**Study Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Study Offboarding Checklist**

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## Instructions

The purpose of this checklist is to ensure quality handoff on the elements needed for study maintenance. The study team should assign a study team member, preferably the study coordinator or project manager, the responsibility of tracking site readiness activities and maintaining this checklist on an ongoing basis.

**Read all documents and be prepared to discuss:**

* Protocol
  + - Objectives/Outcomes
    - Study Design
    - Eligibility Criteria
    - Recruitment Expectations and Procedures
    - Retention
* Operations Manual/Standard Operation Procedures/GCP Guidelines
  + - Informed Consent Procedures
    - Screening/Enrollment and Randomization
    - Active Treatment Phase
    - Follow-up Phase
    - Study Termination/Early Withdrawal
    - Reimbursement
    - Progress Notes/Study Documentation
    - Drug Accountability
    - Laboratory Procedures (collection/storage/shipping)
* Case Report Forms
  + - Direct-entered forms
    - Participant-entered forms
    - Procedures for completing CRFs when Electronic Data System is not operational
    - Source Documents
* Electronic Data System User's Guide

**Document the following:**

* Roles & Responsibilities of each Study Staff: create a table indicating who does what at your site (e.g., the study role and name of the person who draws blood) and be prepared to discuss during the study hand off.
* Study Procedures: briefly outline the operational flow of the study (no more than 2 pages, or flow chart). Review with outgoing coordinator and ensure all items can still function under incoming coordinator.
* Local IRB requirements regarding AE/SAE reporting: review with outgoing coordinator/ monitor
* Local IRB requirements regarding protocol violations: review with outgoing coordinator/ monitor

# Study Offboarding Checklist

**Study Name**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date started**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date of completion**: \_\_\_\_\_\_\_

**Incoming Coordinator (IC): \_\_ \_\_\_\_\_\_\_\_\_\_\_\_**

**Outgoing Coordinator(OC): \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**PI: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Department:\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Business Manager: \_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

# Administrative Tasks Not Applicable

| **Activity/Task** | **Completed?** | **Comments** | **N/A** |
| --- | --- | --- | --- |
| Add IC to Study Protocol in IRB system |  |  |  |
| Grant access for IC to institutional tracking system |  |  |  |
| Ensure IC has access to study in EMR (if applicable) |  |  |  |
| Inform IC of all relevant contacts for study |  |  |  |
| Ensure an updated copy of study SOP is available to IC (if one exists) |  |  |  |
| Ensure IC has all keys, building access, etc. required for study |  |  |  |
| Notify Sponsor/CRO of change |  |  |  |

# 

# Study Specific Access Not Applicable

| **Activity/Task** | **IC** | **Additional staff** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Grant access to EDC for IC and any backups |  |  |  |  |
| Grant access to IWRS to IC and any backups |  |  |  |  |
| Grant access to any study technology (site pads, phones, tablets, EKG, etc.) to IC and any backups |  |  |  |  |
| Grant access to study portal for IC and any backups |  |  |  |  |
| Grant access to lab portal/reports for IC and any backups |  |  |  |  |
| Grant access to safety reports portal for IC and any backups |  |  |  |  |

# 3.0 Study Status Not Applicable

| **Initiation Visits** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Local Pre-Initiation Visit Scheduled |  |  |  |  |
| Local Pre-Initiation Visit Conducted |  |  |  |  |
| Local Pre-Initiation Visit Action Items Resolved |  |  |  |  |
| Lead Site/Sponsor Initiation Visit Scheduled |  |  |  |  |
| Lead Site/Sponsor Initiation Visit Conducted |  |  |  |  |
| Lead Site/Sponsor Initiation Visit Action Items Resolved |  |  |  |  |
| Study Enrollment Started |  |  |  |  |
| EMR Lab Orders Requested |  |  |  |  |
| EMR Lab Orders Built |  |  |  |  |
| ClinCard Services Requested |  |  |  |  |
| ClinCard Services Completed and Cards Recieved |  |  |  |  |
| Clinic/Lab Services Requested |  |  |  |  |
| Clinic/ Lab Services Inserviced and Approved |  |  |  |  |
| Pharmacy Services Requested |  |  |  |  |
| Pharmacy Services Approved and Build Complete |  |  |  |  |

