Standard Operating Procedures

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<th>SOP #406.1 Revision 1</th>
<th>TITLE: Directed and Self-Audits</th>
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<td>Approved By: OIRB Director</td>
<td>Signature</td>
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<td>Approved By: IRB Chair</td>
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PURPOSE
The purpose of conducting audits 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
Alignment with Post Approval Monitoring SOP

POLICY
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.

RESPONSIBILITIES
Execution of SOP: Researchers, IRB, OIRB, Research Integrity Officer (RIO)

PROCEDURE
Types of audits

Audits for cause: If a concern or compliant about the conduct of a project is discovered or reported to the OIRB staff, any member of the IRB, the university Research Integrity Officer (RIO), 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 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;
- Involves large numbers of participants;
- PI has large number of active projects and pattern of noncompliance;
- More than minimal risk to participants;
- IRB Reviewer recommendation.

**Conducting an Audit or Assessment**

1. The OIRB has the principal 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, RIO, IT staff, or other experts.
2. 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.
3. All on-site records may be reviewed and compared to OIRB office records to ensure compliance.
4. Any written SOPs or procedures and plans that should be followed by the research staff may be reviewed to ensure appropriate conduct of the research.
5. Interviews with the PI, members of the project team, or research participants may be conducted.
6. 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.
7. 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 Principal Investigator (PI) of a project randomly selected for full assessment shall be notified at least five (5) working days in advance of the assessment. The PI of a project that has been selected for audit for cause shall be notified at least one (1) working day in advance of the audit.
Response to findings
If, based on the conduct of an audit/assessment, the OIRB has reasonable suspicion of noncompliance or of research misconduct as defined by UNM policy, a written Findings Report shall be submitted to the IRB Chair. At the discretion of the IRB Chair, the IRB members may be notified of some or all individual findings.

Review by the IRB
The IRB Chair (and/or IRB) will be given the Findings Report 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.

The project may have additional stipulations or restrictions placed on it or the researcher 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 to the IO annually.

REFERENCES
45 CFR 46.109(e)
21 CFR 56.109(f)