National Institute on Aging (NIA)

Guidelines for Developing a Single-Site

Manual of Operations and Procedures (MOP)

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# 1.0 Introduction

The purpose of this document is to provide guidelines for reference when writing each section of a Manual of Operating Procedures (MOP) for single site clinical trials. However, since each study is unique, sections can be omitted and/or added at the investigator’s discretion depending on the nature and complexity of the study.

In preparing the MOP, the Principal Investigator must be aware of the terms of award with respect to required reporting, data and safety monitoring, and Institutional Review Board (IRB) approval (see [*NIA* *Implementation of Policies for Human Intervention Studies*](http://www.nia.nih.gov/research/dea/implementation-policies-human-intervention-studies)*).*

The protocol, case report forms (CRFs), informed consent documents, and administrative forms (e.g., screening and enrollment log, protocol deviation log, etc.) should be finalized before the development of the MOP. Additionally, the MOP should be drafted prior to study commencement.

A single-site MOP Outline is available on the NIA Toolbox.

# 2.0 Brief Overview of the Study Protocol

The study protocol, presented as an appendix, provides a scientific rationale of the proposed investigation. In this section of the MOP a brief overview of the study protocol should be included. See the NIA [Protocol](http://www.nia.nih.gov/sites/default/files/ProtocolTemplate_11_12_2007_Final.doc) Template for protocol for protocol development information.

# 3.0 Study Staff Responsibilities

The staff responsibilities are described in this section.

In a single-site study, the site staff is likely to perform the duties of both the study site and a data coordinating center and the responsibilities include the following as relevant:

* Developing all study materials including the MOP and study forms
* Reporting and monitoring of Adverse Events (AEs) and Serious Adverse Events (SAEs)
* Obtaining informed consent from each participant
* Recruiting, screening, and enrolling of participants
* Randomizing participants
* Collecting study data and following participants through study completion
* Complying with study intervention administration
* Protecting participants' rights
* Submitting documents to regulatory bodies (i.e., IRB or FDA)
* Developing and implementing:
* Data management procedures including the data flow and procedures for data entry, error identification and correction
* Quality control procedures
* Reports - enrollment, participant status (e.g., withdrawals), adverse events, independent safety monitoring body reports

# 4.0 Study Flow Diagram

An overview of the study processes, presented in a flow diagram in Figure 1, describes each of the study's major steps. It should be uniquely tailored to the study and is helpful in describing the study to new staff members.

## Figure 1: Study Flow Diagram



# 5.0 Recruitment and Retention

This section describes the target population, recruitment and retention strategies. The NIA Toolbox document [Recruitment and Retention Tips](http://www.nia.nih.gov/sites/default/files/RecruitmentandRetentionTipsFINAL.doc) describes these strategies in detail. Plans and suggestions for participant retention should be described and may include strategies such as phone calls, birthday cards and reminder postcards.

An action plan for correcting retention problems should also be provided in this section.

## 5.1 Screening and Eligibility Criteria

This section details the screening procedures outlined in the protocol to determine if an individual is eligible to participate in the study. If individuals must be enrolled in the study within a specific window of time following completion of the screening procedures, then such requirements should be included in the MOP.

## 5.2 Screening Log

A Screening Log usually provides documentation of all individuals evaluated for study eligibility. It should include the identification number and individual’s initials, age, gender, screening date, and eligibility status.

It may also contain the randomization number if different from the screening number. The MOP describes the contents of the Screening Log, specifically how data are entered, and processes for secure storage. A Sample Screening Log is available in [Appendix B](#AppendixB).

Note: This information is usually part of the reporting requirements for data and safety monitoring.

# 5.3 Eligibility Criteria

This section of the MOP describes the study population i.e. defines individuals who are eligible for the study (e.g., men and women with elevated above 140/90 mm Hg blood pressure, etc.) and the specific forms needed to document eligibility (e.g., medical history form, physical examination form).

