## 1. Purpose

To establish and describe the Office of Sponsor and Regulatory Oversight (OSRO) Clinical Trial Records policy.

## 2. Scope

2.1. OSRO in the Center for Cancer Research (CCR), National Cancer Institute (NCI) shall establish and control the policy.

2.2. Investigators, research team members, and other departmental personnel and external NIH collaborators and contractors when they are working on studies conducted under a CCR-held Investigational New Drug application (IND), Investigational Device Exemption (IDE), or a National Institutes of Health (NIH) Institutional Review Board (IRB)-approved protocol using a Non-Significant Risk device (NSR) under OSRO oversight or supported by a CCR-held Master File under OSRO oversight shall follow the policy.

2.3. FDA regulated research records which are required by 21 CFR and pertain to the clinical trial, investigational drugs or devices, safety reports, and annual and final clinical study reports, are within scope.

2.4. Limitations

2.4.1. This policy does not apply to personnel working on studies that are not under a CCR-held IND, IDE, or is an NSR device study and/or when no OSRO oversight or interdepartmental collaboration is required.

2.4.2. Nothing in this policy will supersede NCI, NIH, or Health and Human Services (HHS) requirements.

## 3. Responsibilities

3.1. CCR Management is committed to providing resources to meet the requirements for implementing a Clinical Trial Records policy and supporting its continual improvement.

3.2. OSRO personnel are responsible for understanding the Clinical Trial Records policy.

3.3. OSRO Sponsor and Regulatory Oversight Support (SROS) Contractor staff assisting OSRO Functional Groups are responsible for understanding the Clinical Trial Records policy.

3.4. The OSRO Director is responsible for establishing and maintaining the Clinical Trial Records policy.

3.5. Investigators are responsible for complying with this policy.

## 4. References

4.1. 101 Good Documentation Practices Policy

4.2. 206 Clinical Site Activation Policy

4.3. ICH E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) Guidance for Industry (FDA), March 2018

4.4. 21 CFR 312.62 Investigational New Drug Application: Investigator recordkeeping and record retention

4.5. 21 CFR 812.140 Investigational Device Exemptions: Records

4.6. NIH Records Management Program, NIH Intramural Records Retention Schedule Items

4.7. 45 CFR 46.115(b) Protection of Human Subjects: IRB records

## 5. Definitions

Refer to the OSRO Lexicon.

## 6. Policy

6.1. The Office designation of OSRO shall refer both to the Office of Sponsor and Regulatory Oversight staff and the OSRO Sponsor and Regulatory Oversight Support contractor staff.

6.2. Records

6.2.1. The investigator/institution will maintain adequate and accurate source documents and trial records that include all site essential regulatory documents and pertinent observations on each of the trial participants.

6.2.1.1. Source data should be attributable, legible, contemporaneous, original, accurate, and complete (refer to Reference 4.1).

6.2.1.2. Changes to source data should be traceable, should not obscure the original entry, and should be explained if necessary (e.g., via an electronic automated audit trail).

6.2.2. Investigators will retain records for 2 years after FDA approval of the investigational drug, or for device trials 2 years after the study is discontinued and FDA is notified or for 2 years from date the records are no longer required for device approval action in compliance with Federal Regulations, whichever is longer.

6.2.3. OSRO will determine if documents should be retained for a longer period, if required by the applicable regulatory requirements. It is the responsibility of OSRO to inform the investigator/institution as to when these documents no longer need to be retained.

6.2.4. If an investigator or Sponsor transfers custody of IDE records to another person, FDA must be notified within 10 working days after the transfer occurs.

6.2.5. NIH maintains its own records management program. It is the Investigator's responsibility to meet the most restricted document retention time.

6.3. Record Access

6.3.1. The Sponsor should ensure that the protocol or other written agreement specifies that the investigator(s)/institution(s) provide direct access to source data/documents for trial-related monitoring, auditing, Institutional Review Board (IRB) review, and regulatory agency inspection.

6.3.2. The Sponsor should verify that each participant has consented, in writing, to direct access to his/her original medical records for trial-related monitoring, auditing, IRB review, and regulatory inspection.

6.3.3. Authorized FDA employees shall be permitted at reasonable times and in a reasonable manner to inspect and copy all records relating to an inspection.

