SPONSOR-INVESTIGATOR IDE TRAINING: MODULE 3

GOOD CLINICAL PRACTICE (GCP), ESSENTIAL DOCUMENTS, & IDE TRIAL MASTER FILE

IND/IDE Support Program

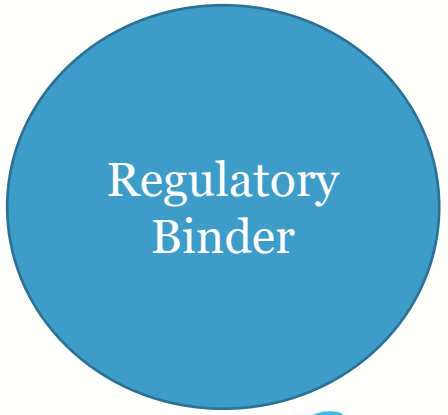
May 22, 2024

Children's Hospital of Philadelphia®

STUDY RECORDS

- Sponsor
  - IDE Maintenance
  - Selecting/Informing site investigators
  - Monitoring
  - Device Records/Control

- Investigator
  - Protocol Maintenance
    - Compliance
    - IRB review
  - Selecting/Informing subjects
  - Device Records/Control
  - Subject Case Histories



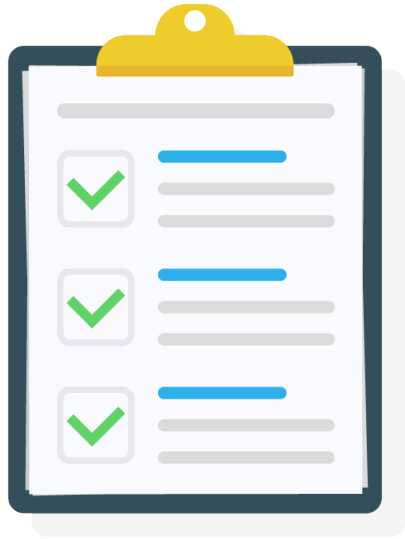
ESSENTIAL DOCUMENTS

- Essential Documents are study documents which:
  - Allow for the evaluation of the trial and of the data produced
  - Show that the Sponsor, Investigator, and Monitor all follow Good Clinical Practice (GCP) and other applicable regulatory requirements

- Are usually audited by monitors and inspected by the FDA to:
  - Ensure the study was conducted appropriately
  - Confirm data integrity

- Should be filed timely, as audits and inspections can happen at any time.

ESSENTIAL DOCUMENTS: ICH E6 SECTION 8



- The minimum list of essential documents is grouped according to the stage of the trial during which they will normally be generated:
  - before the clinical phase of the trial starts
  - during the clinical conduct of the trial
  - after completion or termination of the trial
- Description of each document and what it is for, as well as where it should be filed (sponsor files, institution files, or both)
- Some documents can be combined, as long as the data that was required for each form is collected on the combined document
- A trial master file for the IDE should be established at the beginning of the trial by the sponsor.

TRIAL MASTER FILE

- All of the essential documents (from all study sites), and documentation developed/created during the study
- Must be sufficient to adequately reconstruct
  - The trial activities
  - Key decisions made concerning the trial
- All versions of documents must be retained
- Documentation should be in chronological order
- Relevant regulatory and sponsor correspondence must be kept and filed.

STUDY REGULATORY BINDER/MASTER FILE

- Protocol
- Informed Consent
- FDA Correspondence
- IRB Correspondence
- Other Regulatory Approvals
- Clinical Procedures
- Research Procedures
- Device Information
- Device Accountability
- Training
- Study Personnel
- Subject Tracking and Recruitment
- Data Collection
- Safety Management and Reporting
- Monitoring
- Clinical Trials.gov
- Subject Case Histories
- External Audit Support
- Contracts/Agreements/Financial Documents

PROTOCOL MANAGEMENT

- This section of the regulatory binder/master file should have all versions of the protocol (starting with the initial version that had SRC, FDA or IRB approval).

