**NIMH Clinical Research Education Support and Training (CREST)**

**Comprehensive Visit Report Template**

**Tool Summary** (*Remove Tool Summary before finalizing and distributing the document)*

***Purpose:*** *This template provides a recommended structure for a CREST site visit report as well as a sample matrix of regulatory criteria that CREST monitors look at while at site initiation visits (SIVs), interim monitoring visits (IMVs) and close out visits (COVs). It is to be used as a starting point for preparing for a CREST site visit or for writing a site visit report.*

***Audience/User:*** *Clinical Research Associates (CRAs) or Principal Investigators (PI) responsible for preparing for a CREST site visit.*

***How to Use This Template***

*This template contains two types of text: instruction/explanatory and example text.* ***Instruction/ explanatory text*** *are indicated by italics and should deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.* ***Example text*** *is included to further aid in document development and should either be modified to suit the drug, biologic or device (study intervention), design, and conduct of the planned clinical trial or deleted. Example text is indicated in [brackets with regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.*

***Version control*** *is important to track document development, revisions, and amendments. It is also necessary to ensure that the correct version of this document is used by all staff conducting the study. With each revision, the version number and date located in the header of each page should be updated*

|  |  |  |  |
| --- | --- | --- | --- |
| Protocol Title and Grant Number: |  | Date of Monitoring Visit: |  |
| Study Monitor(s): | <Name>Clinical Research Monitor Office of Clinical Research [OCR]NIMH Clinical Trials Operations and Biostatistics Branch (CTOBB) | Monitoring Visit Type: | <Visit Type> |
| Study Site Name & Location: |  | Principal Investigator(s): |  |

# Clinical Site Personnel Present <at GCP presentation/ at the Visit >:

|  |  |
| --- | --- |
| **Name:** | **Study Role:** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

1. **<Visit Summary / Visit type Overview>**

*Summary of on-site activities; any additional meetings (e.g. met with pharmacist); general statement about the visit findings*

1. **<Recruitment Summary>**

*Not included in SIV*

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Group**  | **Goal**  | **Consented** | **Screen Fail** | **In Screening**  | **Enrolled** | **Active**  | **Lost to Follow-up** | **Completed** |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |
| **Total** |  |  |  |  |  |  |  |  |

1. **Action Items**

While the NIMH Monitor recommends implementing all suggestions in this report, the following action items require clarification. Please address the following with the NIMH Program Officer within 30 calendar days of this report date or advise if additional time is needed.

**SIGNATURE PAGE**

 <Date>

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

VISIT CONDUCTED BY: Date

<Name>

Clinical Research Monitor

<Email>

Clinical Research, Education, Support, and Training (CREST) Program

NIMHCTOBB\_CREST@nih.gov

National Institutes of Health (NIH)

National Institute of Mental Health (NIMH)

Office of Clinical Research (OCR)

Clinical Trials Operations and Biostatistics Branch (CTOBB)

6001 Executive Blvd, Rm <Number>

Bethesda, MD 20892-9649

**APPENDIX**

**<Site Initiation Visit:>**

1. **Review of Protocol and GCP Expectations with Study Staff**

***Add and delete topics as applicable***

| **ITEMS DISCUSSED** | **COMMENTS** |
| --- | --- |
| Implementing ICH GCP guidelines |  |
| Study Objectives and Design |  |
| Changes made to the study post-award |  |
| Inclusion/exclusion criteria determination and documentation |  |
| Conducting informed consent process according to regulatory and IRB requirements (including capacity to consent). |  |
| Process and documentation for subject randomization |  |
| Process for interim analyses/unblinding to ensure completion rates are similar for each randomized group (if applicable) |  |
| [Investigational Product (IP) accountability process and documentation] |  |
| [For drug studies, clarify who will be performing drug accountability prior to drug destruction (e.g. study team, pharmacy, NIMH Monitor?)] |  |
| Subject confidentiality safeguards (e.g. de-identifying data and specimens) |  |
| Secure storage of subject data |  |
| Recording/ reporting Protocol Deviations and Unanticipated Problems |  |
| Confounding Factors |  |
| Safety Reporting Process and Documentation |  |
| Safety Oversight, Independent DSMB (if applicable) |  |
| Study Endpoints, stopping rules, and documenting final subject status |  |
| Process for reporting subjects in the NIMH Recruitment Milestone Reporting System (RMR) |  |
| Target Start date of Enrollment |  |
| Target monthly accrual rate |  |
| Target End Date of Enrollment |  |

