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Site Initiation Visit Agenda

I. Protocol Overview

A. Background
B. Study Design and Study Objectives
C. Inclusion / Exclusion Criteria
D. Time and Events Schedule including visit windows
E. Study Procedures Overview
F. Study Product(s) Overview
G. Specimen Collection and Processing
H. Risks and Benefits
I. Safety Reporting
J. Study Flow / Study Plan and Logistics
K. Data Analysis Plan

II. Recruitment Strategy

A. Project Timelines / Recruitment Goals
B. Study Population
C. Screening / Identification of potential participants
D. Recruitment Methods (Advertisements, social media, radio, print, scripts etc.)
E. Competing Protocols Workload
F. Enrollment / Informed Consent Process including a mock study visit
G. Participant Compensation / Coverage Analysis / RBNFs, as applicable
H. Subject Retention Procedures

III. Site Staff Responsibilities

A. Communication Plan and Contact List
   1. Potentials
   2. Study Status
   3. Adverse events, unanticipated problems, protocol deviations

IV. Investigational Products, Devices and Specimens

A. Receipt, shipment and storage
B. Inventory, accountability and reconciliation
C. Handling Instructions / Transport

V. **Supplies and Equipment**

A. Storage and Calibration
B. Emergency Response Supplies and System

VI. Data Management (Collection, Data Entry, Good Documentation Practices)

1. Source Documents and Case Report Forms
   a. Study Data Storage and Archiving
2. Electronic Data Capture (EDC) / Remote Data Capture (RDE) / REDCap
   a. Location for Data Entry Area and/or EDC (RDC) entry
3. Electronic Medical Record Use and Access-Inpatient and Ambulatory
4. Regulatory maintenance of essential documents
5. Monitoring Plan, Internal QA & QA Plan

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VII. Facilities Discussion & Tour (as applicable**)**

B. Regional Sites / Study Locations
C. Patient Exam Rooms / Intake Areas
D. Monitoring Plan and Monitoring Area