# Inspection Preparedness Standard Operating Procedure Template

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| Version: | 1.0 | | |
| Author(s): | ,  , | | |
| Approval: | **Approved By** |  | **Date** |
| [signature] | , Principal Investigator |  |  |
| [signature] | , |  |  |

[Sites may use the following language, some version of it, or use their own. Make sure you use your CRS Standard Operating Procedure (SOP) shell]

[This SOP may be modified to apply to all regulatory agencies (United States Food and Drug Administration [U.S. FDA], European Medicines Agency [EMA], and local Regulatory Agencies) that may conduct a regulatory inspection at the CRS to assess compliance with applicable regulatory agency, Division of AIDS (DAIDS), Institutional Review Board [IRB]/Ethics Committee [EC], International Council for Harmonisation (ICH) Good Clinical Practices (GCP) requirements, and site SOPs for conducting clinical trials. This SOP may also be adapted to any CRS study and is not necessarily limited to DAIDS CRSs.]

## 1.0 PURPOSE:

The purpose of this SOP is to outline the various roles and responsibilities, activities, and procedures that should be undertaken at [insert site name] from the time the inspection is announced, during the inspection, and beyond, until all related follow-up activities have been completed.

## SCOPE:

This SOP applies to all CRS staff and describes the procedures to prepare for a regulatory inspection of any applicable clinical trial conducted at [insert site name].

## 3.0 DEFINITIONS:

[Include a list of terms and acronyms that are helpful for the proper understanding of the SOP. Add items to this list as appropriate. Consider country, state, local, or institutional terms and acronyms that may be specific to your site. Some examples include:]

*Bioresearch Monitoring (BIMO) Program: The United States (U.S.) FDA program designed to monitor all aspects of the study and reporting of U.S. FDA-regulated research by conducting on-site inspections and data audits.*

*Establishment Inspection Report (EIR): The report written by the U.S. FDA inspector that describes the observational findings of the inspection and what actions should be taken regarding those findings.*

*EMA Inspection Grading of Findings:*

* ***MI (Minor):*** *The inspector(s) identified conditions, practices, or processes that would not be expected to adversely affect the rights, safety, or well-being of the participants and/or the quality and integrity of data.*

*Numerous minor observations might indicate poor quality data and the sum might be considered equivalent to a major finding.*

* ***MA (Major):*** *The inspector(s) identified conditions, practices, or processes that might adversely affect the rights, safety, or well-being of the participants and/or the quality and integrity of data. Major observations are serious deficiencies and are direct violations of ICH E6 principles.*

*Observations classified as major may include a pattern of deviations and/or numerous minor observations.*

* ***CR (Critical):*** *The inspector(s) identified conditions, practices, or processes adversely affecting the rights, safety, or well-being of the participants and/or the quality and integrity of data. Critical observations may include a pattern of deviations classified as: major, poor quality of the data, and/or absence of source documents. Manipulation and intentional misrepresentation of the data would be classified as critical.*

*Form FDA 482 – Notice of Inspection: The U.S. FDA written notice of inspection presented by the U.S. FDA inspector at the beginning of the inspection.*

*Form FDA 483 – Inspectional Observations: A summary report of inspectional observations. It is a list of objectionable conditions or practices observed during the inspection, prepared by the FDA inspector and presented to the Principal Investigator (PI)/Investigator of Record (IoR) at the conclusion of an inspection.*

*U.S. FDA Inspection: The act by a regulatory authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority to be related to the clinical trial and that may be located at the site of the trial, at the sponsor’s and/or Contract Research Organization facilities, or at other establishments deemed appropriate by the regulatory authority (**ICH E6 1.29).*

*U.S. FDA EIR Report Classifications:*

* *NAI (No Action Indicated): No objectionable conditions or practices were found during the inspection or the significance of the documented objectionable conditions found does not justify further U.S. FDA action.*
* *VAI (Voluntary Action Indicated): Objectionable conditions were found and documented, but the conditions do not meet the threshold for regulatory action.*
* *OAI (Official Action Indicated): Objectionable conditions were found, and a regulatory action is recommended.*