Recommendations:

- Always download most current copy of protocol from 'Approved Documents' section of eIRB
- Useful study tracking tools may include:
  - Protocol tracking log
  - Unanticipated problems tracking and reporting form

Policies/Guidance:
ORC Unanticipated Problems Tracking and Reporting Guidance: Located in CHOP policy library under ORC
IRB Protocol Deviations: Located on CHOP IRB website

PROTOCOL MANAGEMENT

- For IDE Sponsors, amendments to the study protocol have more implications than just IRB reporting.
- Protocol amendments must also be submitted to the FDA and other applicable regulatory groups (for example, DSMB)
- There are also operational changes, such as updating all relevant study documents and re-training the study team.

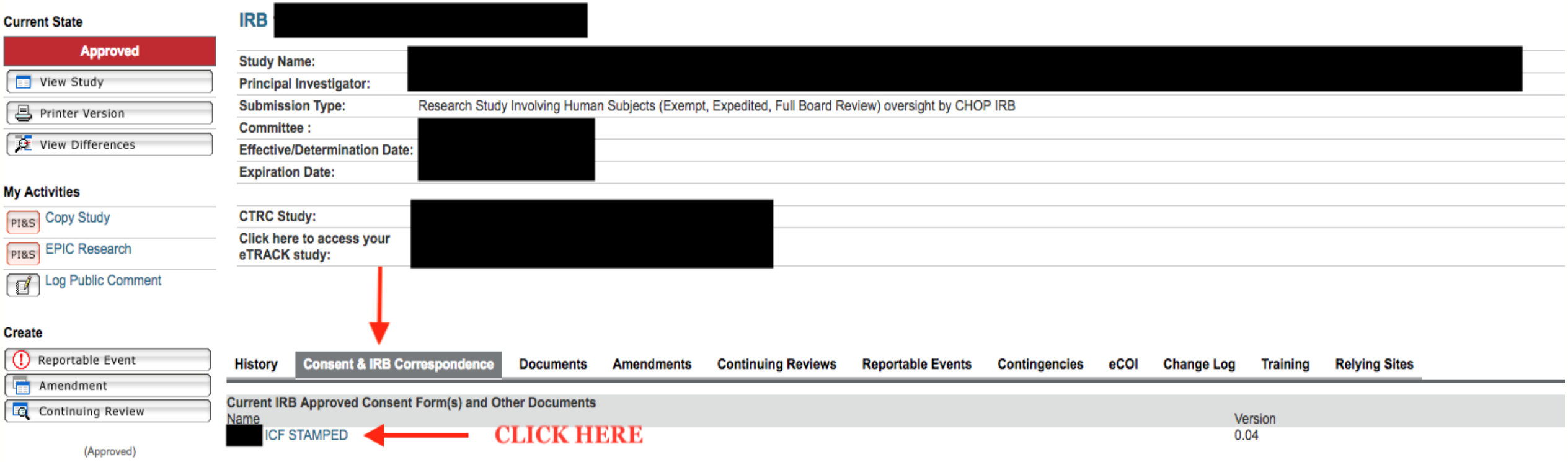
INFORMED CONSENT MANAGEMENT

- This section of the regulatory binder/master file should have:
  - All approved versions of the study informed consent form beginning with the initial FDA or IRB approved version.
  - Should include all translations and assent forms.
- IND/IDE Support Program recommendations:
  - IMPORTANT: When consenting and re-consenting subjects, ALWAYS download the IRB-approved stamped Informed Consent Form from within eIRB using the following pathway:
    - Log in to eIRB and click into your study link
    - Select the 'Consent & IRB Correspondence' tab
    - Select the link below the header 'Current IRB Approved Consent Form(s) and Other Documents'.
    - The IRB-approved ICF will open into a new webpage. You may now print this document.

Retain the ENTIRE SIGNED ICF, or entire electronic copy in the study records.

INFORMED CONSENT MANAGEMENT

Where do I find the IRB stamped ICF?



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TO RE-CONSENT OR NOT TO RE-CONSENT?

