Appendix : Participant and PI Records Review

This A

- 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?