|  |  |
| --- | --- |
| Self-Assessment ToolThis form is for researchers to use to conduct self-assessments of their IRB approved projects to ensure they are being conducted in compliance with the approved procedures and IRB regulations and policies. The UNM IRB encourages researchers to conduct self-assessments at least annually. The IRB may also request that self-assessments be conducted and reported to the UNM IRB. Please keep copies of completed assessments with your IRB related records. If needed, use additional pages for notes. | 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)* |  | *Assessment completed by:* | [ ]  PI [ ]  SI | *Date Conducted:* |  |
| *IRB reference number:* |  | *Project title:*  |  |

|  |
| --- |
| Records Review |
| 1. **Approval and Record Keeping**
 | **Yes** | **No** | **N/A** | **Notes** |
| Does the project have current IRB approval? | [ ]  | [ ]  | [ ]  |       |
| Are all IRB related records being retained in an accessible location? All records must be kept for at least 3 years after closure of the project. Examples: approval letters, signed applications, approved consent forms, correspondence, protocol, etc. | [ ]  | [ ]  | [ ]  |       |
| Are all project team members current (completed in last 3 years) in their human participants’ protections training (CITI)?  | [ ]  | [ ]  | [ ]  |       |
| Are all project team member training certificates on file?  | [ ]  | [ ]  | [ ]  |       |
| Are annual COI disclosure on file for all project team members? | [ ]  | [ ]  | [ ]  |       |
| If a COI decision memo or management plan has been issued for any project team member, has it been uploaded in IRBNet? | [ ]  | [ ]  | [ ]  |       |
| Have all revisions to the project been reviewed and approved by the IRB prior to implementation?  | [ ]  | [ ]  | [ ]  |       |
| 1. **Participant Recruitment and Screening**
 | **Yes** | **No** | **N/A** | **Notes** |
| Were participants identified and recruited according to the procedures approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Were the advertising and/or recruitment materials used approved by the IRB prior to use? | [ ]  | [ ]  | [ ]  |       |
| Were all inclusion and exclusion requirements followed as listed and approved by the IRB?  | [ ]  | [ ]  | [ ]  |       |
|  If **no**, were the deviations reported to the IRB? | [ ]  | [ ]  | [ ]  |       |
| For participants that did not meet eligibility requirements (failed screening), were IRB approved procedures followed? | [ ]  | [ ]  | [ ]  |       |
| How many participants have been enrolled to date?       |  |  |  |       |
| Is the number of participants enrolled no greater than the IRB approved participant enrollment? | [ ]  | [ ]  | [ ]  |       |
| 1. **Informed Consent Process and Documentation**
 | **Yes** | **No** | **N/A** | **Notes** |
| Was the IRB approved version of the consent(s)/assent(s) used to enroll participants? | [ ]  | [ ]  | [ ]  |       |
| If using an oral or online consent, was the IRB approved script/text used to enroll participants? | [ ]  | [ ]  | [ ]  |       |
| Were all consent forms used to enroll participants approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| **Informed Consent Process and Documentation (cont.)** | **Yes** | **No** | **N/A** | **Notes** |
| Did an appropriately trained project team member obtain consent from all participants? | [ ]  | [ ]  | [ ]  |       |
| Is there a signed and dated consent form on file for every participant enrolled in the project? | [ ]  | [ ]  | [ ]  |       |
| Did the project team member sign and date each consent form? | [ ]  | [ ]  | [ ]  |       |
| Do the participant and researcher consent dates match? | [ ]  | [ ]  | [ ]  |       |
| If changes were made to the consent form, were the changes submitted and approved by the IRB prior to use? | [ ]  | [ ]  | [ ]  |       |
| Did every participant receive a copy of the consent form? | [ ]  | [ ]  | [ ]  |       |
| 1. **Research Protocol**
 | **Yes** | **No** | **N/A** | **Notes** |
| Was the research conducted consistent with the description and procedures as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Were the data collection tools (e.g. surveys, interview questions, etc.) used approved by the IRB, prior to use? | [ ]  | [ ]  | [ ]  |       |
| For each participant, was consent obtained prior to any project procedures? | [ ]  | [ ]  | [ ]  |       |
| Are all participant compensation records being documented and stored appropriately? | [ ]  | [ ]  | [ ]  |       |
| If changes were made to the protocol, were the changes submitted and approved by the IRB prior to implementation? | [ ]  | [ ]  | [ ]  |       |
| Have all reportable events been addressed as required by the UNM IRB? | [ ]  | [ ]  | [ ]  |       |
| 1. **Privacy, Data Storage, and Confidentiality**
 | **Yes** | **No** | **N/A** | **Notes** |
| Were privacy standards and procedures implemented as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| If you collected data anonymously, has anonymity been maintained in the physical/electronic records? | [ ]  | [ ]  | [ ]  |       |
| Are signed consent forms and coded project data stored separately?  | [ ]  | [ ]  | [ ]  |       |
| Are signed consent forms secured as approved by the IRB? Provide location:       | [ ]  | [ ]  | [ ]  |       |
| Are project data secured as approved by the IRB? Provide location(s):       | [ ]  | [ ]  | [ ]  |       |
| If electronic data are being stored on a desktop, is it secured as approved by the IRB? Provide computer location:       | [ ]  | [ ]  | [ ]  |       |
| Are electronic data secured (e.g. password protected, encrypted, etc.) as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Are you aware of the security on your computer and server? | [ ]  | [ ]  | [ ]  |       |
| Is access to computer, electronic files, and physical files limited to appropriate project personnel? | [ ]  | [ ]  | [ ]  |       |
| Was/are identifiers stored/disposed of as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |
| Was/is the research data (raw) stored/disposed of as approved by the IRB? | [ ]  | [ ]  | [ ]  |       |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 1. **Continuing Review**
 | **Yes** | **No** | **N/A** | **Notes** |
| Are you aware of when the IRB approval for this project expires? Expiration date:       | [ ]  | [ ]  | [ ]  |       |
| Have you placed a reminder on your schedule to submit continuing review documents 30 days prior to expiration? | [ ]  | [ ]  | [ ]  |       |
| Has IRB approval for this project ever expired?  | [ ]  | [ ]  |  |       |
|  If **yes**, did you report any research activity that was done while IRB approval was expired? | [ ]  | [ ]  |  |       |
| Have there been any adverse events, unanticipated problems, or complaints while conducting this research?  | [ ]  | [ ]  |  |       |
|  If **yes**, have all details been reported to the IRB? | [ ]  | [ ]  | [ ]  |       |
| Has the researcher become aware of new information that changes the risk benefit ratio of this project? | [ ]  | [ ]  |  |       |
| Does the enrollment number reported in the continuing review application include all individuals who signed an informed consent document? | [ ]  | [ ]  | [ ]  |       |
| 1. **Project Completion**
 | **Yes** | **No** | **N/A** | **Notes** |
| Is data collection complete for this project? | [ ]  | [ ]  | [ ]  |       |
|  If data collection is ongoing**, what is your anticipated end date for data collection?** Antic. End date        |
| Have all identifiers been destroyed in accordance with IRB approved procedures? | [ ]  | [ ]  | [ ]  |       |
| If **yes to both questions above**, submit a Closure Application (and supporting documentation) to the OIRB. |

|  |
| --- |
| Certification |
| I certify that all information provided in this document is accurate and that the IRB has been informed of any necessary issues. |
|  |  |  |  |
| Principal Investigator Signature | Date | Student Investigator Signature | Date |