Standard Operating Procedures

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<th>SOP #406.0 Revision 0</th>
<th>TITLE: Directed and Self-Audits</th>
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<tr>
<td>Approved By: OIRB Director</td>
<td>Signature</td>
<td>Date 12/2/2015</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 protocols, identifying areas that need improvement, targeting education needs of researchers, and gathering information for continuing improvement of OIRB processes.

REVISIONS FROM PREVIOUS VERSION
None

POLICY
Audits of approved research protocols 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 study participants;
- Surveying participants enrolled in the study 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 research study 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 study-oriented (focused on a specific study) or researcher-oriented (focused on all the studies of a particular researcher).

**Random audits:** Approximately 5% of all open, non-exempt research protocols shall be selected for random audit on an annual basis. Random audits may occur at any time. The OIRB will conduct routine audits of studies for the purposes of quality assurance oversight with a specific focus on the following study criteria:
- Recruitment of vulnerable populations;
- Federal funding;
- Involves large numbers of participants;
- PI has large number of active studies and pattern of noncompliance;
- More than minimal risk to participants.

**Conducting an Audit**

1. The OIRB has the principal responsibility for conducting audits of research studies involving human participants. At the discretion of the OIRB, assistance conducting an audit 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 study and if the study is in compliance with written procedures and regulations, the auditor may review the researcher’s files, participant research records, signed consent/assent forms, and other documents that could serve to provide factual information.
3. The auditor may review all records on site and compare those records with information in the OIRB office records to ensure compliance.
4. The auditor may review any written SOPs or procedures and plans that should be followed by the research staff to ensure appropriate conduct of the research.
5. The auditor may conduct interviews with the PI, members of the study team, or research participants.
6. The auditor will record findings during the audit and, when feasible, review the summary of findings with the research staff at the close of each audit day to allow clarifications or additional information to be communicated as appropriate.
7. Alternatively, the OIRB may elect to conduct an audit of consent forms only or other limited scope audits to screen for potential quality issues. For a consent only audit, the researcher will be informed to submit all signed consent/assent signature pages for all participants enrolled during a specified period. These documents must be submitted at the time requested by the OIRB. The researcher will also be notified that failure to submit documents will result in an on-site audit of study documents.
8. External sponsors of human subject 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 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 of Investigators
The principal investigator of a study randomly selected for audit shall be notified at least five (5) working days in advance of the audit. The principal investigator of a study 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, the OIRB has reasonable suspicion of non-compliance or of research misconduct as defined by UNM policy, a written Audit 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 audit findings.

Review by the IRB
The IRB Chair (and/or IRB) will be given the Audit Report and will make a determination regarding any restrictions or additional monitoring to ensure compliance:
- Study is in full compliance with the regulations and policies, no deficiencies noted;
- Study has objectionable practices or conditions noted, but no major departures from regulations and policies; or
- Study has objectionable practices or conditions representing major departures from regulations and policies.

The study 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 audit 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)