- When there are changes to the Informed Consent Form, the study team and IRB must evaluate the changes and determine if subjects on the study would need to go through the documentation of informed consent process with the new version of the consent.
- Typically, re-consent is required when there is a:
  - change in the risks,
  - study procedures, or
  - any other changes that may impact the subject's willingness to participate in the clinical investigation
- Re-consent requirement, imposed by the IRB if it is needed

ICF AMENDMENT AND TRIAL UPDATES

When an ICF amendment occurs, please be sure to:

- Update version and date of ICF and file tracked changes in the Trial Master File/Regulatory Binder
- Document if change requires re-consent and track re-consent using the re-consent tracking log
- File re-consent in the Subject's Case History file

FDA CORRESPONDENCE

This section of the regulatory binder/master file should have all correspondence from the FDA (email, phone, electronic and paper submissions).

The purpose of this section is to document:

- The trial is subject to FDA review and is conducted in accordance with the general investigational plan.
- The Sponsor is maintaining an effective IDE with respect to the investigations.
- Appropriate authorization has been obtained prior to initiation of the trial.
- Initial and ongoing compliance with applicable regulatory requirements (21 CFR 312.50 and 21 CFR 812.40).

FDA CORRESPONDENCE

Best Practices:

- An FDA correspondence tracking log is recommended to serve as a tool for managing and tracking all FDA correspondence, including document versions submitted to the FDA.
- For electronic organizational management, it is recommended that folders and files are named by some predetermined standardized naming convention. Take into consideration how these folders(or files) may be automatically sorted by the system.

SN_0000_11Feb2016 Initial Application	20160211 SN_0000 Initial Application
SN_0001_1Mar2016 CMC Info	20160301 SN_0001 CMC Info
SN_0002_8Aug2016 Protocol AMD	20160808 SN_0002 Protocol AMD
SN_0003_21Nov2016 Info AMD	20161121 SN_0003 Info AMD
SN_0004_22Feb2017 AR	20170222 SN_0004 AR
SN_0005_6Apr2017 Info AMD	20170406 SN_0005 Info AMD

FDA CORRESPONDENCE

- CHOP IND/IDE Support is the holder of the institutional record

- Sponsors at CHOP are required, per CHOP policy, to send all FDA correspondence to the IND/IDE Support Office: INDIDE@chop.edu
  - Sponsor should also let CRC/Program Manager know of any FDA correspondence

- CHOP Policy for Sponsors: IND and IDE Sponsor Requirements and Responsibilities Policy

FDA CORRESPONDENCE

The IDE Sponsor is responsible for reporting the following to the FDA:

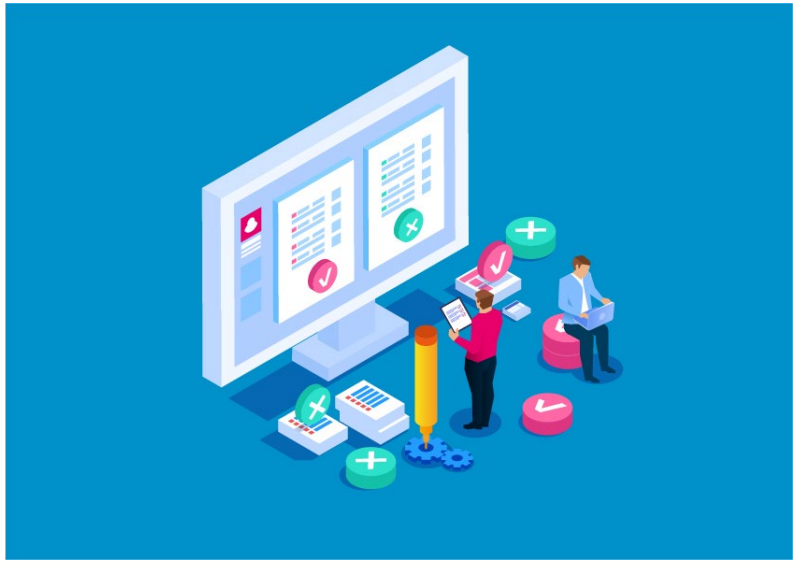
1. Change in protocol
2. Updates in safety information about the device
3. Updates in manufacturing, controls, or results of tests conducted on the device
4. Progress Reports / Annual Reporting, List of Investigators
5. Change in investigators or change in the Sponsor or Primary Point of Contact (PPOC) and/or address.
6. Transfer of Obligations
7. Completion or termination of a protocol under the IDE
8. New trials under the IDE
9. Closure or withdrawal of the IDE
10. Final Report