# 6.0 Informed Consent

This section of the MOP describes the specific instructions for obtaining informed consent. If there are multiple consent documents (e.g. collecting data from additional sources, participation in ancillary studies), then each informed consent form should be outlined in the MOP and accompanied by detailed instructions, which should include the following:

* When consent be obtained
* Name of the person that will discuss the nature of the study with the individual and sign the consent form
* When a copy of the signed consent will be given to the individual and where the original signed copy of the consent be stored
* Re-consent process, if individuals need to be re-consented at any part of the study.

The IRB approved Informed Consent form should be included as an appendix in the MOP.

[NIA Informed Consent Template and Guidelines](http://www.nia.nih.gov/sites/default/files/NIAInformedConsentTemplateFINAL.doc) and [NIA Informed Consent Checklist](http://www.nia.nih.gov/sites/default/files/informed_consent_checklist_1_14_08_updated.doc) provide additional details.

## 6.1HIPAA Authorization

The Health Insurance Portability and Accountability Act authorization form may be a separate document from the informed consent form and must be reviewed and signed by the study participant in addition to reviewing and signing the informed consent form. The format of the HIPAA authorization is established by the local IRB. Investigators should review information provided in the “[Impact of the HIPAA Privacy Rule on NIH Processes Involving the Review, Funding, and Progress Monitoring of Grants, Cooperative Agreements, and Research Contracts](http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html)” document (and contact their appropriate institutional officials to learn how the Privacy Rule applies to them, their organization, and their specific research project. Another helpful resource is “[Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, NIH Publication 03-5388](http://privacyruleandresearch.nih.gov)”

If the study is collecting any personal identifiable health information, this should be explained in this section of the MOP. Additionally, the IRB approved HIPAA form should be included in the appendix.

# 7.0 Study Intervention

This section should include a detailed description of the intervention and how it will be implemented.

The intervention must be thoroughly described so that all participants have the same exposure:

**Pharmaceutical** studies, including biological, nutritional and hormonal interventions, the distribution, preparation and handling, labeling, and administration are detailed along with the duration of treatment and criteria for treatment discontinuation. A detailed description of the information that must be provided is documented in the [ICH E6 Guideline for Good Clinical Practice.](http://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E6_R1/Step4/E6_R1__Guideline.pdf)

The MOP should describe how the investigational agent is to be stored, prepared, dispensed, and returned or destroyed. It should also provide instructions for completing drug accountability and administrative records.

**Device studies** require a detailed description of the device and its intended use. Information on device studies is provided in the [Code of Federal Regulations (CFR) Title 21, Part 812, revised as of April 1, 2011](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812&showFR=1)

**Behavior** and **life style** studies require a detailed description of how the intervention is to be carried out as well as documentation of the process.

**Surgical** studies require a detailed description of the procedure.

# 8.0 Randomization

This section of the MOP describes the randomization approach and procedures, including:

* ***Randomization Plan:*** The method used for generating randomization codes for assigning participants into treatment groups are describe in detail.
* ***Process Responsibilities***: The individual who maintains the master randomization list must be identified. This person is responsible for assigning randomization codes, notifying appropriate study staff that the participant has been randomized and securely storing all randomization files.
* ***Procedure for Randomizing a Participant:***  At each site, the individual who is responsible for initiating the randomization procedure must be identified. This individual must know who to contact once a participant is determined eligible for a study and which forms must be completed prior to randomization (e.g., informed consent form and participant eligibility form).

Randomization assignments must be documented so that they can be reviewed during a data review or audit. Some studies maintain the assigned and blinded randomization code in an automated, computerized log that is separate from the study data while other studies maintain the assignment in a paper based randomization log. In either case, the method for documenting randomization must be described.

# 9.0 Blinding and Unblinding (Masking and Unmasking)

The Investigators’ procedures for unblinding should be described in detail in the MOP.