6.3.4. Collaborator representatives, according to Agreements, may be permitted at reasonable times and in a reasonable manner, coordinated by OSRO, to inspect records relating to a protocol.

6.4. Site Essential Regulatory Documents for the Conduct of a Clinical Trial

6.4.1. Essential documents permit evaluation of the trial conduct and the quality of the data produced. They serve to demonstrate the compliance of the investigator, sponsor and monitor with the standards of Good Clinical Practices (GCP) and applicable regulatory requirements.

6.4.2. The trial master file should be established at the beginning of the trial by the Sponsor. Each site will maintain a site study file that contains the site essential documents.

6.4.3. The Sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents including source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval.

6.4.4. When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies.

6.4.5. The investigator/institution should have control of all essential documents and records generated by the investigator/institution before, during, and after the trial.

6.5. Documents needed before a site initiation meeting and the start of participant screening and enrollment.

6.5.1. During the planning stage, the following documents must be on file in the Sponsor eTMF before site initiation and, as specified, before the site will be activated by the Sponsor.

6.5.1.1. Table 1 is a generic list of required documents before the clinical trial starts.

6.5.1.2. All Table 1 documents require review for applicability, versioning, accuracy, and appropriateness before acceptance and posting to the Sponsor eTMF.

6.5.1.3. Before a **Site Initiation Visit (SIV)** is scheduled, the Table 1 documents that appear in **BOLD BLUE font** must be in the Sponsor eTMF.

6.5.1.4. Before **OSRO Site Activation** authorizing the start of screening and enrollment, all Table 1 documents must be in the Sponsor eTMF. Refer to the OSRO Site Activation Policy 206 for a complete list of activation requirements.

6.5.2. An exception for SIV requirements may be granted on a case-by-case basis. A request for a waiver from any of the above may be required to be submitted by the site Principal Investigator

(PI) directly to the OSRO Director. The request must be written and include justification for the waiver.

*Table 1. Generic list of required documents before the trial starts*

*Important notes:*

- *The items that appear in **BOLD BLUE font** are required before a Site Initiation Visit (SIV) will be scheduled.*
- *The documents required are per the protocol and planned single or multicenter design. As such, the documents are required, as applicable.*
- *OSRO specific forms and instructions can be found and downloaded from the following location, click on link: https://ccrod.cancer.gov/confluence/display/CCRCRO/Office+of+Sponsor+and+Regulatory+Oversight*