1. **Regulatory Documents, Study Oversight, and Site Operations Review**

| Review Category | Criteria | Yes | No / Deficient | N/A |
| --- | --- | --- | --- | --- |
| Regulatory Oversight Documents & Processes | A current IRB-approved copy of the protocol is on file. |  |  |  |
| All previous versions of the protocol are on file. |  |  |  |
| A current and IRB-approved copy of the informed consent form (ICF) is on file. |  |  |  |
| The initial IRB approvals for the protocol and the ICF are present. |  |  |  |
| Continuing review approval(s) are present (annually). |  |  |  |
| IRB approvals for information given to study subjects are on file (i.e. advertisements, recruitment scripts, subject information materials). |  |  |  |
| Approvals for any protocol/consent/assent amendments are present. |  |  |  |
| IRB approval letters specify which version of the protocol and/or ICF was approved. |  |  |  |
| The IRB Roster or Membership composition is on file and has been updated annually. *If the IRB does not provide a roster, official IRB documentation is present stating that names are not released.* |  |  |  |
| [FDA Form 1572 or Investigator of Record Agreement (IoRA) is on file.] |  |  |  |
| Current Federal Wide Assurance is present and includes expiration dates. |  |  |  |
| [All local, state, and/or special authorizations related to the protocol are maintained and up-to-date (if applicable).] |  |  |  |
| FDA IND/IDE submission and correspondence are on file (if applicable). |  |  |  |
| DSMB protocol/ICF approval letter is on file (if applicable). |  |  |  |
| Comments |  |  |  |  |
| [Investigational Product (IP)] | [Investigator brochures are current and available for investigational products. Documentation of IRB submission is present (if applicable). ] |  |  |  |
| [Package inserts are available for approved drugs. Documentation of IRB submission is present (if applicable).] |  |  |  |
| [An IP prescription template is on file and includes all fields required by state and institutional regulations (e.g. subject’s address, prescriber name, pharmacy address, etc.)] |  |  |  |
| [A sample of the label that will be affixed to each IP container at the time of dispensation is available. The label is in compliance with applicable labelling regulations and contains appropriate instructions for subject dosage and storage (if taken home by subjects).] |  |  |  |
| [IP shipping records are on file documenting the receipt date, quantity, and lot numbers of all test articles (in pharmacy if PI is blinded).] |  |  |  |
| [IP inventory matches the quantity received per the shipping records and the master drug accountability log.]  |  |  |  |
| [Certificate of analysis for IP shipped is available to document identity, purity, and strength of IP.] |  |  |  |
| [Drug destruction policy is on file.]  |  |  |  |
| [SOP for emergency unblinding is on file or contained in the MOP. A back-up contact is provided in case the primary person performing emergency unblinding is unavailable. ] |  |  |  |
| [Comments] |  |  |  |  |
| Study Staff Qualifications | [The staff ordering and dispensing IP are qualified to do so per state, federal, and institutional regulations.] |  |  |  |
| Current signed and dated CVs/biosketches are present for the Principal Investigator and staff listed on the Delegation of Authority Log. |  |  |  |
| Appropriate licenses are present and current for Principal Investigator and all sub-investigators listed on the Delegation of Authority Log. |  |  |  |
| Financial disclosure forms and/or conflict of interest forms for all key personnel are on file (per institutional policy). |  |  |  |
| Documentation of Human Subjects Protection Training for all relevant personnel is present and complete *(note: this is different from GCP training).* |  |  |  |
| Documentation of GCP training for all relevant personnel is present and complete per NIH and IRB policies. |  |  |  |
| Documentation of OSHA/IATA training is present for individuals shipping specimens (if applicable). |  |  |  |
| Documentation of study-specific training for all relevant personnel is present and complete. |  |  |  |
| Study Operations/ Facilities Oversight | A current copy of the Manual of Operations (MoP) is on file. *This document is not meant to be duplicative of the protocol. It explains how each site will operationalize the protocol.* |  |  |  |
| Documentation of internal correspondence is present and current (e.g. weekly study meeting minutes). |  |  |  |
| Documentation of external correspondence is present and current (e.g. important communications with NIMH PO, DSMB, FDA, CTOBB Site Monitor, collaborating sites, etc.). |  |  |  |
| Study facilities are appropriate for the conduct of the study.  |  |  |  |
| Study supply inventory is adequate and not expired (e.g. blood collection tubes, urine toxicology kits, urine pregnancy kits, any food given to subjects, etc.). |  |  |  |
| Laboratory certifications and accreditations are present for U.S. labs (CAP and CLIA Accreditation, JCAHO, CLIA Compliance, CLIA exempt, etc.) (as applicable). |  |  |  |
| Current and historical Normal Ranges for all protocol-required tests are present (as applicable). This must include all clinical laboratory tests required by the protocol, the unit of measure, the laboratory name, and the date of the document. |  |  |  |
| Comments |  |  |  |  |
| Study Logs and Forms | The Delegation of Authority Log is present and accurate. |  |  |  |
| A subject screening log template is present and accurate. |  |  |  |
| A subject enrollment log template is present and accurate, reflecting the chronological order of subjects who meet eligibility criteria/are enrolled. |  |  |  |
| A confidential subject identification code template is present, which will link subject numbers to subject names/contact info. |  |  |  |
| A template for a subject-specific and study-wide (can be compiled electronically) Protocol Violations and Deviations Log is available. |  |  |  |
| A subject-specific and study-wide (can be compiled electronically) AE/SAE log template is available. |  |  |  |
| A template log of retained body fluids/tissues to document location and identification of retained samples if assays need to be repeated is available. |  |  |  |
| Randomization procedures are acceptable. A master randomization list is on file to show how subjects will be randomized. The list yields the required number of subjects for each randomization group.  |  |  |  |
| [A subject-specific IP dispense log will be placed in each subject’s binder and captures at minimum: protocol number, subject number, date, visit number, staff dispensing, quantity dispensed, quantity returned, and compliance rate. In a double-blind study, the pharmacy will record the medication names, doses, and lot numbers distributed to each subject (for drug studies).] |  |  |  |
| [A master IP accountability log template is available (often maintained as a balance/forward log at the pharmacy) which will account for all IP received and dispensed.] |  |  |  |
| Data Quality  | Both paper and electronic Case Report Form (CRF) templates have a form title, version date/version number, and page numbers, and have fields for subject number, visit number, visit date, and initials of staff collecting data. |  |  |  |
| [The electronic data capture system (EDC) is compliant with 21CFR11. ] |  |  |  |
| The EDC is password-protected and only trained study staff are given access to the EDC. |  |  |  |
| The EDC captures all protocol-required data fields.  |  |  |  |
| Subject data will be centralized to allow for appropriate tracking of adverse events, protocol deviations, and GCP adherence. |  |  |  |
| SOPs are in place to ensure continuous QA/QI of study data and site operations.  |  |  |  |
| For multi-site studies, SOPs are in place to ensure data are collected consistently across sites. |  |  |  |
| Comments |  |  |  |  |