In most studies with randomization, participants and the treating physician are "blinded" or "masked" to the treatment and do not know if the participant is receiving the experimental or a control intervention. The study statistician and/or a designated study staff member securely maintains the randomization codes so that the treatment assignments are not revealed. Randomization and blinding/unblinding procedures must be determined prior to the enrollment of the first participant*.*

Unblinding is a serious action and should be limited to reduce potential bias. In the event that unblinding occurs, the following should be recorded:

* The ID of the unblinded participant,
* The reason for unblinding,
* The study staff person responsible for unblinding
* A list of person(s) who have been unblinded.

# 10.0 Safety Reporting

This section of the MOP details the definitions of and procedures for reporting adverse events and serious adverse events, as applicable. [The Adverse Event (AE) and Serious Adverse Event (SAE) Reporting Guidelines](http://www.nia.nih.gov/sites/default/files/niaaeandsaeguidelinesfinal011012_0.doc) and [Events Process Flow](http://www.nia.nih.gov/sites/default/files/ae_saeprocessflow.doc) should be used when developing this section. The Guidelines provide:

* Definitions of adverse events, serious adverse events and unanticipated problems
* Responsibilities of NIA and investigators
* Reporting processes
* Description of terms used in reporting

Additionally, template reporting forms are available for [Adverse Events](http://www.nia.nih.gov/sites/default/files/adverseeventsform.doc) and [Serious Adverse Events](http://www.nia.nih.gov/sites/default/files/seriousadverseeventsform_0.doc).

# 11.0 Study Compliance

This section should describe what constitutes a protocol deviation and process for reporting deviations to appropriate parties, including the NIA, site investigator, and the DSMB or Safety Officer. Please note, only protocol deviations that impact participant safety should be reported within 24 hours of occurrence if possible, or as soon as they are discovered. All other deviations should be reported routinely to the independent safety monitoring body. Investigators need to follow their IRB requirements for reporting protocol deviations to the Board. In addition, if monitors discover any of these deviations during a site visit, they should list any such occurrence in their monitoring report. The site study coordinator should maintain a log of all protocol deviations.

Protocol deviations/violations may include, but are not limited to, the following:

* Randomization of an ineligible participant
* Failure to obtain Informed Consent
* Enrollment of a participant into another study
* Failure to keep IRB approval up to date
* Wrong treatment administered to participant

A log for recording protocol deviations should also be included in the appendix. See [Protocol Deviations Form Template](http://www.nia.nih.gov/sites/default/files/ProtocolDeviationsCoreform.doc).

# 12.0 Data Collection and Study Forms

This section of the MOP describes the study’s data collection and data management procedures and should include copies of all forms in the appendix.

## 12.1 Participant Binder

This section describes how participant data are maintained in the study. All essential study documents must be retained by the investigator in a Participant Binder and generally include the following:

* Source documents (e.g., lab reports, x-rays, etc.)
* Signed informed consent forms
* Questionnaires completed by the participant
* Case Report Forms (CRFs)
* Data correction forms
* Workbooks

## 12.2 Study Forms

In this section of the MOP, the following should be provided: :

* List and description of study forms and their collection schedule
* Forms maintenance

For your reference, [Study Form templates](http://www.nia.nih.gov/research/dgcg/clinical-research-study-investigators-toolbox/study-forms) are available in the NIA Toolbox.

## 12.3 General Instructions for Completing Forms

If paper CRFs are used in the study, in this section of the MOP, please provide a set of instructions for completing the CRFs to ensure quality and consistency in data collection. A set of guidelines for incomplete or illegible forms must be included.

For examples on frequently used instructions, please visit the [Data Management Tips](http://www.nia.nih.gov/sites/default/files/DataManagementTipsFINAL.doc) document in the NIA Toolbox.

## 12.4 Data Flow

This section of the MOP describes data flow, data entry, and data correction procedures. Specifically describe how the team will ensure that all forms are complete, intact, and transmitted to the data manager or how the data are directly entered into an electronic CRF (eCRF).