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 1. | **Investigator's Brochure** | To document that relevant and current scientific information about the investigational product has been provided to the investigator. | The version and version date should match the information listed on the corresponding IRB Approval Letter. |
| 2. | **Package Insert** | To ensure the site has access to the most current information for the licensed FDA approved product administered to trial participants per protocol. | The version and version date should match the information listed on the corresponding IRB Approval Letter. |
| 3. | **Electronic Case Report Form (eCRF) technical specifications** | To document the technical planning, data elements and logic checks required to build the protocol-specific data capture system and database. | The documentation provided must include the clinical study team's approval.<br>The eCRF specifications are not required if the blank annotated eCRFs are provided and accepted before the Site Initiation Visit.<br>If a multicenter protocol, the non-NIH sites are not required to provide eCRF specifications. |
| 4. | Blank annotated electronic Case Report Form (eCRF) | To document the protocol-specific data collection forms, including the data elements, logical arrangement, navigation between the different forms, and data logic checks required to build the clinical trial database. | The documentation provided must include the clinical study team's approval.<br>The blank annotated eCRFs must be reviewed and accepted before site activation.<br>If a multicenter protocol, the non-NIH sites are not required to provide blank annotated eCRFs. |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 5. | **Investigator Agreement** | To document the investigator agreement to conduct the protocol according to the approved protocol/amendment(s). | If the study is under a CCR-held IND, the agreement must be a current **Form FDA 1572**.<br>If the study is under a CCR-held IDE or an NSR Device study, the agreement must be an **OSRO Form F01-406-S02 Investigator's Agreement for IDE**. |
| 6. | **Financial Disclosure Form for each Investigator listed in Form FDA 1572 or OSRO Form F01-406-S02 Investigator's Agreement for IDE** | To document the investigator financial interest and risk mitigation. | **OSRO Form F01-401-S01** is required for each PI and Sub-Investigator. |
| 7. | **Information given to trial participants (must be IRB-approved)**<br>• **Informed Consent Form(s)**<br>• **Other written information**<br>• **Advertisement for participant recruitment** | To document the informed consent.<br>To document that participant will be given appropriate written information (content and wording) to support their ability to give fully informed consent.<br>To document that recruitment measures are appropriate and not coercive. | Only non-NIH sites are required to submit IRB approved 'Advertisement for Participant Recruitment' documents. |
| 8. | Financial Aspects of Trial | To document the financial agreement between the investigator/institution and the Sponsor for the trial. | Only applicable to non-NIH sites when an agreement governs the payments to non-NIH sites. |
| 9. | Insurance Statement | To document that compensation to the participant(s) for trial-related injury will be available. | |
| 10. | **Signed Agreement Between Involved Parties**<br>• **Clinical Trial Agreement**<br>• Site – Pharmaceutical Collaborator agreement<br>• Other agreements as necessary | To document agreements. | A Clinical Trial Agreement (CTA) between CCR and non-NIH site participating in a CCR sponsored multicenter study.<br>Agreement with pharmaceutical collaborator is not required prior to the SIV but is required prior to activation. |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 11. | **IRB Approval(s) - Dated, Documented Approval/Favorable Opinion of IRB of the following:**<br>• **Protocol and any amendments**<br>• **Informed consent form(s)**<br>• **Any other written information to be provided to the participant(s)**<br>• **Advertisement for participant recruitment (if used)**<br>• **Participant compensation (if any)**<br>• **Any other documents given approval/favorable opinion** | To document that the trial has been subject to IRB review and given approval/favorable opinion. To identify the version number and date of the document(s). | If the approved version-controlled documents are not detailed in the IRB-approval letter/documentation, the list of IRB submission attachments and approved documents must be included. |
| 12. | **IRB Composition** | To document that the IRB/IEC is constituted in agreement with GCP. | NIH IRB Memo regarding IRB Rosters suffice for the NIH Clinical Center IRB. Copy to be retained in the essential document files of the Sponsor.<br>However, non-NIH sites must provide an IRB roster for multicenter IDE studies not under a reliance agreement with the NIH Intramural IRB. |
| 13. | Regulatory Authority's Authorization / Approval / Notification of Protocol (where required) | To document appropriate authorization / approval / notification by the regulatory authority(ies) has been obtained prior to trial initiation in compliance with the applicable regulatory requirement(s). | |
| 14. | **Curriculum Vitae (CV) and/or other relevant Documents Evidencing Qualifications of Investigators** | To document qualifications and eligibility to conduct trial and/or provide medical supervision of participants. | Includes all investigators listed on the current Form FDA 1572 for IND studies or the OSRO Form F01-406-S02 for IDE/NSR studies.<br>Staff identified as:<br>1. Principal Investigator<br>2. Sub-Investigators<br>The CV must include the investigator's signature and signature date. The signature date must be within four (4) years of the current date. |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 15. | **Site Study Personnel Training Records** | To document site study personnel training pertinent to clinical research and, even more specifically, to the clinical trial. | • Protocol<br>• Good Clinical Practice (GCP)<br>• Human Subjects Protections (HSP)<br>• Electronic Data Capture (EDC) system for non-NIH PI and Staff responsible for use of the EDC system. Note: due before site activation.<br>• Dangerous Goods Handling or International Air Transport Association (IATA)<br>• Other, specialized procedures, e.g., study product preparation |