*U.S. FDA Warning Letter: The U.S. FDA may issue a warning letter if objectionable conditions were found, such as regulatory violation(s) uncovered during the inspection that were repeated or deliberate and/or involve submission of false information to the U.S. FDA or to the sponsor. If the regulatory violation(s) uncovered are significant/serious and/or numerous in scope, severity, or pattern of violation(s), a Warning Letter may be considered when the violations can be corrected through specific action(s) by the investigator (e.g., preparation of and compliance with a detailed corrective action plan that is acceptable to the U.S. FDA) and adherence to the corrective action plan has a high probability of preventing similar or other violations from occurring in the future.*

## 4.0 Roles And Responsibilities - Staff

[Identify the staff who will participate in the regulatory inspection. Clearly specify the roles assigned to each staff member identified as they relate to this SOP, and ensure training is documented. Please note the following:

* The PI/IoR should consider each staff member qualifications and the protocol-specific duties they have been delegated when assigning responsibilities outlined in this SOP.
* Job titles/roles should be used in this SOP instead of specific staff members’ names to limit revisions due to staff turnover.
* Staff training on this SOP should be documented.]

## 5.0 PROCEDURES

[Describe the specific actions to be completed before, during, and after a regulatory inspection. Use simple language and be clear and concise. Refer to appendices (checklists, tools, logs) throughout each subsection as needed.]

**BEFORE THE INSPECTION**

### 5.1 Initial Contact with the Regulatory Agency:

[Describe the ways in which the PI/IoR is notified of an inspection, such as the following:

* Email from DAIDS
* Call from regulatory agency (specify how the PI/IoR will ensure that relevant information listed below is obtained from the regulatory agency in the event that site inspection notification is made via a telephone call)
  + Letter from regulatory agency

Specify the information that may be relayed in the communication, such as the following:

* + Proposed dates for the inspection
  + Duration of the inspection
  + Protocol to be inspected
  + Dataset being inspected (cohort, etc.)
  + Items that the inspector would like to review (such as source documentation, the informed consent process, etc.)
  + Name of the inspector(s)]

### 5.2 Notifying Relevant Parties:

[Describe the process for notifying relevant entities of the site inspection as follows:

* List all parties that should be informed of the inspection (PI/IoR, all site staff, IRB/Ethics Committee [EC], the DAIDS Office of Clinical Site Oversight [OCSO] Program Officer [PO]).
* Specify by title the person responsible for disseminating inspection notifications, and detail how the relevant entities will be informed and how this will be documented. For example, immediately upon receipt, the PI/IoR will send an email to the OCSO PO sharing the regulatory agency letter that the site will be inspected.]

### 5.3 Organizing Site Preparation Activities:

[Describe the process for organizing site staff to prepare for the inspection visit and consider the following:

* The PI/IoR is ultimately responsible for overall site inspection preparation and all inspection activities conducted by the site.
* Which staff are to be trained on this SOP so that they may familiarize themselves with roles and responsibilities.
* Is the oversight of all inspection activities assigned to one person (e.g., PI/IoR)?
* Will pre-inspection meeting(s) be conducted to prepare staff?
* Staff assigned to their respective areas will be responsible for addressing inspection questions.
* A main point of contact is needed at the site for the inspection.
* A scribe should be assigned to take notes during meetings with the inspector, and to log documents requested to be copied by the inspector.]

### 5.4 Organize and Prepare Documents:

[Describe the process for organizing and preparing relevant documents before the inspection visit, including the following:

* Create a list of relevant documents that need to be organized before the inspection.
* Specify by title who will be responsible for organizing and reviewing the documents for each area of the CRS (clinic, pharmacy, laboratory).
* Describe the process and required timeframes for obtaining records from other departments (e.g., medical records) prior to the inspection, if applicable.
* Specify the process for obtaining missing documents and expected processing time for requests (e.g., requesting regulatory documents from the IRB/EC).]

### 5.5 Prepare Site/Site Staff:

[Describe the process for collective preparation of site/site staff for the inspection as follows:

* Include review of clinic schedules to ensure staff availability during the inspection.
* Include details for rescheduling nonessential participant visits/meetings that would have been during the proposed inspection days/times.
* Consider facilitating role-playing and/or mock inspection activities, so staff can practice how to communicate with the inspector and be at ease during the inspection.
* Consider including daily preparation meetings for the anticipated inspection.
* Consider storyboarding with relevant staff any issues that have occurred during the conduct of the study, which may require explanation of root cause, and also corrective and preventive actions implemented by the site to resolve the issue.
* Review “*Tips for Inspector Interviews with Staff*” in the *Guidance on Site Regulatory Inspection* appendix to this section.]

