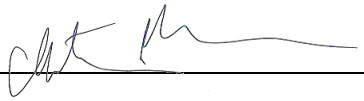
OFFICE OF THE INSTITUTIONAL REVIEW BOARD

Standard Operating Procedures		
SOP #105.5 Revision 5	**TITLE: IRB Records Management and Retention**	Effective Date: 5/8/2022
Approved By: OIRB Director	Signature 	Date 5/2/2022
Approved By: IRB Chair	Signature 	Date 5/2/2022

PURPOSE

To describe policies and procedures for the University of New Mexico Institutional Review Board (IRB) record keeping.

REVISIONS FROM PREVIOUS VERSION

Update references to electronic research administration (ERA) system

POLICY

The Office of the IRB (OIRB) maintains IRB records in accord with applicable regulatory and institutional requirements.

RESPONSIBILITIES

Execution of SOP: OIRB Staff, IRB, Researchers

PROCEDURE

Storage of and Access to Records

1. OIRB staff secure all active IRB records in the OIRB database and limit access to the IRB Chair, IRB members, OIRB staff, Institutional Official (IO) and delegates, and officials of federal and state regulatory agencies, the Office for Human Research Protections (OHRP), Food and Drug Administration (FDA), and accrediting bodies. OIRB staff may grant UNM employees with administrative appointments access to the records on an as-needed basis for official UNM business. Researchers or their authorized research team have reasonable access to files related to their research activities. OIRB staff limit all other access to IRB records to those who have legitimate need for them, as determined by the OIRB Director, IO, and/or UNM Legal Counsel when submitted through state open records statutes. Records are accessible for inspection and copying by authorized representatives of federal agencies and department at reasonable times and in a reasonable manner.
2. Administrative requests for access (e.g. Dean, Associate Dean for Research, Department Chair) must be in writing and contain the following information:
    - The name of the person requesting the information;
    - The information requested;
    - The reason for the request;
    - Assurance of confidentiality.
3. Principal Investigators (PIs) and research staff have access to project documents through the ERA system. PIs can share access to the project in the ERA system and the level of access at their discretion.

4. If the person requesting the record is not on the approved research team for the record requested, the OIRB Director or designee makes a determination before releasing any records as to whether the request is from appropriate accreditation bodies, University officials, administrators, or regulatory agencies that should have access. Unless the individual states an acceptable reason for not informing the PI of the request for a record, OIRB staff inform the PI that OIRB has received a request for access to the applicable protocol.
5. Records are stored in the electronic OIRB database as well as in an electronic file (e-file room) on the UNM network. The OIRB maintains records in the e-file room for a minimum of three years after a project is closed. This storage requirement applies even if the project has not enrolled a single participant. OIRB staff destroy e-file protocol records for projects that have been closed for three years unless the OIRB Director waives the requirement for a specific project.
6. In addition to protocol files, the OIRB maintains the following information and records. OIRB staff organize and store records as electronic documents as appropriate which include, but are not limited to, the following categories:
    - Standard operating procedures;
    - IRB membership rosters;
    - Meeting minutes, which include documentation of convened IRB meetings and non-committee reviews;
    - Federalwide Assurance;
    - Other IRB correspondence;
    - Agendas for IRB meetings, which include all items to be reviewed;
    - Alleged noncompliance case records;
    - Mandated reports;
    - Curriculum vitae of currently active IRB members;
    - Electronic records documenting completion of mandatory IRB training for IRB members and OIRB staff.
7. OIRB staff maintain records indefinitely that are not part of specific protocol files, such as meeting minutes, agendas, standard operating procedures, membership rosters, or periodically destroy them, as determined by the OIRB Director.
8. The OIRB also maintains communications to and from the IRB and keeps any relevant communication related to a specific research protocol in the electronic protocol record.

Protocol Records

1. OIRB staff maintain a separate record for every project. The IRB protocol record includes, but is not limited to:

<u>Full Review Protocol</u>

- Signed initial IRB application (or Project Information Form);
- Scientific evaluations of the proposed research (Scientific Validity Review);
- Data Safety and Monitoring Board reports, if any;
- Results of Quality Improvement Program reviews, if any;
- IRB approved informed consent document(s) and assent document(s), if applicable;
- Documentation of all IRB review and approval actions, modifications and all relevant correspondence to and from the researcher, including initial and, if applicable, IRB continuation and amendment review;
- Documentation of type of review;

- Documentation of project close-out;
- Specific findings (federal and institutional requirements);
- Continuation/Closure/Administrative Check-in review materials;
- Significant new findings provided to human subjects, if any;
- Reports of unanticipated problems/adverse events involving risks to participants or others;
- Reports of protocol deviations;
- Any reports of complaints;
- All relevant correspondence to and from the researcher and any other correspondence related to the project;
- IRB Authorization Agreements;
- Any existing contractual agreements for off-site research;
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- Advertising or recruiting materials, if applicable;
- Protocol amendments or modifications;
- Data collection tools, if applicable;
- Department of Health and Human Services/National Institutes of Health (NIH) approved sample informed consent form and protocol, if applicable;
- Human research protection training for principal investigator and research teams, as applicable;
- Health Insurance Portability and Accountability Act (HIPAA) forms, if applicable;
- Institutional Biosafety Committee correspondence and approval letters, if applicable;
- Other committee approvals/correspondence, if applicable;
- Mandated reports, if applicable;
- IRB Reviewer Checklists.

<u>Minimal Risk Review Protocol</u>

- All of the items listed above under full review protocol, as applicable to individual projects;
- Documentation and determinations required by the regulations and protocol-specific findings justifying those determinations, including that the project is eligible for expedited, exempt, or minimal risk review and the applicable review category;
- IRB Reviewer Checklists.

OIRB Database

1. The OIRB maintains an electronic database. Examples of data included in the database include the following:
   - IRB number; IRB providing review; designated reviewer and OIRB staff managing review;
   - Current status (active/closed);
   - Title of the research project (protocol);
   - Review type (full, expedited, exempt, minimal risk);
   - Board action (pending, modifications requested, approved, suspended, terminated);
   - Risk category;
   - Approval period;
   - Names of the PI and project team as appropriate;
   - Number and age level of participants;
   - Enrollment status (open or closed to accrual);
   - Other committee approvals (e.g. Conflict of Interest Committee);

- Funding source type;
- Research sites (if other than UNM campus);
- Dates of initial and most recent approvals;
- Submission and review dates for each submission (initial review, continuation review, closure review, amendment review, reportable event review);
- Other information, such as meeting dates or project notes.

2. The ERA system maintains the OIRB computerized tracking system and performs a backup of this system on a regular basis.

Records Destruction

1. The OIRB will retain records for at least three (3) years following closure of the project and for projects closed without participant enrollment. Following the required three-year minimal data retention period, existing e-file room records may be deleted.
2. Electronic versions of all minutes and project records will be maintained indefinitely either in the ERA system or on an institutional server.

REFERENCES

45 CFR 46.115
21 CFR 56.115
1.21.2 NMAC, *et seq.*