| 16. | **Clinical Site Delegation of Authority Log** | To document who has been authorized by the PI to carry out protocol-specific activities, tasks and functions.<br>To document who requires training on the protocol and related tasks, topics, and procedures. | The OSRO F01-203-S01 Clinical Site Delegation of Authority Log form must be used by all CCR sites.<br>• A different delegation of authority log format confirmed by the SROS Monitor to include elements similar to the F01-203-S01 form may be used by non-NIH sites.<br>It is the PI's responsibility to ensure Staff are trained and a current record of training is available. |
| 17. | **Normal Value(s)/Range(s) for Medical/Laboratory/Technical Procedures and/or Test(s) included in the Protocol** | To document normal values and/or ranges of the tests. | |
| 18. | **Medical/Laboratory/Technical Procedures/Tests**<br>• Certification<br>• Accreditation<br>• Established quality control and/or external quality assessment<br>• Other validation (where required) | To document competence of facility to perform required test(s), and support reliability of results. | |
| 19. | Sample of Label(s) attached to Investigational Product Container(s) | To document compliance with applicable labeling regulations and appropriateness of instructions provided to the participants. | Only located in the essential document files of the Sponsor.<br>For Device Studies – copy of the device labeling. |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 20. | **Instructions for Handling of Investigational Product(s) and Trial-Related Materials (if not included in protocol or Investigator's Brochure)** | To document instructions needed to ensure proper storage, packaging, dispensing, and disposition of investigational product(s) and trial-related materials. | |
| 21. | Shipping Records for Investigational Product(s) and Trial-Related Materials | To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability. | |
| 22. | Certificate(s) of Analysis of Investigational Product(s) | To document identity, purity, and strength of investigational product(s) to be used in the trial. | Only located in the essential document files of the Sponsor. |
| 23. | Decoding Procedures for Blinded Trials | To document how, in case of an emergency, identity of blinded investigational product can be revealed without breaking the blind for the remaining participants' treatment. | |
| 24. | Master Randomization List | To document method for randomization of trial population. | Only located in the essential document files of the Sponsor. |
| 25. | Pre-Trial Monitoring Report | To document that the site is suitable for the trial. | |
| 26. | Trial Site Initiation Visit (SIV) Report | To document that trial procedures were reviewed with the investigator and the investigator's trial staff. | SIV report issues/action items must be resolved before site activation to begin screening and enrollment will be authorized by the Sponsor. |
| 27. | **IRB Approved Protocol with Protocol Number and Version** | To document the approved protocol. | |
| 28. | **IRB Approved Protocol Amendment with Protocol Number and Amendment Code/Version** | To document the approved protocol amendment. | As applicable, if the amendment is IRB-approved prior to the SIV. |
| 29. | **Protocol Signature Page (Initial and Amendment(s))** | To document the investigator and sponsor agreement to the protocol/amendment(s) and corresponding case report forms/data collection forms. | As applicable, if the amendment is IRB-approved prior to the SIV.<br>OSRO Form F01-202-S01 |
| 30. | Sponsor Activation Notice | To document the Sponsor Approval to Activate the study. | Issued after all pre-site activation requirements are met. |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 31. | Data Management Plan (DMP) | To document how the data will be handled according to how the study is anticipated to be run. A DMP describes the clinical data management activities to be followed in the trial, including case report form (CRF) specifications, database design, data collection, CRF tracking, data entry, data storage and privacy, medical coding, data reconciliation (e.g., serious adverse events and central laboratory data), data review, discrepancy management, data extraction, and database lock. | Only located in the essential document files of the Sponsor.<br>Standalone document only. |
| 32. | **Medical Licenses** | To document the Principal Investigator and Sub-Investigator's professional licenses qualifying them to conduct the trial and/or to provide medical supervision of participants. | Medical and nursing licenses must be submitted for physicians and nurses listed on the current Form FDA 1572 for IND studies or the OSRO Form F01-406-S02 for IDE/NSR studies.<br>This includes the Principal Investigator in Section 1 and all Sub-Investigators listed in Section 6 of the Form FDA 1572 for IND studies or the OSRO Form F01-406-S02 for IDE/NSR studies.<br>If the PI is not an MD, then a Sub-Investigator with a medical license is required. |
| 33. | **IRB Reliance Agreement / Memo of Understanding (if applicable)** | To document the authority of the IRB of record. | |
| 34. | **OHRP Federal Wide Assurance** | To document the FWA of the IRB of record. | |
| 35. | **Source Location Record** | To document the location of source data for eCRF source data verification and source documentation/records for assessment of and adherence to the protocol. | |
| 36. | **Coordinating Center Communication Plan for Multicenter Clinical Trials** | To document the Points of Contact for study administrative and protocol-related topics, as well as the CCR Coordinating Center's oversight of the sites' conduct of the study. | As applicable |

