|  |  |
| --- | --- |
| **Study Title:** |  |
| **Principal Investigator:** | **Location:** |
| **CHS #:** | **Initial Approval Date:** |
| **Sponsor:** | **Special Subject Population:** |
| **Reviewer:** | **Review Date:** |
| **Reason for Review:** |  |
| **Research Staff Present:** |  |
|  |  |
|  |  |

**Research Team**

If other than PI, identify the individual(s) responsible for:

Recruiting/informed consent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Eligibility determination \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Conducting research procedures \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Educating research team \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Records management \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Data analysis \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Adverse events reporting \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

🞏 Key study personnel completed appropriate education

🞏 Delegation of research activities documented

🞏 No changes in personnel roles, responsibilites, location or participation documented

If no for any item, explain:

**Record-Keeping**

Research records organized and labeled to allow identification and review

🞏 Approved protocols (all versions)

🞏 Correspondence from IRB

🞏 Letters of support

🞏 Grant contracts or agreements with funding agency

🞏 Conflict of Interest disclosures

If no for any item, explain:

**Recruitment**

Participants identified and recruited according to approved methods

🞏 All advertising and recruitment materials used were approved prior to use and are on file

🞏 Eligibility (inclusion) and ineligibility (exclusion) requirements followed as approved

🞏 Any deviations reported to IRB

🞏 Recruitment on schedule

🞏 Documentation of any compensation

If no for any item, explain:

**Consent/Assent**

Consent process being implemented according to protocol

🞏 Form on file for every participant enrolled in study, signed by both participant and researcher

🞏 Approved version used to enroll all participants (any changes approved by IRB prior to use)

🞏 Participants signed forms before enrollment

🞏 If minors, participant assent form and parental consent both on file

🞏 If using oral consent, approved script used to enroll subjects

If no for any item, explain:

**Research Protocol**

Research conducted complies with approved project description and procedures

🞏 Changes to project since prior review have been submitted to IRB and approved

🞏 All data collection instruments used were approved

🞏 Screening/enrollment logs complete and up-to-date

🞏 Subject withdrawals and dropouts documented

If no for any item, explain:

**Privacy/Confidentiality**

Privacy of participants and confidentiality of data protected by appropriate safeguards

🞏 Research data stored/disposed of as approved

🞏 If anonymous collection, anonymity maintained in physical and electronic records

🞏 Physical copies stored in secured location

🞏 Electronic data stored in secure manner

🞏 Researcher aware of security measures and adequacy

🞏 Access to electronic and physical files limited to appropriate study personnel

If no for any item, explain:

**Continuing Review**

🞏 PI aware of research approval dates

🞏 Any lapses reported to IRB

🞏 Research suspended during lapse

🞏 Adverse events, unanticipated problems, complaints, subject withdrawals:

🞏 Identified and noted in research files

🞏 Details reported to IRB

🞏 Identify any new findings that change risk/benefit ratio

🞏 Notify IRB when project is complete

If no for any item, explain: