

APPENDIX F:

NIAMS Clinical Trial Closeout Procedures Single-site

NIAMS CLINICAL TRIAL CLOSEOUT PROCEDURES SINGLE-SITE

I. INTRODUCTION

Purpose

The purpose of this document is to describe an orderly approach to the separation of participants from a clinical trial and the administrative procedures associated with the trial's completion.

Types of Close-out

- A. ***Scheduled*** - upon completion of the trial.
- B. ***Unscheduled*** - as a result of failure to obtain continuation funding, negative or positive findings, findings in other studies that impact on the clinical trial, or other unforeseen events.

II. SITE CLOSE-OUT

The study site is responsible for ensuring the following activities are completed prior to study close-out along with the Participant Close-out Procedures described in Section III below.

A. ***Study Forms***

- All outstanding Case Report Forms (CRFs) should be collected, organized, and corrections made, where necessary.
- All data queries should be corrected and resolved.

B. ***Safety Reporting***

- All adverse events (both serious and non-serious) should be recorded and followed up to resolution in accordance with procedures detailed in the protocol.
- All serious adverse events (SAEs) should have been reported to the Data and Safety Monitoring Board (DSMB) or Safety Officer, Institute, Institutional Review Board (IRB), and other organizations, as specified in the protocol and Data and Safety Monitoring Plan (DSMP).
- All adverse events should have been reported as specified in the protocol.

C. ***Study Files***

- The investigator's study files should be complete and up-to-date with originals of the following maintained in the Study Binder, as relevant:
 - Investigators Curriculum Vitae(s) (CVs), Investigator's Brochure(s) as relevant
 - IRB approval letters for the protocol, all amendments, Informed Consents, annual reviews and advertisements (including updated approvals)

- IRB membership list
- All IRB correspondence
- Institute correspondence
- Site signature log
- Drug accountability records documenting the investigational product received, dispensed and returned or destroyed
- Copy of randomization code for randomization, if applicable
- All informed consents should be signed and on file.
- Record retention procedures should be documented with respect to type and length of retention and consequences of improper record retention, and should conform to protocol and institutional requirements. The site should be completely familiar with required record retention policies.

D. ***Clinical Supplies***

- Clinical supplies, including any treatment intervention materials, must be shipped or disposed of according to protocol directions.
- As relevant, drug accountability records (shipping, receipt, dispensing, return or destruction) should be up-to-date.

E. ***Laboratory Records and Specimen Retention***

- The site should ensure that the laboratory records are complete and up-to-date (reference ranges, laboratory certifications, specimen tracking records, specimen storage records).
- If specimens are to be stored, a plan should be in place to address issues such as specimen retention, use, and methods for protecting patient confidentiality. As relevant, study specimens should be transmitted to the analysis center, analyzed, results recorded for the study, and specimens stored with proper documentation.

F. ***Notifications and Equipment Removal***

- A final report should be submitted to the IRB and should conform to institutional reporting requirements. The report is likely to include, but is not limited to, study conduct and outcome, pertinent safety and efficacy observations, complete disclosure of any SAEs experienced during the course of the study, and the study close-out date.
- As relevant, arrangements should be made for the removal and shipment of any study-specific equipment received by the site (e.g., computers, diagnostic equipment, and participant monitoring devices).

Figure 1 provides a sample study documentation list, and Figure 2 provides a sample Close-Out Checklist.

Figure 1: Sample Study Documentation List

Document	Purpose
Completed Participant Identification Code List	Permits identification of all participants enrolled in the trial in case follow-up is required. List should be kept in a confidential manner (double locked system) and for agreed upon time.
Treatment allocation and decoding documentation	Study Records
Treatment intervention product(s) accountability at site	Documents that the treatment intervention product(s) have been used according to the protocol. Documents the final accounting of treatment product(s) received at site, dispensed to participants, returned by the participants, and returned or destroyed.
Final report by investigator to IRB, as required	To document completion of the trial
Final Trial Closeout Monitoring Checklist, if relevant	To document that all activities required for trial closeout are completed, and copies of essential documents are held in the appropriate files
Audit Certificate (if relevant)	To document that audit was performed

Figure 2: Sample Study Close-out Checklist

- Investigator has signed and dated all Case Report Forms (CRFs).
- CRFs for all participants have been filed or transmitted as described in the Manual of Procedures.
- All appropriate documents are in the study files.
- As relevant, study drug has been shipped or destroyed, as described in the study protocol and/or Manual of Procedures.
- Report has been submitted to the IRB.
- Documents are retained as specified in the Manual of Procedures or IRB directives, whichever is longer.
- There is a plan in place in the event of an audit by the NIAMS, as relevant.
- Final report has been submitted to the NIAMS.

III. PARTICIPANT RIGHTS AND NOTIFICATION

The study site should prepare a letter that thanks each study participant and could include the following information:

- Study findings
- Treatment assignment, as relevant
- Treatment options, as relevant, whether continued treatment with the assigned intervention is indicated, and how and where treatment may be obtained
- Transfer of care responsibilities
- Rights to confidentiality, privacy, and to no further contact from study staff, if that is participant's preference
- Subsequent updates or recalls if new and important information emerges following separation
- Contact information of study staff

A copy of the letter should be included in the participant's file.

IV. INSTITUTE RESPONSIBILITIES

The NIAMS may wish to send staff or a Contractor to ensure that close-out procedures are appropriately conducted at the study site.