| # | Document | Purpose | Comment or Clarification |
|---|---|---|---|
| 37. | **Manual of operational procedures (MOP) or standard operating procedures (SOPs) for clinical trial-related procedures, tests, assessments, and activities required per protocol but not detailed in the Protocol** | To document the procedures not detailed in the protocol. | |
| 38. | **NIH Office of Research Support and Compliance (ORSC) confirmation that manufacturing facilities are qualified (when applicable)** | To document that the NIH Clinical Center has approved the study product manufacturing facilities. | It is a PI's responsibility to ensure compliance with NIH ORSC requirements for qualification of manufacturing facilities. |
| 39. | **Significant communications other than site visit arrangements, i.e., memos, correspondence, meeting notes, telephone contact notes** | To document relevant communications. | |

6.6. Documents needed <u>during</u> the conduct of the trial.

6.6.1. The documents listed in Table 2 should be added to the study files listed in Section 6.5 as evidence that all new relevant information is documented as it becomes available.

*Table 2. Required documents during the trial.*

| # | Document | Purpose | Comment |
|---|---|---|---|
| 1. | Investigator's Brochure Updates | To ensure that the investigator is informed in a timely manner of relevant information as it becomes available. | Requested for observance only |
| 2. | Any Revision to:<br>• Protocol/amendment(s) and Case Report Forms<br>• Informed Consent form<br>• Any other written information to be provided to the participant(s)<br>• Advertisement for participant recruitment (if used) | To document revisions of these trial related documents that take effect during trial. | If an amendment requires CRF revision, the technical eCRF specifications and the revised or new blank case report form corresponding to the amendment must be submitted with documentation of Study Team Approval (a signed memo). |

| # | Document | Purpose | Comment |
|---|---|---|---|
| 3. | Dated, Documented Approval/Favorable Opinion of IRB of the following:<br>• Protocol amendments<br>• Revision(s) of:<br>  ○ Informed consent form(s)<br>  ○ Any other written information to be provided to the participant(s)<br>  ○ Advertisement for participant recruitment (if used)<br>• Any other documents given approval/favorable opinion<br>• Continuing review of trial (where required) | To document that the amendment(s) and/or revision(s) have been subject to IRB/IEC review and were given approval/favorable opinion. To identify the version number and date of the document(s). | • If the approved version-controlled documents are not detailed in the letter, the list of IRB submission attachments and approved documents must be included.<br>• Requirement for recruitment advertisements applies to non-NIH multicenter study participating sites. |
| 4. | Regulatory authorities Authorization/Approval/Notification of Protocol (where required) | To document compliance with applicable regulatory requirements. | |
| 5. | Curriculum Vitae for New Investigator(s) and/or Sub-investigator(s) and/or other relevant Documents Evidencing Qualifications of Investigators | To document qualifications and eligibility to conduct trial and/or provide medical supervision of participants. | Includes all investigators listed on the current **Form FDA 1572** for IND studies or **OSRO Form F01-406-S02 Investigator's Agreement** for IDE/NSR studies.<br>Staff identified as:<br>• Principal Investigator<br>• Sub-Investigators<br>The CV must include the investigator's signature and signature date. The signature date must be within four (4) years of the current date. |
| 6. | Updates to the Clinical Site Delegation of Authority Log | To document who has been authorized by the PI to carry out protocol-specific activities, tasks and functions.<br>To document who requires training on the protocol and related tasks, topics, and procedures. | Include updates to Log as needed.<br>However, if the PI changes, a **new** OSRO Clinical Site Delegation of Authority Log (OSRO Form F01-203-S01) initialed and signed by the new PI is required. |
| 7. | Updates to Signed Financial Disclosure Form for each Investigator listed in Form FDA 1572 or OSRO Form F01-406-S02 Investigator's Agreement for IDE | To document investigator financial interest and risk mitigation. | |

| # | Document | Purpose | Comment |
|---|---|---|---|
| 8. | Updates to Site Study Personnel Training Records following amendments or adding of new study personnel | To document site study personnel training pertinent to clinical research and, even more specifically to the clinical trial. | For new Staff only:<br>• Protocol<br>• HSP<br>• GCP<br>• Electronic data capture (EDC) system for non-NIH PI and Staff responsible for use of the EDC system.<br>• Study product preparation and handling, if applicable<br>• International Air Transport Association (IATA), if applicable<br>• Other, specialized procedures, if applicable |
| 9. | Updates to reference Normal Value(s)/Range(s) for Medical/Laboratory/Technical Procedures and/or Test(s) included in the Protocol | To document normal values and/or ranges that are revised during the trial. | |
| 10. | Updates of Medical/Laboratory/Technical Procedures/Tests<br>• Certification<br>• Accreditation<br>• Established quality control and/or external quality assessment<br>• Other validation (where required) | To document that tests remain adequate throughout the trial period. | |
| 11. | Updates to Source Location Record | To document the location of source data for eCRF source data verification and source documentation/records for assessment of and adherence to the protocol. | |
| 12. | Updates to Coordinating Center Communication Plan for Multicenter Clinical Trials | To document the CCR Coordinating Center's overall communication among all participating Sites and the Sponsor, as well as the general oversight of the study. | As applicable |
| 13. | Documentation of Investigational Product(s) and Trial-Related Materials Shipment | To document shipment dates, batch numbers and method of shipment of investigational product(s) and trial-related materials. Allows tracking of product batch, review of shipping conditions, and accountability. | |

