"Study Title." IRB #/IND #

Sample Site Initiation Visit Agenda

Date

I. Regulatory Binder
   a. CVs for PI and Sub-I's
   b. Medical Licenses for PI and Sub-I's (where applicable)
   c. FDA Form 1572
   d. Financial Disclosure Forms
   e. IRB approval letter
   f. IRB-approved protocol
   g. IRB-approved informed consent form
   h. Laboratory certification and normal ranges
   i. Delegation of Responsibility Log
   j. Monitoring Visit Log

II. Investigator Responsibilities (PI present)

III. Protocol Review (PI present)

IV. Case Report Forms and Source Documentation

V. Informed Consent Procedures

VI. IRB Procedures

VII. Adverse Event Reporting

VIII. Monitoring Procedures/Schedule

IX. Investigational Drug Dispensation and Accountability

X. Questions?