Study Initiation Meeting

Study Name

Date

Time

Meeting Location:

Attendees: Sponsor's Representative(s), Clinical research coordinator(s), Investigator(s), Administrator(s)

Agenda

1. Introduction of participants
2. Protocol and study procedures
• Review of protocol and study requirements
• Discussion of handling missed visits and drop outs
• Review of case report forms, including training on proper completion and electronic access, if required
• Required documentation for medical records and source documents
• IRB reporting requirements
• Informed consent requirements
• Regulatory document binder requirements
• Laboratory procedures, reports, and abnormal values
3. Review of Good Clinical Practice regulations and guidelines
4. Drug supplies (storage, control, regulations, and documentation and returns)
5. Monitoring and inspection of investigator records
6. Adverse event reporting
7. Data management and review process, including discussion of variables and query resolution
8. Study closure and reporting (including publication, if applicable)