

# Tool Summary Sheet: Division of Extramural Research (DER) Site Initiation Visit Agenda Template

**Purpose**: This template can be used as a starting point for planning an initiation visit meeting for NIDCR Extramural studies.

## Audience/User

Investigators and study team members of NIDCR Extramural studies, the NIDCR Program staff, NIDCR Grants Management staff, NIDCR’s Office of Clinical Trials Operations and Management (OCTOM) staff, and the Clinical Research Operations and Management Support (CROMS) team

## Details

Initiation visits occur prior to approval for activation for a specific protocol. These visits have several goals: to orient and train staff on the protocol and study related processes; to confirm readiness for study implementation; and to identify additional requirements that must be satisfied prior to activation and recruitment/enrollment.

This template provides a suggested list of items to be discussed during an initiation visit. Provided durations are estimates only.

## Best Practice Recommendations

* Define who is responsible for customizing the agenda, leading the meeting, and ensuring that all relevant parties are informed of the meeting date and time commitment well in advance. This will be done in collaboration with NIDCR, OCTOM, and/or CROMS.
* Customize the list of topics, order of presentation, and duration of each discussion item to the specific needs and requirements of the study. Sections marked with *{if applicable}* can be removed if they do not apply to the study. Include the name of each individual who will be the owner/presenter of each item.
* The order of agenda topics is a best practice recommendation. Irrespective of customization, it is recommended that protocol overview and Manual of Procedures (MOP) review remain together. It is also recommended that review of roles and responsibilities occur early in the meeting.
* The following pre-requisites should be completed prior to the initiation visit: protocol and consent have been submitted to any required scientific review committee, the DSMB/CSOC (if applicable), and the IRB; the case report forms and data collection system are near final; the MOP and/or Standard Operating Procedures (SOPs) are near-final; the Quality Management Plan (QMP), if required, is near final; the Data Management Plan (DMP), if required, is near final and all necessary site staff have been identified

## Technical/Formatting Notes

* In the template, the instructions and explanatory text are indicated by *{blue italics}* (CROMS\_Instruction style). Instructional text will also be enclosed in braces to signify this text for screen-readers used by the visually impaired.
* Delete template-specific *instructional text* as well as this Tool Summary Sheet and the Tool Revision History when customizing the agenda for the meeting.
* Text enclosed with <> is a placeholder for a specific detail (e.g., <protocol title>); replace as appropriate.

## Tool Revision History:

| **Version Number** | **Version Date** | **Summary of Revisions Made:** |
| --- | --- | --- |
| **1.0** | **26AUG2019** | First approved version |
| **2.0** | **28JUL2021** | Added NIDCR Grants Management to list of attendees in TSS.  |

# NIDCR Division of Extramural Research (DER)

# Site Initiation Visit Agenda

<Insert protocol title>

**Protocol Number:** <insert NIDCR protocol number>

**NIDCR Grant Number:** <insert grant number>

**Principal Investigator(s):** <insert Principal Investigator(s)>

<Insert Site Location>

**Meeting Date/Start Time:** <insert date/time of meeting Month, DD, YYYY XX:XX am – XX:XX pm>

## Attendees:

| **Affiliation** | **Name** | **Role or Title** |
| --- | --- | --- |
| <Study Team> |  |  |
| <Study Team> |  |  |
| <Study Team> |  |  |
| <NIDCR> |  |  |
| <NIDCR> |  |  |
| <CROMS> |  |  |
| <CROMS> |  |  |

*{This agenda assumes a 1-day visit of 7.25 working hours, not including lunch or breaks.}*

| **Topic** | **Presenter** | **Duration** |
| --- | --- | --- |
| 1. Welcome and Opening Comments
	1. Statement of visit objectives
	2. Review of agenda
 | Principal Investigator(s) | 15 min |
| 1. Introductions/Roles and Responsibilities
	1. Study Team
	2. NIDCR
	3. CROMS
	4. Communication Flow

{Consider using the Delegation of Responsibilities Log to guide some of the introductions. PI to verbally note any trainings already completed by study team and that GCP will be followed.} | All Attendees  | 15 min |
| 1. Protocol Overview
	1. Type of study
	2. Study objectives
	3. Enrollment goals
		1. Recruitment plans
	4. Informed consent discussion
	5. Key inclusion/exclusion criteria
	6. Study visit schedule/schedule of events
	7. Study procedures
		1. Randomization Process *{if applicable}*
 | Principal Investigator(s) | 60 min |
| 1. Manual of Procedures (or Discussion of SOPs and General Study Procedures, if no MOP exists)
	1. Review/participant “walk through” for each visit
	2. Discussion of necessary MOP updates
	3. Study supplies
 | Principal Investigator(s) and/or Study Team Representative | 45 min |
| 1. Safety: Definitions, Recording, and Reporting
	1. Adverse Events (AEs)
	2. Serious AEs (SAEs)
	3. Unanticipated Problems (UPs)
	4. Protocol Deviations
	5. Queries resulting from the above
 | Principal Investigator and/or Study Team Representative | 30 min |
| 1. Data Collection/Source Documentation
	1. Source Documents
		1. Definitions of CRF and Source
		2. Retention of records
		3. Access
	2. Training and Demonstration of Electronic Data Capture (EDC)
	3. Query process
	4. Randomization – mechanisms for blinding *{if applicable}*
 | Principal Investigator and/or Study Team Representative | 60 min |
| 1. Quality Management
	1. Quality Management Responsibilities
	2. Quality Management Processes and Frequency
 | Principal Investigator and/or Study Team Representative | 15 min |
| 1. Specimen Processing *{if applicable}*
	1. Collection
	2. Storage
	3. Shipping
	4. Training and Demonstration of Lab Tracking System *{if applicable}*
 | Principal Investigator and/or Study Team Representative | 15 min |
| 1. Investigational Product *{if applicable}*
	1. Description of product
	2. Review of Investigator Brochure (IB) or Package Insert *{if applicable}*
	3. Storage
	4. Dosing instructions
	5. Dispensing
	6. Documentation
	7. Accountability
	8. Return/destruction considerations
	9. Unblinding procedures *{if applicable}*

Randomization *{if applicable}* | Principal Investigator and/or Study Team Representative | 30 min |
| 1. Clinical Monitoring
2. Contacts
3. Responsibilities
4. Frequency and duration
5. Review of visit activities

Close out procedures | CROMS | 30 min |
| 1. NIDCR Expectations
2. Investigator responsibilities

Reporting to NIDCR  | NIDCR | 30 min |
| 1. Review of Action Items

Review of Activation Action Item Tracker | All Attendees | 30 min |
| 1. Investigator Site File Review

Structure of the Regulatory Binder as well as Essential Documents to include: *{update with applicable list of documents}*1. IRB-approval documents: protocol, patient handouts, advertisements, consent document
2. Document updates

*{This agenda item will include limited attendees and may be conducted prior to the start of this agenda if applicable parties are available.}* | Study Team/ CROMS CRA | 15 min |
| 1. Tour of Facilities and Review of Drug and Supplies

*{This agenda item will include limited attendees and may be conducted prior to the start of this agenda if applicable parties are available. This item is often scheduled adjacent to the lunch break. Note, the facilities tour should include a tour of the pharmacy and review of IP, if applicable.}* | Principal Investigator and/or Study Team Representative/CROMS CRA | 30 min |
| 1. Closing/Review of Action Items
 | All Attendees | 15 min |

Template Version 2.0– 2021-07-28