IRB CORRESPONDENCE

- This section of the regulatory binder/master file should have all correspondence with the IRB including, when applicable, full document versions.
- The purpose of this section is to:
  - Document that the trial has been subject to IRB review and has IRB approval.
  - Identify the version number and date of the document(s).
  - Document ongoing compliance with applicable regulatory requirements.
- Best Practices:
  - At a minimum include all IRB approval or acknowledgment letters and indicate that all IRB correspondence is maintained in the eIRB.

IRB CORRESPONDENCE

- The IDE investigator should report the following to the IRB:
  1. Change in protocol
  2. Change in ICF
  3. FDA Clinical Holds
  4. Changes in study procedures
  5. Changes in research procedures
  6. Changes in labeling of device
  7. Changes in use or accountability of the device
  8. New or removed study personnel
  9. Continuing Reviews including enrollment, safety reporting, and protocol deviations
  10. Unanticipated problems, Medical Monitor reports, Data Safety Monitoring Board reports, interim analysis results, and/or trial stopping rules met
  11. Transfer of obligations (including change in PI, transfer of IDE)



OTHER REGULATORY APPROVALS

- This section of the regulatory binder/master file should have:
  - All correspondence with the additional regulatory authorities including, when applicable, full document versions
  - Other approvals may include: IND/IDE SRC, CHOP PPRC, DSMB, or other agencies
- The purpose of this section is to document that the appropriate authorization/approval/notifications were obtained from the regulatory authority(ies) prior to start of the study
- Best Practices: Organize the correspondence by the regulatory authority

CLINICAL AND RESEARCH PROCEDURES

- This section of the regulatory binder/master file should have:
  - Certification of accreditation of facility or laboratory
  - Established quality control and/or
  - External quality assessment or other validation (where required)
  - Examples include: CLIA, CAP, Normal Ranges, Laboratory Manual, Sample Lab Requisition Form, and Schedule of Assessments
- The purpose of this section is to:
  - Document the normal values and reference ranges for the tests to be done during the course of the study.
  - To document ability of facility identified to perform test(s) required by the protocol and support reliability of results that come from that facility
- Best Practices: Organize by procedure or test

CLINICAL PROCEDURES

- Clinical laboratories require ongoing accreditation and validation, such as a new CLIA or a new CAP, so you will need to collect that documentation every 2 years for the entirety of the time that the study is ongoing.

- Note: If there are changes in study procedures or tests, that may require:
  - A supplement to the protocol (requiring submission to the IRB, FDA)
  - Update study Standard Operating Procedures, Laboratory Manual, and/or Sample Requisition Form

DEVICE INFORMATION

- Instructions for Use or Other Device Information
  - **Purpose:**
    - To provide relevant and current information about the proper use of the investigational product.

DEVICE INFORMATION

- Best Practices and other documents:
  - Any changes to the device safety profile, product suppliers, manufacturing, certificate of analysis, or additional controls or testing that are conducted either by the Sponsor or a third party must also be kept here.
- Examples:
  - Control Testing i.e., sterility, biocompatibility
  - Design History File
  - Manufacturing and Design Controls Document

DEVICE INFORMATION

- The IDE Sponsor is responsible for managing and tracking the following information and ensuring change control and reporting for:
  - Updates or making updates to the labeling information or Instructions for Use
  - Updates or making updates to the Manufacturing, and Design Controls
  - Results of sterility, biocompatibility, and leaching tests
  - Changes to any of the above device information may require updating study documents and possibly reporting to the IRB, FDA, etc.