**4.0 Regulatory** Not Applicable

| **Activity/Task** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Obtain signed CV’s and training certificates (CITI) and send to study sponsor for IC and backups, file in site file |  |  |  |  |
| Obtain signature of IC and backups on DOA Log (once trained) |  |  |  |  |
| Ensure proper protocol training and documentation of training for IC and back ups |  |  |  |  |
| Add end date for OC to DOA log, ensure signed by OC (additionally add end date to shared calendar for reference) |  |  |  |  |
| Remove OC from IRB application |  |  |  |  |

# *4.1 Regulatory Files (that should be available at handoff)* Not Applicable

| **Name of Document** | **Location** | **Emailed to the Lead Site/ Sponsor** | **Present?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- | --- | --- |
| Copy of current IRB/IBC Approved Protocol on file |  | N/A |  |  |  |  |
| Copy of original IRB/IBC Approved Protocol v1.0 on file |  | N/A |  |  |  |  |
| Current Protocol Signature Page on file |  | Required |  |  |  |  |
| Protocol Change Log |  | N/A |  |  |  |  |
| Package Insert/ Investigator’s Brochure |  | N/A |  |  |  |  |
| Shipping Records for Study Supplies/Medication from Sponsor/Lead Site |  | N/A |  |  |  |  |
| Site Staff Delegation of Responsibilities and Signature Log |  | Required |  |  |  |  |
| FDA Form 1572 |  | Original Copy |  |  |  |  |
| Signed and Dated CVs for Investigators |  | Required |  |  |  |  |
| Appropriate Licenses for site staff, if required per study role (i.e., Medical Clinicians) |  | Required |  |  |  |  |
| Financial Disclosure Certifications for everyone listed on the FDA Form 1572 |  | Required |  |  |  |  |
| Training Plan on file |  | N/A |  |  |  |  |
| Copy of the Current IRB Approved Consent Form |  | Required |  |  |  |  |
| ICF Change Log |  | N/A |  |  |  |  |
| Copy of other participant agreement documents (HIPAA Authorization, CA Bill of Rights, W-9, and ROIs) |  | N/A |  |  |  |  |
| Certificate of Confidentiality |  | N/A |  |  |  |  |
| Other Regulatory Approvals, if applicable |  | Required |  |  |  |  |
| Initial IRB Submission |  | N/A |  |  |  |  |
| Any Amended Protocol IRB submissions |  | N/A |  |  |  |  |
| Federal Wide Assurance |  | Required |  |  |  |  |
| Data and Safety Monitoring Plan |  | N/A |  |  |  |  |
| Quality Assurance Monitoring Plan |  | N/A |  |  |  |  |
| Site Visit/Monitoring Log |  | N/A |  |  |  |  |

**5.0 Site Specific Processes and Procedures** Not Applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Standard Operating Procedures** | **Completed?** | **Date** | **Location** | **Not Applicable** |
| Informed Consent SOP |  |  |  |  |
| Recruitment SOP |  |  |  |  |
| Study Flow SOP |  |  |  |  |
| Emergency and Safety Management SOP *(document internal process for managing emergent safety related events, addressing how/by whom safety events might be identified, who must be contacted/consulted, and how events will be managed)* |  |  |  |  |
| Medication Management SOP *(document internal processes, including who receives, dispenses, and accounts for study medications, how it is stored, who has access, how/when it is returned/destroyed, etc.)* |  |  |  |  |
| Financial Management SOPs *(document internal processes for reviewing billing, invoicing sponsors, paying participants and/or service providers, etc.)* |  |  |  |  |
| Other SOPs, as needed, for local procedures if divergent from Operations Manual or not otherwise specified in protocol or Ops Manual |  |  |  |  |

**6.0 Study Medication** Not Applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Medication** | **Supplied by** | **Initial quantity/Location** | **On-hand or Completed** | **Not Applicable** |
| Study Medication Kits |  |  |  |  |
| Subject Materials for Administration |  |  |  |  |
| Temperature Log |  |  |  |  |
| Access to Fridge/ Freezer |  |  |  |  |

