five (5) working days in advance of the assessment. The OIRB will attempt to coordinate a convenient date and time for the

assessment. The PI of a project that has been selected for an audit for cause shall be notified at least one (1) working day in advance of the audit.

Response to findings

Upon completion of the audit/assessment, OIRB will prepare an Audit Findings Report. If no findings are noted, the report will be published in IRBNet for access by the PI. If there are findings noted, the report will be reviewed by the IRB Chair as noted below.

Review by the IRB

The IRB Chair or Vice Chair will review the Findings Report to ensure agreement with any recommended actions and will make a determination regarding any restrictions or additional monitoring to ensure compliance:

- project is in full compliance with the regulations and policies, no deficiencies noted;
- project has objectionable practices or conditions noted, but no major departures from regulations and policies; or
- project has objectionable practices or conditions representing major departures from regulations and policies. In this case, the PI will be instructed to submit an Event Report which, along with the Audit Report, will be sent to a fully convened meeting for review.

At the discretion of the IRB Chair, the IRB may be notified of some or all findings. If noncompliance is found, the project will be reviewed according to SOP 402 Research Noncompliance. The project may have additional stipulations or restrictions placed on it or the PI may be required to attend additional training sessions or other reasonable remedial actions may be taken as agreed upon by a majority of IRB members at a convened meeting.

Reports

A summary report of all findings including corrective action plans and preventive measures, but excluding personal identifiers, shall be made available to the IRB and IO annually.

REFERENCES

45 CFR 46.109(e)

21 CFR 56.109(f)