STUDY PRODUCT ACCOUNTABILITY

Document	Purpose
Instructions for Use of IP/trial related materials	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of the investigational products and trial-related materials.
Sample of label(s) attached to study product containers	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects.
Shipping records for study and trial related materials	To document shipment dates, batch numbers and methods of shipment of investigational product(s) and trial related materials. Allows tracking of product batch, review of shipping conditions, and accountability.
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 subjects' treatment
Master randomization list	To document method for randomization of trial population
Investigational products accountability at the site	To document that investigational product(s) have been used according to the protocol.
Documentation of investigational product(s) destruction	To document destruction of unused investigational product(s) by sponsor or at site.

DEVICE ACCOUNTABILITY

- **Best practices and other documents:**
  - Accountability Log
  - Quarantine of Devices
  - Coordination with Supply Chain Management
  - Chain of Custody

- **Policies/Guidelines:** Located in the policy library under CRSO, ORC & IDS policies

DEVICE ACCOUNTABILITY

The IDE Sponsor is responsible for managing and tracking the following information and ensuring change control and reporting for:

Instructions for Use of investigational products and trial-related materials

- Sample of label(s) attached to investigational product containers
- Shipping records for investigational product(s) and trial-related materials
- Decoding procedures for blinded trials
- Master randomization list
- Investigational products accountability at the site
- Documentation of investigational product(s) destruction
- Ordering and Implanting Procedures

Changes to any of the above device accountability information may require updating study documents and possibly reporting to the IRB, FDA, and any other applicable regulatory bodies.

TRAINING

- The Sponsor is responsible for providing and documenting appropriate training of all relevant personnel, consultants, team members, and collaborators. Training may be in person, virtual or via other methods such as email.
- This section of the regulatory binder/master file should have:
  - All documentation of training during the course of a study, including but not limited to site initiation visit training documentation, study team meeting minutes, training records for study staff, pharmacy staff, lab staff, etc.
    - Documentation could be a meeting attendance sign in sheet, meeting minutes, telephone contact log, or email confirmation or receipt/review of training materials.

TRAINING

- The purpose of this section is to document:
  - That trial procedures were reviewed with the investigator and investigator's trial staff, prior to them starting their trial related responsibilities (as listed on the delegation of authority log)
  - The site is suitable for the trial
- Best Practices:
  - Schedule (and document) Regular Team Meetings
  - Communication is KEY

STUDY PERSONNEL QUALIFICATIONS AND DELEGATIONS

- This section should include:
  - Signature and Delegation of Responsibility Log
  - CVs, Medical Licenses, Applicable Training Records for Investigator and Sub-Investigators and staff listed in the Signature and Delegation of Responsibility Log

- The purpose of this section is to:
  - Document the qualifications and eligibility of Sponsor and Investigators/Sub-Investigators to conduct the trial and/or provide medical supervision of subjects.
  - Document signatures and initials of all persons authorized to make entries and/or corrections on CRFs (on the Signature and Delegation of Responsibility Log)
  - Document agreement to follow the IDE investigational plan and protocol

STUDY PERSONNEL QUALIFICATIONS AND DELEGATIONS

- The IDE Sponsor is responsible for qualifying and delegating personnel for the conduct of the trial
- When new personnel are added, or personnel are changed or removed, next steps include:
- Report new personnel to IRB
- Make required updates to the Signature and Delegation of Responsibility Log
- Any change impacting the Investigator Agreement should be reported to the FDA

SUBJECT TRACKING AND RECRUITMENT

The IDE Sponsor is responsible for ensuring accurate trial-related subject tracking and recruitment. This section should include:

Subject Tracking and Recruitment Section	
Subject Screening Log	This log documents the subjects who entered the screening phase
Subject Identification Code List	This list links the subject identifier/trial number to the individual subject's protected health information/identity
Subject Enrollment Log	This is a log of chronological enrollment of subjects by trial number
Recruitment Materials	The materials that were approved for recruitment of subjects to the trial

SUBJECT TRACKING AND RECRUITMENT

Subject tracking information is included in FDA Annual Progress Report

- A subject tracking log should contain:
  - age at consent,
  - race,
  - ethnicity.
- Subjects who were discontinued or completed the study should be reported, along with the date and reason (as applicable).

