|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Principal Investigator:** |  | **IRB Log No.:** |  | | | **Date:** |  |
| **Study Title:** |  | | | | | | |
|  | | | | | | |
|  | | | | | | |
|  | | | | | | | |
| **Approval and Record Keeping** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| The project has current IRB approval. | | |  |  |  |  | |
| All IRB related records (approval letter, application, signed consent forms, continuing review activities & correspondence) has been retained in an accessible location.  ***Note:*** *All records must be kept for at least 3 years after completion of research.* | | |  |  |  |  | |
| All investigators listed on this project are currently certified in the human subjects protection training. | | |  |  |  |  | |
| Were there any changes to the approved project since the last continuing review? If yes, was a revision submitted to the IRB? | | |  |  |  |  | |
|  | | | | | | | |
| **Consents** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| Was the IRB approved (with footer or stamp) version of the consent(s)/assent(s) used to enroll subjects? | | |  |  |  |  | |
| Were all consent forms (with footer or stamp) signed by subjects prior to enrollment? | | |  |  |  |  | |
| If using an oral consent, the IRB approved script was used to enroll subjects. | | |  |  |  |  | |
| Do you have a signed and dated consent form on file for every subject enrolled in the study? | | |  |  |  |  | |
| If changes were made to the consent form, were the changes submitted and approved by the IRB? | | |  |  |  |  | |
| Special considerations for vulnerable participants in research. | | |  |  |  |  | |
| **Research Protocol** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| Research conducted complies with the project description and procedures as approved by the IRB. | | |  |  |  |  | |
| All data collection instruments used were approved by the IRB. | | |  |  |  |  | |
|  | | | | | | | |
| **RECRUITMENT** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| Subjects were identified/recruited as per methods approved by the IRB. | | |  |  |  |  | |
| All advertising or recruitment materials used to recruit subjects are IRB approved. | | |  |  |  |  | |
| All eligibility and ineligibility requirements as listed and approved by the IRB were followed. Any deviations were reported to the IRB. | | |  |  |  |  | |
| If subjects received any compensation, is there documentation? | | |  |  |  |  | |
|  | | | | | | | |
| **Privacy, Data Storage and Confidentiality** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| The subject’s privacy is protected &safeguards are in place as per IRB Policy. | | |  |  |  |  | |
| If you proposed to collect the data anonymously, has anonymity been maintained in the physical or electronic records? | | |  |  |  |  | |
| Are hard copies (consent forms& forms) stored in a secure, locked location? | | |  |  |  |  | |
| Is electronic data on a secure and protected computer? Are you aware of the security on your computer and server? | | |  |  |  |  | |
| Are electronic data files password protected? | | |  |  |  |  | |
| Is access to computer, e-files, and physical files limited to study personnel? | | |  |  |  |  | |
| Was the research data stored/disposed of as per IRB Policy? | | |  |  |  |  | |
|  | | | | | | | |
| **Continuing Review** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| Are you aware of when your project expires? Have you placed a reminder on your schedule to submit a renewal form 4 weeks prior to the expiration? | | |  |  |  |  | |
| Have there been any lapses in IRB approval? If yes, did you report any research activity that was done during the lapse? | | |  |  |  |  | |
| Have there been any adverse events or unanticipated problems, complaints or subject withdrawals while conducting this research? If yes, have details been reported to the IRB? | | |  |  |  |  | |
| Have there been any new findings to change the risk benefit ratio? | | |  |  |  |  | |
| Is there a Financial or non-financial Conflict of Interest? | | |  |  |  |  | |
|  | | | | | | | |
| **Closure** | | | **YES** | **NO** | **N/A** | **COMMENTS** | |
| If your project is complete or you are performing data analysis only on anonymous or de-identified data, can you close the protocol? | | |  |  |  |  | |
|  | | | | | | | |
| **If you would like to discuss any aspects of your self-assessment with the IRB Staff or Chair, please call at IRB office.** | | | | | | | |