# 7.0 Supplies and Equipment Not Applicable

| **Supplies and Equipment** | **Supplied by** | **Initial/ minimum quantity/**  **Location** | **On-hand** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Gloves, gauze, surgical tape, alcohol wipes, and band aids (for blood draws and handling of urine samples) |  |  |  |  |
| Mounted measuring rod (for subject height) |  |  |  |  |
| Digital or Manual Scale (for subject weight) |  |  |  |  |
| Digital time |  |  |  |  |
| Blood pressure cuff/monitor |  |  |  |  |
| Stethoscope |  |  |  |  |
| Sani-wipes, cleaning supllies |  |  |  |  |
| Biohazard waste containers (sharps container, bags, etc.) |  |  |  |  |
| Refrigerator (for study medication storage) |  |  |  |  |
| Freezer for specimen storage (-20 or -70) |  |  |  |  |
| Exam table / paper |  |  |  |  |
| Lockbox / Safe |  |  |  |  |
| Participant compensation |  |  |  |  |
| Study specific technology |  |  |  |  |
| Digital thermometers |  |  |  |  |
| Urine Cups w/Temp Strips |  |  |  |  |
| Lab Kits |  |  |  |  |
| Shipping supplies (labels, boxes, cool packs, etc.) |  |  |  |  |
| Pipettes (bulk supply) |  |  |  |  |
| Fax machine / Scanner |  |  |  |  |
| Office Supplies (as needed) |  |  |  |  |

# 

# 7.1 Storage and Space Not Applicable

| **Storage and Space** | **Identified and Available?** | **Date** | **Comments/ Location** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Plan/space for storage of participant “data files” in locked and secure area |  |  |  |  |
| Plan/space for storage of participant “name files” in locked and secure area |  |  |  |  |
| Plan/space for storage of regulatory binders |  |  |  |  |
| Storage of participant compensation in locked, secure, limited access area |  |  |  |  |
| Storage of study medication in an appropriate (i.e. refrigerated etc.), locked, secure, limited access area |  |  |  |  |
| Adequate storage space for supplies |  |  |  |  |
| Private office space and/or interview rooms for conducting study visits |  |  |  |  |
| Space for physical exams and biological assessments, collection and processing (e.g., UDS, Blood draws, etc) |  |  |  |  |
| Space for monitoring visits |  |  |  |  |

# 7.2 Study Documentation and Related Supplies Not Applicable

| **Study Documentation and Related Supplies** | **Supplied by** | **Initial/ minimum quantity** | **On-hand** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- | --- |
| Name/PHI Files/Folders |  |  |  |  |  |
| Data Binders/Files/Folders |  |  |  |  |  |
| Screen Failure Binders/ Data |  |  |  |  |  |
| Master Enrollment Log File |  |  |  |  |  |
| Pre-Screen Master Log File |  |  |  |  |  |
| Other Study Logs (temperature, monitoring, compensation, drug accountability etc.) in place and ready for use. |  |  |  |  |  |
| Supply of IRB-approved consents/HIPAAs, Bill of Rights, and other required consent documents duplicated and on-hand |  |  |  |  |  |
| Supply of other IRB-Approved documents (including flyers, referral cards, appointment reminders, info sheets, etc.) duplicated and on-hand |  |  |  |  |  |
| Supply of ***paper*** CRFs, forms, visit checklists, and progress notes duplicated and on-hand |  |  |  |  |  |
| Paper copies of all eCRFs in case of computer/power malfunction. |  |  |  |  |  |
|  |  |  |  |  |  |

# 8.0 Study Participant Status Not Applicable

| **Activity/Task** |  |
| --- | --- |
| How many participants enrolled? |  |
| How many participants active? |  |
| How many screen fails? |  |
| Next upcoming visit dates: |  |
| Outstanding Subject Items (unreported events, deviations, items requiring follow up, etc.): |  |
| Location of subject tracker |  |

I affirm that the information on this sheet has been reviewed and is correct. All action items have been adequately addressed and the study is deemed ready to hand off.

Signature of Outgoing Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Incoming Coordinator: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_