**<Interim Monitoring Visit: >**

| Review Category | Criteria | Yes | No / Deficient | N/A |
| --- | --- | --- | --- | --- |
| Regulatory Oversight Documents & Processes | A current IRB-approved copy of the protocol is on file. |  |  |  |
| All previous versions of the protocol are on file. |  |  |  |
| A current and IRB-approved copy of the informed consent form (ICF) is on file. |  |  |  |
| Continuing review approval(s) are present (annually). |  |  |  |
| Approvals for any protocol/consent/assent amendments are present. |  |  |  |
| IRB approval letters specify which versions of the protocol and/or ICF were approved. |  |  |  |
| Previous monitoring/audit reports are on file.  |  |  |  |
| Action items from previous monitoring/audit reports have been resolved. |  |  |  |
| [Investigator brochures or package inserts are current and available for investigational products. Documentation of IRB submission is present (if applicable).] |  |  |  |
| [IP shipping records for any new IP shipped are on file.] |  |  |  |
| [Certificates of analysis for any new batches of IP shipped are on file.] |  |  |  |
| Comments |  |  |  |  |
| Study Staff Qualifications | Current signed and dated CVs or biosketches are up-to-date for the Principal Investigator and staff listed on the Delegation of Authority Log. |  |  |  |
| Appropriate licenses are up-to-date for Principal Investigator and all sub-investigators listed on the Delegation of Authority Log. |  |  |  |
| Documentation of Human Subjects Protection Training for all relevant personnel is up-to-date. |  |  |  |
| Documentation of GCP training for all relevant personnel is up-to-date. |  |  |  |
| Documentation of OSHA/IATA training is present for individuals shipping specimens (if applicable). |  |  |  |
| Documentation of study-specific training for all relevant personnel is up-to-date. |  |  |  |
| Comments |  |  |  |  |
| Study Operations/ Facilities Oversight | Documentation of internal correspondence is present and current (e.g. weekly study meeting minutes). |  |  |  |
| Documentation of external correspondence is present and current (e.g. important communications with NIMH PO, DSMB, FDA, CTOBB Site Monitor, collaborating sites). |  |  |  |
| Study facilities continue to be appropriate for the conduct of the study. |  |  |  |
| The PI is adequately supervising the conduct of the study (PI oversight) in accordance with ICH GCP E6 (R2). |  |  |  |
| The study site continues to meet adequate site operational requirements or standards. |  |  |  |
| A review of the signed ICFs indicated that all subjects were consented appropriately and all ICF fields were accurately completed. |  |  |  |
| [IP inventory matches master IP accountability log (often maintained as a balance/forward log at the pharmacy).]  |  |  |  |
| Study supply inventory is adequate and not expired. |  |  |  |
| Comments |  |  |  |  |
| Study Logs and Forms | The Delegation of Authority Log is present and accurate. |  |  |  |
| A subject screening log is present and accurate. |  |  |  |
| A subject enrollment log is present and accurate. |  |  |  |
| Confidential subject identification code linking subject numbers to subject names/contact info is up-to-date.  |  |  |  |
| The study-wide Protocol Violations and Deviations Log is available and up-to-date.  |  |  |  |
| The study-wide AE/SAE log is available and up-to-date.  |  |  |  |
| Reports are on file for any events that required expedited reporting to regulatory authorities. |  |  |  |
| Subjects are being accurately randomized according to the master randomization code.  |  |  |  |
| Comments |  |  |  |  |
| Data Quality  | Both paper and electronic Case Report Form (CRF) templates have a form title, version date/version number, and page numbers, and have fields for subject number, visit number, visit date, and initials of staff collecting data. |  |  |  |
| [The electronic data capture system (EDC) continues to be compliant with 21CFR11.] |  |  |  |
| The EDC is capturing all protocol-required data fields. |  |  |  |
| Subject data is centralized to allow for appropriate tracking of adverse events, protocol deviations, and GCP adherence. |  |  |  |
| SOPs are being followed to ensure continuous QA/QI of study data and site operations. |  |  |  |
| For multi-site studies, SOPs are being followed to ensure data are collected consistently across sites. |  |  |  |
| Comments |  |  |  |  |

