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Study Initiation

Purposes: This SOP outlines how data will be collected during the conduct of the study.

Procedure: The PI initiates the use of specific documents at the beginning of the study. Documents to be initiated at study start (prior to enrollment and as participants are enrolled) include a screening log, enrollment log, IRB submission log, delegation of duty log, training Log, adverse event log, and protocol deviation log.

A. The PI keeps a **Screening Log** for the duration of enrollment.

The Screening Log includes the following:

1. The participants who were evaluated but may or may not qualify for the study
2. The participant number, a unique number assigned to study participants to allow for cross reference
3. Initial contact information tracks recruitment data to evaluate the recruitment plan
4. The Screen Date(s) is/are the date(s) the participant is screened for the study
5. The screening process may or may not require a consent form to be signed before final eligibility can be determined
6. Use the Enrollment Log to document the date of consent (the date the participant signs the consent form) and to document when final eligibility is determined

B. The PI keeps an **Enrollment Log** throughout the study including participants who may transfer from a different site.

1. The consent date is the date the participant signs the consent form
2. Document the date the subject received a copy of the signed and dated consent form, the date a copy was put in the research record, and date the PI reviewed it
3. Copy of ICF must be placed in the medical record and the date documented
4. By signing the consent form the PI is documenting his/her role in the consent process and/or eligibility evaluation

C. The PI keeps an **IRB Submission Log.** This will include a brief summary of all communication with the IRB and changes submitted. This log will include the following and be kept in the front of the regulatory binder

1. Initial approval of protocol, consent, application form, investigational brochure, advertisements, questionnaires, surveys or other communication to subject
2. Continuing review submissions
3. Any changes to the research after the initial approval including protocol changes, consent form changes, personnel changes, addition of new sites
4. Unanticipated problem reports
5. Other changes submitted to the IRB
6. Correspondence from federal agencies if applicable

D. The PI keeps a **Delegation of Duty** log. This log includes the names of all staff involved with the study and their roles as delegated by the PI. Some of the duties delegated to the staff will require special training. This should be noted in the Training Log described below (See "E"). The delegation log should be updated when there are personnel changes or significant protocol changes

E. The PI keeps a **Training Log.** The PI ensures all staff are initially trained on the protocol prior to study activation using a training checklist. This same checklist should be used to train new personnel that are brought on to the research team once the study has been initiated. If there is new information and/or procedures added to the study, the required training should be added to the training checklist and each staff member must review the required information as dictated by the PI and then the staff member signs and dates specific to the training. It is the PIs responsibility to ensure that all staff members complete the required training.

F. The PI keeps an **Adverse Event / Unanticipated Problem Log.** A copy of the current IRB definition of reportable adverse events and unanticipated problems should be printed and placed in the study binder as a reference tool.

The research team should maintain a log of all adverse events with an assessment of expected or unexpected based on whether the adverse event is listed in the currently

approved protocol, consent and/or investigational brochure to the same severity and frequency. Causality should be determined based on the subject's history of the event and/or medical record reported follow up testing. The PI should facilitate the determination and document concurrence as to whether it is a UAP or AE by signature and date.

Investigators are required to report any instance of noncompliance as an unanticipated problem to the IRB of Record in accordance with IRB policy. Instances of noncompliance include improper consent/authorization, research activities during expiration, etc. Regulatory unanticipated problems can include enrolling prisoners, children or decisionally challenged individuals without prior IRB approval.

The research team needs to establish a clear communication plan for regularly documenting and evaluating all adverse events to ensure that each one is appropriately evaluated and reported to the IRB, and/or lead site and/or FDA within the appropriate timeline.

G. The PI keeps a **Protocol Deviation Log.** A subset of noncompliance is protocol deviation; some protocol deviations are incidental and have no consequences to participants.
    1. If a deviation from the protocol results in risk to participants, it must be reported promptly to the IRB of Record in accordance with IRB policy. Follow the protocol regarding reporting to other entities.
    2. If a deviation from the protocol does not result in risk to participants, it can be summarized in aggregate and reported at the next continuing review.
    3. Description of protocol deviation: any change to the protocol that has not received IRB approval.
    4. Deviation categories – (A) safety, (B) informed consent, (C) eligibility, (D) protocol implementation, (E) noncompliance, (F) other (specify in log)
        i. Date deviation occurred
        ii. Date IRB notified – The IRB policy and protocol/grant dictates which deviations (and AEs) are reported and to whom. Examples include: an actual unforeseen harmful or unfavorable

occurrence to participants or others that relates to the research protocol (injuries, psychological events, drug error)

iii. Complaints about research (this study specifically) should be documented and reported at continuing review.

H. Device and Drug accountability

For any research drugs or devices it is necessary to establish and maintain an appropriate device and/ or drug accountability log. Accountability procedures will document the receipt, dispensing and disposition/return of all study devices and/ or devices.

I. Register for Clinical Trials.gov

Applicable clinical trials must be registered within 21 days of enrollment of the first participant.

Many publications (ICMJE policy) require that the study be registered prior to enrollment of the first subject