# NIAMS Clinical Monitoring and Data Management Plan (CMP/DMP) Checklist

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## Introduction

This checklist is a tool developed by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) to assist applicants and investigators in the development and writing of a Clinical Monitoring and Data Management Plan (CMP/DMP) as described in the [NIAMS Clinical Trial Implementation Cooperative Agreement (U01 Clinical Trial Required)](https://grants.nih.gov/grants/guide/pa-files/PAR-21-036.html) and the [NIAMS Exploratory Clinical Trial Grants in Arthritis and Musculoskeletal and Skin Diseases (R21 Clinical Trial Required)](https://grants.nih.gov/grants/guide/pa-files/PAR-21-045.html) Funding Opportunity Announcements (FOAs). The use of the checklist will ensure the applicant/investigator has considered all required aspects of the plan. **The checklist does not require submission as part of the clinical trial application and is intended for the applicant/investigator to use in developing the CMP/DMP. The use of this checklist is optional.**

The following requirements are taken from the FOAs and must be addressed in the submitted CMP/DMP attachments as part of the clinical trial grant applications.

### Requirements:

**Clinical Monitoring Plan:** The purpose of the CMP is to verify that the clinical trial is being conducted, and documented in accordance with the Protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s):

* Describe the persons/entity responsible for conducting the clinical monitoring (e.g., contracted Clinical Research Associate, Data Coordinating Center, Independent study monitor from the Clinical Coordinating Center)
* Describe the frequency of planned monitoring activities (e.g., Study Initiation, Interim Visits, Study Close Out), locations where the monitoring will occur (e.g., participating clinical sites, data center, clinical coordinating center) and what data will be reviewed
* Provide an overall description of the monitoring plan to ensure adherence to the protocol, adequate documentation of the consenting process, and the quality and consistency of the study intervention(s), including fidelity monitoring for behavioral interventions. Include methods to monitor study data collected and systems to record and manage exceptions and deviations. If applicable, describe monitoring of participating facilities, such as labs or pharmacies for adequate handling and storage of investigational product(s) and study specimens. Include a description to assure that the investigational product(s) accountability and reconciliation are performed adequately during and at the end of the trial per applicable regulatory requirements
* Describe plans for handling any deficiencies that are uncovered and in cases of serious deficiencies the appropriate reporting to relevant authorities, including but not limited to the Institutional Review Board (IRB) of record, Data and Safety Monitoring Board if one is assigned, Food and Drug Administration (FDA) if applicable, institutional officials and the National Institutes of Health (NIH).

**Data Management Plan:** The purpose of the Data Management Plan is to ensure that validated systems and controls are in place to assure the integrity of the clinical research data being collected for the proposed study:

* Describe methods and systems for data collection (e.g., Case Report Forms (CRFs)), data entry, data verification and data validation. Describe the data query process and frequencies and any planned mitigation strategies in the event of noncompliance
* Describe methods and systems to ensure data confidentiality and subject privacy
* Describe process for locking the final trial datasets and the planned procedures on data access and sharing, as appropriate.

### How to use this checklist

* Complete the checklist sections and fields as the CMP/DMP is developed. This is intended to guide the development of the document and ensure the study team has thought through developing and implementing these processes.
* If the required section is included, mark an X in the Yes column.
* If the required section is not included, mark an X in the No column. Use the comment section to note what is missing or needed to complete the section.
* If a section is not applicable, mark an X in the NA column.
* The comment box may be used to provide clarification or notetaking for the team developing the CMP/DMP.
* The checklist is intended to be a tool for internal use only and does not require submission with the completed CMP/DMP document as part of the clinical trial application.

### Checklist items:

#### A. Clinical Monitoring Plan (CMP)

##### 1.0 Introduction

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the purpose of the CMP described (i.e., to verify that the clinical trial is being conducted and documented in accordance with the protocol, Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), and the applicable regulatory requirement(s))? |  |  |  |  |
| Is an overall description of the CMP provided to ensure adherence to the protocol, adequate documentation of the consenting process, and the quality and consistency of the study intervention(s), including fidelity monitoring for behavioral interventions? |  |  |  |  |
| Are all stakeholders reflected in the plan (e.g., investigators, NIAMS, etc.)? What is their role in the CMP? |  |  |  |  |
| Are the persons/entity responsible for conducting the clinical monitoring (e.g., contracted Clinical Research Associate, Data Coordinating Center, independent study monitors from the Clinical Coordinating Center, etc.) described? Is their role clearly delineated? |  |  |  |  |
| Is it specified how a monitor’s initial training on the study will be conducted, and by whom? |  |  |  |  |
| Is it indicated whether ongoing training for monitors will be conducted (and if so, how often and by whom)? |  |  |  |  |
| Is it noted where documentation of the training will be maintained? |  |  |  |  |

##### 2.0 Communication

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the process/method for distributing monitoring communication to relevant stakeholders described (e.g., via email)? |  |  |  |  |
| Is it indicated who is responsible for sending out monitoring communication, and to whom this is sent? |  |  |  |  |
| Is the type of information to be included in monitoring communication described (e.g., site visit confirmation letters, agendas, follow-up letters, action item trackers, etc.)? |  |  |  |  |

