SOP #: I-A-6
SOP Area: Investigator Site Audit
University of Pittsburgh
Education and Compliance Program RCCO

Standard Operating Procedure
Pre-Audit Interview

1. PURPOSE

To define the procedures necessary to prepare for and conduct a pre-audit interview.

2. SCOPE

This procedure applies to all investigator audits performed by the Education and Compliance Office.

3. RESPONSIBILITIES

The Education and Compliance Coordinators are responsible for preparing for and conducting pre-audit interviews for each audit performed.

4. PROCEDURES

4.1. A pre-audit interview is to be held prior to the conduct of an investigator site audit with a member or members of the respective research staff.

This interview is performed to identify the names of individual(s) responsible for various protocol-related activities, such as:
- preparing IRB protocol submissions;
- obtaining informed consent;
- recruiting study participants;
- reporting adverse events;
- maintaining study documentation;
- analyzing study data.

4.2. During the pre-audit interview, information is also obtained regarding:
- number of subjects screened and enrolled into the study;
- number of sites involved, if the study is multicenter;
- occurrence of adverse events;
- occurrence of site monitoring visit(s);
- presence of data and safety monitoring plans;
- difficulties in subject recruitment or in study conduct.

4.3. The pre-audit interview is to be utilized as an opportunity to clarify any questions or issues that the Education and Compliance Coordinators may have regarding the conduct of the study.

5. REFERENCES/DOCUMENTATION

Attached example of pre-audit interview form.

SOP #: I-A-3 Version # 1
SOP Area: Investigator Site Audit

Signature: _____ Date:_____
Director, Research Conduct and Compliance Office

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University of Pittsburgh
Education and Compliance Program RCCO

Standard Operating Procedure
Pre-Audit Interview

IRB # _____ QA# _____

Principal Investigator _____

Previous Principal Investigators _____

Study Coordinator_____

Previous Study Coordinators _____

Number of subjects screened to date: _____ Number of subjects enrolled to date: _____

If multicenter, number of centers: _____ Number of multicenter subject enrollment: _____

Procedure	**Responsibility / Comment**
IRB Submissions	
Recruitment Measures Advertising	
Screening	
Informed Consent	
Randomization	
Physical Exam	
Blood Draw Lab Used Blood Storage	
Questionnaires	
Record-Keeping Regulatory Records	
Storage of Records	
Drug Accountability	
Data Security	
Data Analysis	
Data monitoring	
Staff education	

Source: University of Pittsburgh.