## 12.5 Administrative Forms

In this section please list the study forms that will be used. Administrative forms (e.g., screening log) provide documentation of study processes and assist with study operations. For additional examples of administrative forms, please see [Appendix E.](#AppendixE)

## 12.6 Retention of Study Documentation

NIH policy requires that studies conducted under a grant retain participant forms for three years and studies conducted under contract retain participant forms for seven years. Individual IRBs, institutions, states and countries may have different requirements for record retention. Investigators should retain forms for the longest applicable period, and this period should be stated in this section of the MOP. Additionally, for select studies that must meet FDA requirements, informed consent forms be retained for two years after a marketing application is approved for a product or, if an application is not approved, until two years after shipment and delivery of the product is discontinued for investigational use and the FDA is notified.

# 13.0 Data Management

This section of the MOP describes the computer system and data management approach that will be used to support the study and details how data are to be collected, entered (e.g., if eCRFs are used), edited or corrected. In some studies, this information will be documented in a separate document, the “Data Management Plan.” See [NIA’s Data Management Tips](http://www.nia.nih.gov/sites/default/files/DataManagementTipsFINAL.doc) for additional details on data capture and data processing.

Investigators should be aware that systems for studies that will be submitted to the FDA must be documented and validated. “[Guidance for electronic systems is found on the FDA Web site, Title 21 Code of Federal Regulations (21 CFR Part 11) Electronic Records; Electronic Signatures-Scope and Application](http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm)”

## 13.1 External Data

This section of the MOP should describe how external data (e.g., blood samples) will be collected, labeled, handled, shipped, tracked and reconciled, so that study data are not lost. As stated in the Health Insurance Portability and Accountability Act (HIPAA) guidelines, personal identifiers such as name, geographic location, social security number, and fifteen other specific individual identifiers should not be used (see the comprehensive list in “[Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule, NIH Publication 03-5388”](http://privacyruleandresearch.nih.gov/pdf/HIPAA_Booklet_4-14-2003.pdf)) Therefore, it is important to specify how participant materials will be identified (e.g., by participant identification number) during transmission.

## 13.2 Quality Control Procedures

This section should detail the Quality Control plan and describe any training and certification procedures. It may include standard operating procedures (SOPs), data and forms checks, monitoring, routine reports, and correction procedures.

### 13.2.1 Standard Operating Procedures

Standard Operating Procedures (SOPs) which relate to conduct of clinical trials should be listed in this section of the MOP. Note: Printed SOPs should not be inserted in the MOP. The location of each SOP (i.e., electronic file name) can be included in this section for staff to reference.

### 13.2.2 Data and Form Checks

Most studies today used computerized systems that provide data edits as a form of quality control. This section of the MOP (or alternatively, the Data Management Plan) can provide a summary of the checks that will be implemented for data quality control.

Data quality control checks may identify potential data anomalies such as:

* Missing data or forms
* Out-of-range or erroneous data
* Inconsistent and illogical dates over time
* Data inconsistency across forms and visits
* Not completing all fields of a "completed form" or no reason for missing data is provided

# 14.0 Concomitant Medications

The MOP provides a rationale for the concomitant medications that are required and restricted in the protocol. Please list all required and/or excluded concomitant medications in this section.

***Note:*** This section applies to pharmaceutical (drug) studies.

# 15.0 Data and Safety Monitoring Activities

The roles and responsibilities of the entities monitoring participant safety and study quality are described in this section.

To assist in preparing a monitoring plan, visit the [Data and Safety Monitoring](http://www.nia.nih.gov/research/dgcg/clinical-research-study-investigators-toolbox/data-and-safety-monitoring) page of the NIA Toolbox.

## 15.1 Study Completion and Close-Out Procedures

This section of the MOP should briefly outline the Study Completion and Close-out procedures. Examples of Close-out activities include, but are not limited to, the following:

* Verification that study procedures have been completed, data have been collected, and study intervention(s) and supplies are returned to the responsible party or prepared for destruction.
* Assurance that all data queries have been completed.
* Assurance that correspondence and study files are accessible for external audits.
* Assurance that the study records are maintained and any relevant study information reported to the NIA.
* Assurance that the investigator will notify the IRB of the study’s completion and store a copy of the notification.
* Preparation of a report summarizing the study’s conduct.
* Participant notification of the study completion.