**<Close Out Visit:>**

| Review Category | Criteria | Yes | No / Deficient | N/A |
| --- | --- | --- | --- | --- |
| Regulatory Oversight Documents & Processes | All IRB-approved copies of the protocol are on file. |  |  |  |
| All IRB-approved copies of the informed consent form (ICF) are on file. |  |  |  |
| Continuing review approval(s) are present. |  |  |  |
| Approvals for any protocol/consent/assent amendments are present. |  |  |  |
| Previous monitoring/audit reports are on file.  |  |  |  |
| Action items from previous monitoring/audit reports have all been resolved. |  |  |  |
| Comments |  |  |  |  |
| Study Staff Qualifications | Documentation for study staff is complete: Current signed and dated CVs or appropriated licenses, documentation of GCP and HSP training are up-to-date for the Principal Investigator and staff listed on the Delegation of Authority Log,  |  |  |  |
| Study Operations/ Facilities Oversight | Documentation of internal & external correspondence are present  |  |  |  |
| A review of the signed ICFs indicated that all subjects were consented appropriately and all ICF fields were accurately completed. |  |  |  |
| [IP inventory matches master IP accountability log (often maintained as a balance/forward log at the pharmacy).] |  |  |  |
| Study supply inventory is adequate and not expired. |  |  |  |
| Comments |  |  |  |  |
| Study Logs and Forms | The Delegation of Authority Log is present and accurate. |  |  |  |
| A subject screening log is present and accurate. |  |  |  |
| A subject enrollment log is present and accurate. |  |  |  |
| Confidential subject identification code linking subject numbers to subject names/contact info is up-to-date.  |  |  |  |
| The study-wide Protocol Violations and Deviations Log is available and up-to-date.  |  |  |  |
| The study-wide AE/SAE log is available and up-to-date.  |  |  |  |
| Reports are on file for any events that required expedited reporting to regulatory authorities. |  |  |  |
| Comments |  |  |  |  |
| Data Quality  | Both paper and electronic Case Report Form (CRF) are complete |  |  |  |
| [The electronic data capture system (EDC) continues to be compliant with 21CFR11. ] |  |  |  |
| Comments |  |  |  |  |

1. **Additional Comments and Recommendations**

*Comment on any findings not covered in the above table*

1. **Individual Participant Record Review and Summary:**

*Not included in SIV*

|  |  |  |
| --- | --- | --- |
| **PARTICIPANT REVIEWED (PID #)** | **FROM VISIT – TO VISIT**  | **SUBJECT STATUS**  |
|  |  |  |
| **SUMMARY OF FINDINGS**  | **Y** | **N** | **N/A** | **COMMENTS** |
| Informed consents/ assent appropriately obtained and documented |  |  |  | Date subject signed ICF:  |
| Participant appears eligible based on source documentation |  |  |  |  |
| Concomitant meds allowable for entry into study and remain allowable per protocol throughout study |  |  |  |  |
| Clinical and laboratory evaluations obtained as per protocol; values allowable per protocol  |  |  |  |  |
| Study physicians are reviewing and signing lab reports within 24 hours of receipt. |  |  |  |  |
| All protocol deviations, violations, and unanticipated problems noted and reported as needed |  |  |  |  |
| [IP accountability logs are accurate and complete.] |  |  |  |  |
| AEs (including SAEs) appropriately documented and reported |  |  |  |  |
| Paper and electronic forms adhere to GCP standards for good documentation practices (ALCOAC) |  |  |  |  |
| Data captured in EDC accurately reflects data on CRFs |  |  |  |  |
| Study tasks were performed by staff who were appropriately delegated on the delegation log |  |  |  |  |
| If complete, the subject’s final status is documented. |  |  |  |  |