Appendix C: Participant and PI Records Review

This Appendix provides a general format of the Research Compliance Monitor's (RCM) process for conducting a Participant Records Review with the Principal Investigator (PI). Please note, that depending on the complexity of the project, questions that arise, and other factors, additional meetings may be required to complete the process.

Document Review

The document review includes a thorough review of the research participant record, the source documents, all regulatory binders, and consent forms, as applicable. This portion of the PAM program is conducted to get the most information in the most efficient way. The order of contents may vary from audit to audit and other documents may be examined as needed. The PI should be present during this part of the process. In general, the following areas must be examined during the participant records review.

Regulatory Binder or Study Documentation Binder (hard copy or electronic)

Should include:

- The complete research protocol
- Informed consent documents
- Investigator CVs
- Training documents
- IRB documents including initial submission, amendments, continuations and adverse reactions/unexpected events that have been sent to the IRB
- IRB approval memos and other correspondence
- All sponsor communications and correspondence, including signed agreements and applicable funding documents
- Signature lists of research staff (for clinical trials)
- Inclusion/exclusion criteria
- Serious adverse event reports
- Monitoring logs and reports (for clinical trials)
- Final study reports
- Investigator's brochure (for clinical trials)
- Other relevant documents

Consent Form

The consent forms for the research protocol will be reviewed for the following items:

- Is there a consent form for each participant?
- Who signed the consent (participant, parent, legally authorized representative)?
- When was the consent document signed in relation to when the first research activity began?
- Was the correct version of the consent/assent document used for the participant?
- Is the consent IRB approved?
- Is the content in the consent document current regarding the most recently approved protocol and amendments to the protocol?

- If the consent form is different from the originally approved form, were amendments submitted for these changes?
- Where the signed consents are kept and what measures are taken to protect the confidentiality of the participant's signatures?
- Where the consent process is conducted and by whom?
- Who obtained the consent signature?
- Has the person who obtained informed consent completed the required on-line training modules?

Eligibility Criteria

- Is determination of eligibility by inclusion/exclusion criteria clearly noted in record?
- Who makes the eligibility decision? How is this communicated to the PI?
- Are source documents (laboratory tests, diagnostic tests, and history & physical exam results) available to verify that the eligibility criteria were met?

Adverse Reactions/Unexpected Events (AR/UE)

- Are the AR/UEs on file all reported to the IRB? (is there a match)
- Is there evidence of follow-up for the AR/UEs?
- Who reports the AR/UEs?
- Were the reports completed correctly and submitted on time to the IRB?
- Have appropriate federal regulatory agencies been notified of all serious, unexpected, and related adverse events or unexpected problems?

Questionnaires

- Are the data collection tools detailed in the protocol in each record (hard copy or on line)?
- Are they the same or different from those that were approved by the IRB?
- If different, was an amendment submitted to cover those changes? Is a change in the consent needed to cover the changes in the questionnaires?
- Are they being administered within the time frame specified by the protocol?
- If questionnaires are completed via interview, how is the privacy of participant maintained?

Protocol Adherence

- Is there evidence of a system that allows for tracking of the participant's experience throughout the protocol (e.g., flow chart)?
- Are there other documents (research worksheets) for recording tests, procedures, questions, comments, complaints, withdrawals, removals and reasons for this action in the research record?
- Is there evidence that the methods for monitoring the safety of the participants are being followed as specified by the protocol?
- Are the timelines specified by the protocol design being followed?
- Have there been any protocol deviations/violations during the course of the study?

- What actions were taken by the research team to remedy these?
- Have any of these been reported as AR/UEs, if appropriate?

Documentation

- Are there consistent procedures being followed for documenting the processes of the research study?
- Is there a system for writing narrative notes when a participant is seen for a visit/ for phone or mail contacts?
- Where are records kept? How are they kept? Who has access to the records?
- Is a Regulatory Binder/Methods/Study Binder in the Research Office/Lab?
- Where is all correspondence regarding the study kept?
- Who is responsible for training research personnel on proper documentation?
- Is the documentation accurate?
- When errors are made in documentation, how are the errors corrected?

Data Collection

- Are source documents available to verify the data collected for the study and recorded on research records?
- Is the system used to document data used consistently from case to case?

Devices:

- How are the devices sent to the institution/PI?
- Where and how are they stored?
- Who manages the device accountability logs?
- Who verifies the device order?
- Who verifies the consent and actual use of the device?
- What methods are used to verify that the device was used properly?
- What are the methods of disposal or return of the unused device to the company?