| # | Document | Purpose | Comment |
|---|---|---|---|
| 14. | Certificate(s) of Analysis for New Batches of Investigational Product(s) | To document identity, purity, and strength of investigational product(s) to be used in the trial. | Only located in the essential document files of the Sponsor. |
| 15. | Monitoring Visit Reports | To document site visits by, and findings of, the monitor. | |
| 16. | Relevant Communications Other Than Site Visits<br>• Memos<br>• Correspondence e.g., letters, email<br>• Meeting notes<br>• Telephone contact notes | To document any agreements or significant discussions regarding trial administration, protocol deviations, trial conduct, serious adverse event (SAE) reporting. | |
| 17. | Signed Informed Consent Forms | To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each participant in trial. Also, to document direct access permission. | Only located in the essential document files of the Site.<br>Can be a description of the NIH Clinical Center informed consent process. |
| 18. | Source Documents | To document the existence of the participant and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of participant. | Only located in the essential document files of the Site.<br>Can be a description of the NIH Clinical Center medical records and research records standard process. |
| 19. | Signed, Dated, and Completed Case Report Forms (CRF) | To document that the investigator or authorized member of the investigator's staff confirms the observations recorded. | Can be a description of the NIH Clinical Center clinical data management standard process. |
| 20. | Documentation of CRF Corrections | To document all changes/additions or corrections made to CRF after initial data were recorded. | Can be a description of the NIH Clinical Center clinical data management standard process. |
| 21. | Notification by Investigator to Sponsor of Serious Adverse Events and Related Reports | Notification by investigator to sponsor of serious adverse events and related reports in accordance with GCP. | |
| 22. | Notification by Sponsor and/or Investigator, where applicable, to regulatory authority(ies) and IRB(s) of Unexpected Serious Adverse Drug Reactions, Unanticipated Adverse Device Effect and of other Safety Information | Notification by sponsor and/or investigator, where applicable, to regulatory authorities and IRB(s) of unexpected serious adverse drug reactions and of other safety information in accordance with GCP. | |
| 23. | Notification by Sponsor to Investigators of Safety Information | Notification by sponsor to investigators of safety information in accordance with GCP. | |

| # | Document | Purpose | Comment |
|---|---|---|---|
| 24. | Interim or Annual Reports to IRB and Regulatory Authority(ies) | Interim or annual reports provided to IRB in and to authority(ies) in accordance with GCP. | |
| 25. | Subject Screening Log | To document identification of participants who entered pre-trial screening. If not enrolled, reason is specified. | • Only located in the essential document files of the Site.<br>• At study closeout, a redacted version will be collected and retained in the Sponsor file. |
| 26. | Subject Identification Code List | To document that investigator/institution keeps a confidential list of names of all participants allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any participant. | Only located in the essential document files of the Site. |
| 27. | Subject Enrollment Log | To document chronological enrollment of participants by trial number. | • Only located in the essential document files of the Site.<br>• At study closeout, a redacted version will be collected and retained in the Sponsor file. |
| 28. | Investigational Products Accountability at the Site | To document that investigational product(s) have been used according to the protocol. | |
| 29. | Record of Retained Body Fluids/Tissue Samples (if any) | To document location and identification of retained samples if assays need to be repeated. | |
| 30. | Documentation of Investigational Product Destruction | To document destruction of unused investigational products by sponsor or at site. | |
| 31. | Investigational product storage temperature records | To document the product storage temperature. | |

