|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Principal Investigator:** |  | **IRB Log No.:** |  | **Date:** |  |
| **Study Title:** |  |
|  |
|  |
|  |
| **Approval and Record Keeping** | **YES** | **NO** | **N/A** | **COMMENTS** |
| The project was deemed Exempt by the IRB. |  |  |  |  |
| All IRB related records (exemption 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. |  |  |  |  |
| Have there been any changes to the protocol which may change the Exempt review category? |  |  |  |  |
|  |
| **Consents** | **YES** | **NO** | **N/A** | **COMMENTS** |
| Was the IRB reviewed version of the consent(s) used to enroll subjects? |  |  |  |  |
| Were all consent forms signed by subjects prior to enrollment? |  |  |  |  |
| If using an oral consent, the IRB approved script was used to enroll subjects. |  |  |  |  |
| Do you have on file a signed and dated consent form for every subject enrolled in the study? |  |  |  |  |
| Subjects were identified and recruited according to the methods reviewed by the IRB in the initial application. |  |  |  |  |
| Any advertising or recruitment materials used to recruit subjects were reviewed by the IRB in the initial application. |  |  |  |  |
| **Consents** | **YES** | **NO** | **N/A** | **COMMENTS** |
| All eligibility and ineligibility requirements as listed and reviewed by the IRB in the initial application were followed. |  |  |  |  |
| If subjects received any compensation, is there documentation? |  |  |  |  |
| Special considerations for vulnerable participants in research? |  |  |  |  |
|  |
| **Research Protocol** | **YES** | **NO** | **N/A** | **COMMENTS** |
| Research conducted complies with the project description and procedures as reviewed by the IRB in the initial application. |  |  |  |  |
| All data collection instruments used were those reviewed by the IRB in the initial application. |  |  |  |  |
|  |
| **Privacy, Data Storage and Confidentiality** | **YES** | **NO** | **N/A** | **COMMENTS** |
| The subject’s privacy was protected and safeguards are in place as reviewed by the IRB in the initial application. |  |  |  |  |
| If you proposed to collect the data anonymously, has anonymity been maintained in the physical or electronic records? |  |  |  |  |
| Are hard copies (consent forms, data) 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, & physical files limited to study personnel? |  |  |  |  |
| Was the research data (raw) stored/disposed of as described and reviewed by the IRB in the initial application? |  |  |  |  |

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| --- | --- | --- | --- | --- |
| **Continuing Review** | **YES** | **NO** | **N/A** | **COMMENTS** |
| Have there been any serious adverse events (AE), unanticipated problems, complaints or subject withdrawals while conducting this research which were not 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 the project is complete, has the IRB been notified through a closure form so they can take it off their records as an active protocol? |  |  |  |  |
|  |
| **If you would like to discuss any aspects of your self-assessment with the IRB Staff or Chair, please call at IRB office.** |