### 15.1.1 Participant Notification

In this section of the MOP, please include the plan for participant notification upon completion of the study. The Principal Investigator and study staff should develop a plan to notify participants that the study is over, ask whether they would like to be informed of the results, and thank them for their participation. It may include either the first article or a reference to the article.

### 15.1.2 Confidentiality Procedures

This section of the MOP will discuss the safeguards which have been put in place to ensure participant confidentiality and data security. It is the responsibility of the Principal Investigator to outline and enforce participant confidentiality and data security guidelines.

The following is a list of study participant confidentiality safeguards:

* ***Electronic files –*** data identifying participantsthat are stored electronically should be maintained in an encrypted form or in a separate file.
* ***Forms -*** forms or pages containing personal identifying information should be separated from other pages of the data formsand retained in a secure location.
* ***Data listings -*** participant name, name code, hospital chart, record number, Social Security Number, or other unique identifiers should not be included in any published data listing.
* ***Data distribution*** - data listings that contain participant name, name code, or other identifiers easily associated with a specific participant should not be distributed.
* ***Data disposal*** - computer listings that contain participant-identifying information should be disposed of in an appropriate manner.
* ***Access*** - participant records should not be accessible to persons outside the site without the express written consent of the participant.
* ***Storage -*** study forms and related documents retained both during and after study completion should be stored in a secure location.

If computers are used to store and/or analyze clinical data, the investigator should address elements of computer security to ensure that the data remain confidential. These elements include but are not limited to: utilization of computer and system passwords, user security training, system testing and verification, and routine system backups to prevent any loss of electronic data.

# 16.0 MOP Maintenance

Each page of the MOP should be numbered, dated, and contain a version number to facilitate any changes and/or additions. The MOP may serve as a history of the project, documenting the time and nature of any changes in procedures and policies.

See MOP Modification Log Template in [Appendix D](#AppendixD).

# BIBLIOGRAPHY

For additional information, please refer to the resources listed below.

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# RELEVANT WEB SITES

## Food and Drug Administration:

<http://www.fda.gov/cber/guidelines.htm>

<http://www.fda.gov/ora/compliance_ref/part11/>

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>

## Gene Therapy, Stem Cells and Fetal Tissue:

<http://grants.nih.gov/grants/policy/gene_therapy_20000307.htm>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-050.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-026.html>

## Information Required in NIH Grant Applications:

<http://grants.nih.gov/grants/policy/policy.htm>

## NIH Policies for Monitoring Clinical Research:

<http://grants.nih.gov/grants/guide/notice-files/not99-044.html>

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-053.html>

## Implementation of NIA Policies for Human Intervention Studies

<http://www.nia.nih.gov/research/dea/implementation-policies-human-intervention-studies>

## Guidelines for Writing Informed Consent Documents

[http://ohsr.od.nih.gov/info/sheet6.html](http://www.hhs.gov/ohrp/policy/ictips.html%22%20%5Co%20%22Office%20for%20Human%20Research%20Protections%20-%20Tips%20on%20Informed%20Consent)