##### 3.0 Essential Documents

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the types of required essential documents listed? |  |  |  |  |
| Is it specified if the sites are maintaining paper files, electronic files, or a combination of both? |  |  |  |  |
| Is the process for review, collection, and submission of required essential documents and reconciliation with the study’s Trial Master File (TMF) as it relates to monitoring described? |  |  |  |  |
| Is the owner of the study’s TMF identified? |  |  |  |  |
| Is the entity designated to maintain the TMF during the course of the study identified? |  |  |  |  |

##### 4.0 Types of Monitoring Visits

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the types of monitoring visits (i.e., Site Initiation Visits (SIVs), Interim Monitoring Visits (IMVs), for-cause visits, and close-out visits) to be conducted during the study and the purpose of each type of visit described? |  |  |  |  |
| Are the attendees of the monitoring visits listed for each type of monitoring visit? |  |  |  |  |
| Are the locations where the monitoring will occur described (e.g., participating clinical sites, Data Coordinating Center, Clinical Coordinating Center)? |  |  |  |  |
| If applicable, is monitoring of participating facilities described, such as labs or pharmacies, for adequate handling and storage of investigational product(s) and study specimens? |  |  |  |  |
| If applicable, is a description included to assure that the investigational product(s) accountability and reconciliation are performed adequately during and at the end of the trial per applicable regulatory requirements? |  |  |  |  |

##### 4.1 Monitoring Visit Schedule

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the process described for scheduling monitoring visits and expectations for the site study team during the visits? |  |  |  |  |
| Is the frequency of planned monitoring activities (e.g., SIVs, IMVs, study close-out, etc.) described? |  |  |  |  |
| Is the expectation of the site and monitor with respect to the timeline for visit scheduling requests described? |  |  |  |  |

##### 4.2 Site Initiation Visit Activities

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the activities conducted during SIV visits described, which may include (but are not limited to) the following?* Review of investigator and site personnel responsibilities
* Review of facilities
* Protocol review
* Review of informed consent process
* Review of Manual of Operating Procedures (MOP)/SOPs
* Study documentation review
* Review of investigator site file and delegation of authority log
* Electronic case report form review and laboratory tracking training
* Review of safety reporting
* Review of source documentation requirements
* Review of laboratory supplies and procedures
* Discussion of site-level quality management activities
* Discussion of general items
 |  |  |  |  |

##### 4.3 Interim Monitoring Visit Activities

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the activities conducted during IMVs described, which may include (but are not limited to) the following?* Consent document review
* Source documentation and case report form review
* Review of unanticipated problems, adverse events, and serious adverse events
* Investigational product review
* Review of laboratory and specimen management
* Protocol deviation review
* Review of quality management documentation
* Review of investigator site file and delegation of authority log
* Review of investigator and site personnel responsibilities
* Discussion of action plan for identified issues
 |  |  |  |  |
| Are the factors that should be taken into consideration when determining the amount of source document verification per participant, frequency of monitoring, and timing of first IMV described?Are the following considerations included?* Complexity of the protocol
* Target enrollment
* Number of participant visits
* Data collected at each visit
 |  |  |  |  |
| Is the type of data that will be reviewed described? |  |  |  |  |
| Are methods included to monitor study data collected, and systems described to record and manage exceptions and deviations? |  |  |  |  |

##### 4.4 For-Cause Visit Activities

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the activities that may be conducted during for-cause visits described, which may include (but are not limited to) the following?* Completing any of the activities listed for an IMV
* Discussing clinical operations and study management methods with the study team
* Providing training to the study team
 |  |  |  |  |

##### 4.5 Close-Out Visit Activities

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the study closure activities conducted during close-out visits described, which may include (but are not limited to) the following?* Consent document review
* Review of investigator site file and delegation of authority log
* Source documentation and case report form review
* Review of unanticipated problems, adverse events, and serious adverse events
* Investigational product review
* Review of laboratory and specimen management
* Review of regulatory obligations
* Review of records retention
* Discussion of action plan for identified findings
 |  |  |  |  |
| Is the method for conducting close-out visits indicated (e.g., series of on-site visits, visits by tele/web-conference, etc.)? |  |  |  |  |
| Is the timeframe for close-out visits indicated (e.g., at study completion or earlier in the case of study termination)? |  |  |  |  |
| Is it noted that the outcome of the visit and other close-out activities will be documented in a final report? |  |  |  |  |

