# Study Implementation Checklist

|  |  |
| --- | --- |
| **Study Name**: | **Date started**: |
| **Completed by**: | **Date of completion**: |

# Study Registration Not Applicable

| **Activity/Task** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Obtain Institutional ID number |  |  |  |  |
| Study Team meeting to review Implementation Checklist and plan |  |  |  |  |

# Budget Development Not Applicable

| **Activity/Task** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Obtain PI and/or department approval for proposed budget/finalized billing plan |  |  |  |  |
| Obtain financial account number |  |  |  |  |

# Regulatory Not Applicable

| **Activity/Task** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Obtain signed CV’s and training certificates (CITI) and send to study sponsor |  |  |  |  |
| Obtain Lab certifications (CAP and CLIA) |  |  |  |  |
| Create staff delegation log and begin obtaining signatures |  |  |  |  |
| Draft Informed Consent and submit to sponsor (if applicable) |  |  |  |  |
| Draft study advertisements and submit to sponsor (if applicable) |  |  |  |  |
| Determine Study Participant Compensation method (if applicable) |  |  |  |  |
| Prepare IRB application |  |  |  |  |
| Prepare IBC application if required |  |  |  |  |
| IRB study approval obtained |  |  |  |  |
| IBC laboratory inspection completed if required |  |  |  |  |
| IBC study approval obtained if required |  |  |  |  |
| Assemble Regulatory Binder/Files (sponsored trial: regulatory binder provided) |  |  |  |  |
| Put study on clinicaltrials.gov if applicable |  |  |  |  |

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# *Regulatory Files* Not Applicable

| **Name of Document** | **Emailed to the Lead Site/ Sponsor** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- | --- |
| Copy of current IRB/IBC Approved Protocol 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 |  |  |  |  |

# Training Documentation Not Applicable

|  | **Completed?** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- |
| Study specific training completed by key personnel and documented on study training log or sponsor provided logs |  |  |  |
| Certificates of completion from sponsor training portals printed and filed |  |  |  |
| All staff have completed Human Subjects Protection (and GCP, if applicable) training/certification and are on file in the regulatory binder. HSP (& GCP) training certification must been current (completed within the past 3 years). |  |  |  |
| Biosafety/Biosecurity training modules completed (If IBC approval is required) |  |  |  |

**Personnel Access** Not Applicable

| **All Study Personnel:** | **Completed?** | **Date** | **Comments/ Names** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Staff granted access to electronic storage locations, as required |  |  |  |  |
| Staff granted access to physical storage locations, as required |  |  |  |  |
| Staff granted access to other Online Systems, as required: |  |  |  |  |
| Electronic Data Capture System (EDC) |  |  |  |  |
| Randomization/Dispensation system (e.g., IVRS, IWRS, IXRS, IRT) |  |  |  |  |
| Lab portal |  |  |  |  |
| Training portal |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Study Medication Not Applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Medication** | **Supplied by** | **Completed** | **Comments** | **Not Applicable** |
| Study Medication Kits |  |  |  |  |
| Storage confirmed |  |  |  |  |
| SOP |  |  |  |  |

# Ancillary Services Not Applicable

| **Activity/Task** | **Completed?** | **Comments**  **(date completed)** | **Not Applicable** |
| --- | --- | --- | --- |
| **Investigational Drug Services (IDS)**  IP on site (storage confirmed) |  |  |  |
| **Electronic Medical Record (EMR)** |  |  |  |
| Clinic In-service completed |  |  |  |
| **Participant remuneration (ClinCard, gift cards, etc) obtained** |  |  |  |
| Other Ancillary Services: |  |  |  |

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# Supplies and Equipment Not Applicable

*Add relevant supplies as received*

| **Supplies and Equipment** | **Supplied by** | **On-hand** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| EKG machine | Sponsor |  |  |  |
| Lab Kits and shippers | Sponsor |  |  |  |
| Tablets | Sponsor |  |  |  |
| Subject phone diaries | Sponsor |  |  |  |
| Digital scale | Sponsor |  |  |  |
| Pregnancy tests |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

# Study Documentation and Related Supplies Not Applicable

| **Study Documentation and Related Supplies** | **Supplied by** | **On-hand** | **Comments** | **Not Applicable** |
| --- | --- | --- | --- | --- |
| Develop source documents | Sites |  |  |  |
| Name/PHI Files/Folders | Sites |  |  |  |
| Data Binders/Files/Folders | Sites |  |  |  |
| Master Enrollment Log File | Sites |  |  |  |
| Pre-Screen Master Log File | Sites |  |  |  |
| Other Study Logs (temperature, monitoring, compensation, drug accountability etc.) in place and ready for use. | Sites |  |  |  |
| Supply of ***paper*** CRFs, forms, visit checklists, and progress notes duplicated and on-hand | Sites |  |  |  |
| Paper copies of all eCRFs in case of computer/tablet/power malfunction (if allowed by sponsor). | Sites |  |  |  |

# Storage and Space Not Applicable

| **Storage and Space** | **Identified and Available?** | **Date** | **Comments** | **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 |  |  |  |  |
| Confirm location for physical exams and biological assessments, collection and processing (e.g., UDS, Blood draws, etc) (indicate in comments)  *Note: confirm location is consistient if specified in protocol* |  |  |  |  |

**Site Specific Processes and Procedures** Not Applicable

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Standard Operating Procedures** | **Completed?** | **Date** | **Comments** | **Not Applicable** |
| **Required** | | | | |
| Informed Consent SOP |  |  |  |  |
| Recruitment SOP |  |  |  |  |
| Study Flow SOP |  |  |  |  |
| **Optional** | | | | |
| 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 |  |  |  |  |