|  |  |
| --- | --- |
| Regulatory Files ChecklistResearchers who conduct human subjects research are required to maintain records to document compliance with federal and state regulations, UNM IRB and Institutional policies, and IRB determinations. This checklist can assist researchers in achieving and maintaining compliance with these requirements. Records can be kept as electronic or hard copy files. | C:\Users\cbcholka\AppData\Local\Microsoft\Windows\INetCache\Content.Word\UNM_OfficeInstitutionalReviewBoard_Horizontal_RGB.PNG1805 Sigma Chi NE | Tel: (505) 277-2644 Website: irb.unm.edu | Email: IRBMainCampus@unm.edu |

|  |
| --- |
| Project Identification |
| *Principal Investigator (PI)* |  | *Student Investigator (SI)* |  |
| *IRB reference number:* |  | *Project title:*  |  |

[ ] Project Team Records:

[ ] Project Team Form: This form should be accurate based on who is engaged in the research and should be updated regularly.

[ ] CITI training: A current copy of the Main Campus Researcher’s CITI training completion report for each person listed on the Project Team Form. This training must be renewed every 3 years.

[ ] COI Disclosure: All researchers are required to submit a COI disclosure annually, at the time of a material change, or submission of a grant to PHS agency. Confirmation emails from the COI office should be maintained to document compliance.

[ ] COI Management Plan: For researchers that are prescribed a Management Plan by the UNM COI Committee, the PI should have a copy with the project records.

[ ] Research Staff Training Logs: A current copy of the research staff training log for each person listed on the project team form.

[ ] Protocol: Current IRB approved Protocol.

[ ] Informed Consent Form(s): Current IRB approved ICFs.

[ ] Protocol Deviation Report: A current copy of the protocol deviation report listing any deviations that occurred since last IRB review.

[ ] Event Reporting Log: A current copy of the event reporting log.

[ ] Participant Tracking Logs: Current copies of any logs used to assist with managing enrollment or tracking participants (e.g. Linking and Screening Log, Participant Contact Information, Compensation Log, etc.)

[ ] IRB Documents: Copies of documents submitted to the IRB filed in date order of submission (including amendments, continuing reviews, etc.). These can also be maintained in IRBNet.

[ ] OIRB Documents: Documents received from the IRB filed in the order of receipt (including determination letters, approved consent form(s), recruitment materials, etc.). These can be maintained in IRBNet but must be accessible to all project team members.

[ ] Funder/Sponsor Communications: If the project is funded, file copies of the grant application, notice of award, progress reports, and communications.

[ ] Data and Safety Monitoring: If applicable to the project, copies of data transfer agreements, charter reports, or DSMB reports.

[ ] Post Approval Monitoring: File copies of any findings and determinations from post approval monitoring activities including self-assessments, IRB requested assessments, etc.