## **I. Site Information**

|  |  |
| --- | --- |
| **Site Name:** |       |
| **ULACNet Protocol Number:** |       |
| **ULACNet Protocol Title:** |       |
| **Meeting Date:** | Enter a date.  |
| **Meeting Modality:** | Choose one. |
| **Meeting Conducted By:** |       |

## **II. Meeting Attendees:**

|  |  |  |
| --- | --- | --- |
| **Name** | **Affiliation** | **Role or Title** |
|       |       |       |
|       |       |       |
|       |       |       |
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|       |       |       |

## **III. Study Initiation Meeting Checklist**

**Completion Instructions for the LAO:** Mark each item below as: ***Yes***, item verified and/or discussed; ***No***, unable to verify and/or discuss item; or ***Not Applicable***. For any item marked ***No*** or ***Not Applicable***, please provide a comment. For items marked ***Yes***, please provide a comment whenever necessary or helpful.

### **ULACNet Overview**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. ULACNet General Overview
 | Choose one. |       |
| 1. Partnership Center Roles/Responsibilities
 | Choose one. |       |
| 1. Leidos Staff Roles/Responsibilities
 | Choose one. |       |
| 1. DCP Staff Roles/Responsibilities
 | Choose one. |       |
| 1. AQuIP Overview (including a description of pre-screening and screening)
 | Choose one. |       |

### **Review of Study**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Background and Purpose of Study
 | Choose one. |       |
| 1. Study Objectives, Endpoints, and Design
 | Choose one. |       |
| 1. Clinical and Laboratory Evaluations
 | Choose one. |       |
| 1. Schedule of Evaluations and Study Visit Windows
 | Choose one. |       |
| 1. Staff training
 | Choose one. |       |
| 1. Study equipment
 | Choose one. |       |

### **Enrollment**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Informed Consent Process
 | Choose one. |       |
| 1. Screening/Pre-Entry Period
 | Choose one. |       |
| 1. Eligibility Verification
 | Choose one. |       |
| 1. No Eligibility Exceptions/Waivers Allowed
 | Choose one. |       |
| 1. Registration/Randomization process
 | Choose one. |       |
| 1. Recruitment/Retention/Adherence
 | Choose one. |       |
| 1. Anticipated Start of Enrollment
 | Choose one. |       |

### **Pharmacy**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Study Drug Availability
 | Choose one. |       |
| 1. Study Drug Packaging and Labeling
 | Choose one. |       |
| 1. Study Drug Storage
 | Choose one. |       |
| 1. Study Drug Accountability
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Specimen Management**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Specimen Collection
 | Choose one. |       |
| 1. Specimen Labeling
 | Choose one. |       |
| 1. Specimen Processing and Shipping
 | Choose one. |       |
| 1. Specimen Storage and Disposition
 | Choose one. |       |
| 1. Specimen Tracking
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Resources**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. ULACNet Website
 | Choose one. |       |
| 1. ULACNet Related Documents
 | Choose one. |       |

### **Essential Clinical Trial Documents**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Study Binder
 | Choose one. |       |
| 1. Submission of Documents to LAO (DTL, In-country approvals, etc.)
 | Choose one. |       |

### **Data Collection**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Study Database/Case Report Forms
 | Choose one. |       |
| 1. Adverse Events/Serious Adverse Events
 | Choose one. |       |

### **Database Management**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Study Database of Record
 | Choose one. |       |
| 1. Data Management Procedures
 | Choose one. |       |
| 1. Data Queries and/or Discrepancy Management
 | Choose one. |       |
| 1. Data Queries for Source Data Verification
 | Choose one. |       |
| 1. Staff Roles and Responsibilities
 | Choose one. |       |

### **Reporting Requirements**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. SAE Reporting
 | Choose one. |       |
| 1. Protocol Deviations
 | Choose one. |       |

### **Record Keeping Requirements**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Original Signed Informed Consent Forms
 | Choose one. |       |
| 1. Study Files and Source Documentation
 | Choose one. |       |

### **Communication with the LAO**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
| 1. Emails/Conference Calls/Meetings
 | Choose one. |       |

### **Additional Study Information**

| **TOPICS** | **VERIFIED/DISCUSSED** | **COMMENTS** |
| --- | --- | --- |
|  | Choose one. |       |
|  | Choose one. |       |

## **IV. Action Items for Site**

**Completion Instructions for the LAO:** List visit findings in the *Action Item Status* tablebelow in order of severity and mark Status as ***Resolved*** or ***Site* *follow-up of action items required***. Sites should follow up on any item marked as ***Site* *follow-up of action items required*** and update the action item status in the table below. Provide a comment whenever necessary or helpful.

In the case where site follow-up of action items is required, the updated Study Initiation Meeting Report must be returned to the LAO Coordinator within 30 calendar days upon receipt of the final meeting report. The LAO documents the resolution of all action items prior to participant enrollment and forwards the updated Study Initiation Meeting Report to the AOs, DCP study representatives, and Leidos.

|  |  |  |
| --- | --- | --- |
| **Action Item(s)** | **Status** | **COMMENTS** |
| 1. |       | Choose one. |       |
| 2. |       | Choose one. |       |
| 3. |       | Choose one. |       |
| 4. |       | Choose one. |       |

**Completion Instructions for the LAO:** Select a response below to guide sites in updating the *Action Item Status* table.

\*Choose one.\*

**Report Prepared By:**

|  |  |  |
| --- | --- | --- |
| **Printed Name** | **Signature** | **Date** |
|       |       | Enter a date. |