# APPENDIX A - ACRONYM GLOSSARY

* ***Adverse Event (AE) –*** Any untoward or unfavorable medical occurrence in a clinical research study participant, including any abnormal sign (e.g. abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the participants’ involvement in the research, whether or not considered related to participation in the research.
* ***Case Report Form (CRF) –*** A printed, optical, or electronic (eCRF) document designed to capture all protocol-required information for a study.
* ***Code of Federal Regulations (CFR)*** *-* is an annual codification of the general and permanent rules published in the Federal Register by the executive departments and agencies of the Federal Government.
* ***Coordinating Center (CC) –*** A group organized to coordinate the planning and operational aspects of a multi-center clinical trial. CCs may also be referred to as Data Coordinating Centers (DCCs) or Data Management Centers (DMCs).
* ***Data and Safety Monitoring Board (DSMB) –***A group of individuals independent of the study investigators that is appointed by the NIA to monitor participant safety, data quality and to assess clinical trial progress.
* ***Food and Drug Administration (FDA) –*** An agency within the U.S. Department of Health and Human Services (DHHS) responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, nation’s food supply, cosmetics, and products that emit radiation.
* **Good Clinical Practice (GCP) *–*** A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.
* ***Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule –*** The first comprehensive Federal protection for the privacy of personal health information. The Privacy Rule regulates the way certain health care groups, organizations, or businesses, called covered entities under the Rule, handle the individually identifiable health information known as protected health information (PHI).
* ***Institutional Review Board (IRB)/Independent Ethics Committee (IEC) –*** An independent body constituted of medical, scientific, and nonscientific members whose responsibility it is to ensure the protection of the rights, safety, and well-being of human subjects involved in a trial by, among other things, reviewing, approving, and providing continuing review of trials, protocols and amendments, and of the methods and material to be used to obtaining and documenting informed consent of the trial participant.
* **Manual of Procedures (MOP) *–*** A “cook book” that translates the protocol into a set of operational procedures to guide study conduct. A MOP is developed to facilitate consistency in protocol implementation and data collection across study participants and clinical sites.
* **Principal Investigator (PI)** - The individual with primary responsibility for achieving the technical success of the project, while also complying with the financial and administrative policies and regulations associated with the award. Although Principal Investigators may have administrative staff to assist them with the management of project funds, the ultimate responsibility for the management of the sponsored research award rests with the Principal Investigator.
* **Quality Control (QC) *–*** The internal operational techniques and activities undertaken within the quality assurance system to verify that the requirements for quality of trial related activities have been fulfilled (e.g., data and form checks, monitoring by study staff, routine reports, correction actions, etc.)
* **Safety *Officer (SO)*** *-* The Safety Officer is an independent individual, usually a clinician, who performs data and safety monitoring activities in low-risk, single site clinical studies. The Safety Officer advises NIA Program Director regarding participant safety, scientific integrity and ethical conduct of a study.
* ***Serious Adverse Event (SAE) –*** Any adverse event that:
* Results in death
* Is life threatening, or places the participant at immediate risk of death from the event as it occurred
* Requires or prolongs hospitalization
* Causes persistent or significant disability or incapacity
* Results in congenital anomalies or birth defects
* Is another condition which investigators judge to represent significant hazards
* ***Standard Operating Procedure (SOPs) –*** Detailed written instructions to achieve uniformity of the performance of a specific function across studies and patients at an individual site.

# Appendix B - Sample Screen Log

**Study:** [Study Name]

**Site:** [Site Name]

**Investigator:** [Investigator Name]

| **Screening Number** | **Date of****Birth** | **Gender** | **Screening****Date** | **Screening****Status****(use codes below)** | **Consent Obtained** | **Enrolled****(if no, indicate****reason from codes below)** | **Date****Enrolled** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| [ ] [ ] [ ] [ ]  | / /mm/dd/yyyy | [ ]  M[ ]  F | / /mm/dd/yyyy |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | / /mm/dd/yyyy |
| [ ] [ ] [ ] [ ]  | / /mm/dd/yyyy | [ ]  M[ ]  F | / /mm/dd/yyyy |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | / /mm/dd/yyyy |
| [ ] [ ] [ ] [ ]  | / /mm/dd/yyyy | [ ]  M[ ]  F | / /mm/dd/yyyy |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | / /mm/dd/yyyy |
| [ ] [ ] [ ] [ ]  | / /mm/dd/yyyy | [ ]  M[ ]  F | / /mm/dd/yyyy |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | / /mm/dd/yyyy |
| [ ] [ ] [ ] [ ]  | / /mm/dd/yyyy | [ ]  M[ ]  F | / /mm/dd/yyyy |  | [ ]  Yes[ ]  No | [ ]  Yes[ ]  No | / /mm/dd/yyyy |

|  |  |  |  |
| --- | --- | --- | --- |
| **Sample Screen Status Codes:** | **1-Eligible** | **If not eligible, Reason:** | **1-Inclusion # (specify)** |
|  | **2-Eligible, declined participation** |  | **2-Exclusion# (specify)** |
|  | **3-Not Eligible** |  | **3-Other (specify)** |
|  | **4-Eligible, lost to follow-up** |  |  |
|  | **5-Other, specify in space provided** |  |  |