### 5.6 Secure a Workspace for Inspector(s)

[Detail the procedures and staff responsible for securing a suitable workspace for the inspector(s), as follows:

* Specify that the workspace is private, away from crowded/noisy areas of the clinic where activities relating to other studies may still be taking place.
* Specify that the workspace includes space for staff supervision without the appearance of crowding or “hovering.”
* Ensure that the workspace does not afford access to other clinical trial documents or to a photocopier.]

**DURING THE INSPECTION**

[Add any specific instructions for CRS staff that need to be followed during the inspection. For example, that:

* CRS staff are to arrive at the site 30 minutes prior to the inspector’s planned arrival time.
* CRS staff are to create a sign-in log for each day of the inspection, as per institutional policy.]

### 5.7 Greeting the Regulatory Inspector:

[Describe the process for greeting the inspector, including:

* Who (by title) is to greet the inspector.
* How the inspector’s credentials are to be verified by staff asking for their badge/identification, and, when applicable, provide the proper inspection notification form.
* That the inspector is to sign a log as per institutional policy.]

### 5.8 Initial Meeting:

[Outline the details of the initial meeting with the inspector, including:

* Who (by title) will attend the meeting.
* The location of the meeting.
* Whether or not the inspector will hold daily debriefings.]

### 5.9 Escorting the Inspector While on Site:

[Describe the fact that a CRS tour will be conducted as per the inspector’s request. Also describe that the inspector will be escorted to their designated workspace and by whom, and that the workspace will be monitored throughout the duration of the inspection to ensure that it continues to meet the criteria outlined in Section 5.6, as follows:

* Who (by title) will lead the tour.
* What areas of the CRS will be visited, e.g., the rooms in which the study was conducted.]

**Note:** A regulatory inspection is not for showcasing all the research or care activities that the site participates in or contributes to.

### 5.10 Document Requests:

[Describe the process for retrieving documents requested by the inspector, as follows:

* The person (by title) that will retrieve the documents and the person (by title) that will photocopy documents for the inspector.
* That duplicate copies are to be made for all copy requests (one for site, one for inspector).
* That copies made are to be documented on the Log of Copied Documents.
* That site copies of documents should be stored in a secure area, and in the order in which they were requested.
* That DAIDS will be notified of copies requested.
* That copies of some documents may contain sensitive information, and as such should be provided after consultation with DAIDS.
* That potential unblinding should be considered when providing pharmacy-specific documents. The site must have a process in place when sharing/copying documents to avoid unblinding when applicable.
* That the inspector(s) may request access to certain databases/electronic systems used at the CRS. The CRS staff must describe the process of requesting and providing access to the inspector.
* That if a read-only access to the database/electronic system cannot be provided to the inspector, CRS staff must access the database/electronic system with their credentials and password in a confidential manner and then show the requested data to the inspector. No CRS staff credentials and/or passwords must ever be shared.]

### 5.11 Closing Meeting/Exit Interview:

[Describe the process for closing the inspection visit and conducting the exit interview, including:

* Who (by title) will participate in the closing meeting/exit interview.
* Who (by title) will speak on behalf of the site staff during this meeting.

Describe the process for reviewing with the inspector any findings, including:

* Who (by title) will speak on behalf of the site during this review.
* Who (by title) will request from the inspector the regulations related to identified issues.
* Who (by title) will take notes of the meeting.
* What will be the turnaround time for responses to any findings and timeline for deliverables.]

**AFTER THE INSPECTION**

### 5.12 Regulatory Inspection Report

[Describe the process for responding to regulatory report findings, as follows:

* The regulatory inspection report should be shared with the OCSO PO.
* OCSO PO will work with the site to prepare a response to the findings.
* The person (by title) who will be responsible at the site for writing the response.]

## 6.0 APPENDICES:

[List forms, templates, examples, or samples referenced in the body of this SOP.]

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|  | 1.0 | (DD-MMM-YYYY) | First Approval |
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