##### 5.0 Monitoring Reports/Action Items

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the following information regarding the visit reports specified?* What the reports will entail (e.g., monitoring visit findings, resulting action items, etc.)?
* Who is responsible for drafting the reports?
* Which stakeholders are responsible for reviewing the draft report, and which stakeholders will receive the final version?
* The timeline for draft report distribution (i.e., number of calendar days from the last day of the monitoring visit)?
* Where the final version of the reports will be stored?
 |  |  |  |  |
| Is the process described for dissemination of site visit reports? |  |  |  |  |
| Is it specified who will be responsible for working with designated site study team members to resolve any outstanding items communicated in the monitoring report? |  |  |  |  |
| Are plans described for handling any deficiencies that are uncovered, and in cases of serious deficiencies, the appropriate reporting to relevant authorities, including but not limited to the Institutional Review Board (IRB) of record, Data and Safety Monitoring Board (if one is assigned), FDA if applicable, institutional officials, and the National Institutes of Health (NIH)? |  |  |  |  |
| Is there a timeline for reporting deficiencies in place?  |  |  |  |  |

#### Administrative

##### CMP Implementation and Updates

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is it indicated who prepared the CMP? |  |  |  |  |
| Is the point-of contact identified for questions related to the implementation of the CMP? |  |  |  |  |
| Is the frequency indicated for how often the CMP will be reviewed and updated as needed? |  |  |  |  |

##### Study Website (If Applicable)

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the website address, website maintenance, and available information provided? |  |  |  |  |
| Is the study webpage password protected and restricted to certain individuals? If so, who can access it? |  |  |  |  |

#### B. Data Management Plan (DMP)

##### 1.0 Methods and Systems for Data Collection

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is the electronic data capture (EDC) system proposed for use on the study described, including its name, version number, or other identifying information, such as if it is a commercial off-the-shelf software or a new developed in-house software? |  |  |  |  |
| If applicable, are any ancillary software or additional system functionalities besides data capture (e.g., ad-hoc report generation, data verification, randomization, etc.) identified? |  |  |  |  |
| Is the EDC system validation status with respect to Title 21, Code of Federal Regulations provided? More generally, are the system’s primary information security, disaster mitigation (backup and recovery), traceability, audit trail, and electronic signature features described? |  |  |  |  |
| Are there descriptions of how EDC system access will be granted and controlled (e.g., user training, user ID and password requirements, user account management, etc.)? |  |  |  |  |
| Are any existing user role-based EDC privileges specified? Is there an assurance that the system access will be limited to only authorized individuals based on their roles and functions? |  |  |  |  |
| Are there descriptions on how changes to the system will be done in a controlled manner using a change control process with accompanying detailed documentation? |  |  |  |  |
| If applicable, is it indicated if there will be any electronic data files generated outside the EDC system as well as how they will be integrated with the EDC system (e.g., clinical laboratory or pharmacokinetic data generated at offsite facilities or the central lab)? Are there details on how often such transfers will take place and in what electronic format? |  |  |  |  |
| Are there details on what security procedures will be implemented to protect against malware in the data files? |  |  |  |  |
| Is it indicated whether the data are integrated directly into the database, stored on a network share drive for later processing, or some combination of the two? |  |  |  |  |

##### 2.0 Data Entry, Validation, and Verification

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are the data source and the method by which data will be collected in the study specified (e.g., entered directly online, entered from paper-based case report forms (CRFs)/electronic medical record (EMR) into electronic database, or a combination of both)? |  |  |  |  |
| Are the entities responsible for data entry identified? |  |  |  |  |
| Are there descriptions included of the data validation and quality control processes to be employed, which may include (but are not limited to) the following?* Built-in procedures of the EDC system such as automated checks, system, or email notifications of pending overdue visit data entry
* Queries manually issued by Study Coordinators, Clinical Research Associates, and Data Managers to ensure all required data fields are completed, data are being entered within the expected range and format, data are consistent, etc.
 |  |  |  |  |
| Is there a description included of the query management process, which may include (but is not limited to) the following?* Identified reports and listings (by title) that will be generated to assist with data quality control and site performance monitoring
* Specific frequency that the reports and listings will be run and the entities that will use them
* Timelines (within x days) for data entry, query resolution, and related communication plan in the event of noncompliance
 |  |  |  |  |

##### 3.0 Methods and Systems to Ensure Data Confidentiality and Subject Privacy

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Is there assurance provided that the EDC system in use is compliant with privacy and security standards (e.g., protected health information/personal identifying information encryption, data de-identification in the EDC system, etc.)? |  |  |  |  |
| Are all other measures to protect confidentiality and privacy described, such as use of participant identifiers in written communication, secure storage of paper and electronic files, relevant internal SOPs, and staff training on regulations pertaining to privacy and confidentiality? |  |  |  |  |

##### 4.0 Final Trial Dataset Lock, Data Archiving, and Data Access and Sharing

| **Brief description** | **Yes** | **No**  | **NA** | **Comment** |
| --- | --- | --- | --- | --- |
| Are there descriptions included of the processes associated with final database closure, including final pre-closure data checks, quality assurance (QA) review, and actual database lock and procedures for unlocking a database in the event that data must be corrected? |  |  |  |  |
| Are electronic datasets, programs, and documents to be maintained in archive status after study completion identified?  |  |  |  |  |
| Is the scope, format, and process described for delivery of final electronic data to other entities if the data are not to be retained solely within the study EDC? |  |  |  |  |
| Are the planned procedures on data access and sharing described, as appropriate? |  |  |  |  |