# Appendix C - Sample Schedule of Events

| Visit Description | Screening | \*TP | \*TP | \*TP | \*TP | \*TP | \*TP | \*TP | \*\*FU | \*\*FU | \*\*FU | \*\*FU | \*\*FU | \*\*FU |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Study Visits/ Study days (or weeks) | Visit-1Day-14 to Day -1 | Visit 1Day 0 | 2W1 | 3W2 | 4W3 | 5W4 | 6W8 | Final VisitW10 | 8W12 | 9W14 | 10W16 | 11W18 | 12W20 | 13W22 |
| Informed Consent | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 12-lead EKG | X |  |  |  | X |  |  | X | X |  |  |  |  | X |
| Medical History | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Prior Medications | X |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Physical Exam | X |  |  |  |  |  |  | X |  |  |  |  |  |  |
| Vital Signs | X |  |  |  |  |  |  | X |  |  |  |  |  |  |
| Chemistries | X |  | X | X | X |  |  | X | X |  |  |  |  | X |
| Liver Function Tests | X |  | X | X | X |  |  | X | X |  |  |  |  | X |
| Hematology | X |  | X | X | X |  |  | X | X |  |  |  |  | X |
| Pregnancy Test | X |  |  |  | X |  |  | X | X |  |  |  |  | X |
| Investigational Agent Administration |  | X | X | X | X | X | X | X |  |  |  |  |  |  |
| Concomitant Medications |  | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Adverse Events |  | X | X | X | X | X | X | X | X | X | X | X | X | X |
| Study completion |  |   |  |  |  |  |  |  |  |  |  |  |  | X |

\*TP – Treatment Phase

\*\*FU – Follow-up Phase

# Appendix D - Sample MOP Modification Log

**MOP MODIFICATION LOG**

| **Section #** | **Version #** | **Date Modified** | **Page #** | **Text Location** | **Brief Modification Summary** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
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|  |  |  |  |  |  |
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# Appendix E - Examples of Administrative Forms

An Administrative Form constitutes any form that would not be included in the study database. The following is a list of administrative forms that should be considered for a study. Given that each study is unique, forms could be omitted and/or added at the investigator’s discretion depending on the nature of the study.

* ***Participant Identification Code List -*** Used to document the participant’s study identification number, name, and other identifying information. Must be stored securely and separate from research records since it is the link between a study ID and participant’s name.
* ***Record of Destruction of Clinical Product\**** *-* This log is used to document the destruction of any unused study drug. The date and time of incineration as well as how many vials/pills were incinerated must be recorded. This record should be attached to the Study Drug Accountability Record.
* ***Screening and Enrollment Log* -** Used to list participants screened; includes those who fail screening and those who are enrolled.
* ***Site-Signature Log /Delegation of Authority Log\** -** Used to list all study personnel and their specific responsibilities, signatures, and dates of obligation during the conduct of a clinical research study. ***Note***: For a template form, please see the [NIA Toolbox Study Forms page](http://www.nia.nih.gov/research/dgcg/clinical-research-study-investigators-toolbox/study-forms).
* ***Site Visit Log* -** Records individuals visiting the site. The most common reasons for visits are site initiation, monitoring, training, and close-out.

***Study Drug Accountability Record\**** – Records help ensure that study drugs have not gone astray and help find them if they do. This record should be maintained in the Pharmacy by the research pharmacist and must not be shared with other members of the study team.

* ***Telephone Contact Log* -** To record and track study-related telephone contact discussions with a study participant.
* ***Training Log\** -** Documents study-specific training completed by staff exhibiting their qualifications to perform tasks involved in the clinical research study. Other training may also be listed on this log.

\*Forms could also be considered a regulatory document rather than an administrative form.