| # | Document | Purpose | Comment |
|---|---|---|---|
| 32. | Protocol Deviation/Non-Adherence Reporting | To document non-adherence/deviation from the protocol as defined by the Sponsor. | The CCR sites should use the Protocol Deviation Tracking System (PDTS) online application to report all non-adherence/deviations from the protocol as defined by the Sponsor.<br><br>The non-NIH sites must use the OSRO Site Protocol Non-Adherence Log (OSRO Form F01-104-S02) to report all non-adherence/deviations. The cumulative Form F01-104-S02 must be submitted by the non-NIH site to the CCR Coordinating Center for their Coordinating Center review and submission to the Sponsor on the 1st of every month (unless otherwise specified). |
| 33. | Site Notes to the Study File | To document the site notes. | |

6.7. Documents needed after completion or termination of the trial.

6.7.1. All the documents identified in Sections 6.5 and 6.6 should be in the study file together with the documents listed in Table 3.

*Table 3. Required documents after trial completion or termination.*

| # | Document | Purpose | Comments |
|---|---|---|---|
| 1. | Investigational Product Accountability at Site | To document that the investigational product(s) have been used according to the protocol. To document the final accounting of investigational product(s) received at the site, dispensed to participants, returned by the participants, and returned to sponsor. | |
| 2. | Documentation of Investigational Product Destruction | To document destruction of unused investigational products by sponsor or at site. | |
| 3. | Completed Subject Identification Code List | To permit identification of all participants enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time. | Only located in the essential document files of the Site. |
| 4. | Audit Certificate (if available) | To document that audit was performed. | Only located in the essential document files of the Site. |
| 5. | Final Site Close-Out Monitoring Report | To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files. | |
| 6. | Treatment Allocation and Decoding Documentation | Returned to sponsor to document any decoding that may have occurred. | Only located in the essential document files of the Site. |
| 7. | Final Report by Investigator to IRB where required, and where applicable, to the Regulatory Authority(ies) | To document completion of the trial. | |
| 8. | Clinical Study Report | To document results and interpretation of trial. | |

6.8. For Nonsignificant Risk (NSR) Device studies, the following documents will be required:

6.8.1. Table 1 – Items: 1, 5, 10, 11, 12, 14, 15, 16, 19, 20, 21, 22, 25, 26, 27, 28, 29, 30, 32, 33, 34, 35, 36, 39

6.8.2. Table 2 – Items: 1, 2, 3, 5, 6, 8, 10, 11, 12, 13, 14, 15, 16, 17, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32

6.8.3. Table 3 – Items: 1, 2, 4, 5, 7, 8

## 7. Change Summary

| Revision Number | Effective Date | Description of Change |
|---|---|---|
| 1 | 19SEP2019 | New Document |
| 2 | 06FEB2020 | 1. Added Non-Significant Risk (NSR) device studies to Scope Step 2.2 and Policy Step 6.7.<br>2. Table 1. Identification of documents required before Site Initiation Visit and before Site Activation. Addition of comments column.<br>3. Tables 2 and 3. Addition of comments column.<br>4. Added hyperlinks to all references (Section 4 References). |
| 3 | 30Dec2022 | • Step 2.4.1 – updated<br>• Step 3.3 – added<br>• Section 4 – added Step 4.2 and updated hyperlinks<br>• Step 6.1 – added<br>• Step 6.8 – removed<br>• Step 6.8 – updated lists of documents required for NSR studies<br>• Updated document language and process as required |
| 4 | 31MAR2023 | Table 1, Number 32 changed from Principal Investigator and Sub-investigators to Medical Licenses. Purpose and Comment/Clarification text updated |
| 5 | TBD | 1. Step 6.5.2 – updated<br>2. Table 1, Number 6 required document text changed to "Financial Disclosure Form for each Investigator listed in Form FDA 1572 or OSRO Form F01-406-S02 Investigator's Agreement for IDE". Comment/Clarification text updated.<br>3. Table 1, Number 16 updated to current name of F01-203-S01 Clinical Site Delegation of Authority Log<br>4. Table 2, Number 6 updated to current name of F01-203-S01 Clinical Site Delegation of Authority Log<br>5. Table 2, Number 7 required document text changed to "Updates to Signed Financial Disclosure Form for each Investigator listed in Form FDA 1572 or OSRO Form F01-406-S02 Investigator's Agreement for IDE" |