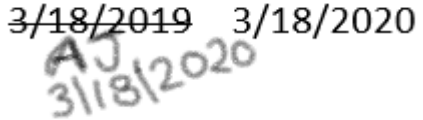
Policies/Guidances:

ORC Subject Outreach Activities: Located in the policy library under ORC policies

FDA Guidance Collection of Race and Ethnicity Data in Clinical Trials Sept. 2005

DATA COLLECTION & MANAGEMENT

- The IDE Sponsor is responsible for ensuring timely and accurate data collection and management.
- Applicable documents:
  - Case Report Forms (current/prior versions)
  - Data Entry Procedures
  - Data Security
  - Data Use agreements
- What is the purpose of data collection/management?
  - To ensure the accuracy, completeness, legibility and timeliness of the data.
  - Ensure consistency with source documents, and that any discrepancies are explained
  - To track and document data collection tools and management in accordance with local and federal requirements.
  - **Changes should not obscure the original entry and should be dated, initialed, and explained**



DATA COLLECTION & MANAGEMENT

Resources for CRF or Electronic Database Capture Forms & Management	
CHOP Center for Biomedical Informatics (CBMi)	
Clinical Reporting Unit	Extract data for analysis, import subjects to REDCap, build registries, recruitment, extract data from EPIC, identify matched controls.
REDCap	Guidance for design (for fee), user help, randomization tool, double data entry for QA, import data from excel, monthly user group open meetings.
OnCore	Resources for creation or use of EDC databases for research.
Westat	Primary data collection design (for fee).

DATA COLLECTION & MANAGEMENT

- If there is a protocol amendment that impacts data management procedures/processes, the following should be updated (as applicable):
  - Case Report Forms
  - Data Entry Procedures
  - Data Security
  - Monitoring Plan
  - Data Safety Monitoring Board Charter
- Contact OTT (techtransfer@chop.edu) for changes or new Data Use agreements

SAFETY MANAGEMENT & REPORTING

The IDE sponsor is responsible for the ongoing safety evaluation of the study device, including submitting all safety and reports to regulatory authority(ies) as required.

The sponsor should promptly notify all investigators, and applicable regulatory authority(ies) of findings that could affect the safety of subjects, impact the conduct of the trial, or alter the IRB approval or decision to continue the trial.

- Includes adverse events that are “serious” and “unexpected."

Documents:

- SAE/Adverse Event Log
- Interim Analysis
- Data Safety Monitoring Board correspondence, reports, and meeting minutes
- Medical Monitor correspondence, reports, and meeting minutes
- Trial Stopping Rules Tracking

MONITORING

- The IDE Sponsor is responsible for ensuring trial-related data collection and management
- The purpose of this section is to document site visits and findings by the monitor
- Documents that should be in this section are:
  - Monitoring Plan
  - Data Safety Monitoring Board Charter
  - Monitoring Log
  - Monitoring visit reports and responses

CLINICALTRIALS.GOV REGISTRATION

- The IDE Sponsor is responsible for ensuring timely updates and trial registration with **Clinicaltrials.gov** which include:
  - Registration updates every 6 months
  - Results data (if applicable)

Contact ORC for questions at ORC@chop.edu

SUBJECT CASE HISTORY TEMPLATE

- The IDE Sponsor is responsible for maintaining and updating subject case histories.

- Recommended documents for this section include:
  - Signed informed consent forms, visit checklists, eligibility checklists, source documents, adverse event logs, device accountability log, specimen tracking log, subject stopping rules tracking.

- Update the following documents if/when applicable with protocol supplements:
  - Eligibility Checklists
  - Visit Checklists
  - Subject Stopping Rules Tracking
  - Adverse Event Tracking
  - Device Accountability Log
  - Specimen Source Documentation

SUBJECT CASE HISTORY TEMPLATE

- Signed informed consent forms:
  - **Purpose:** To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each trial subject.
- Source documents:
  - **Purpose:** To collect source data, defined in ICH-GCP as all information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial.
- Signed, dated, and completed case report forms (CRFs):
  - **Purpose:** To document that the investigator or authorized member of the investigator's staff confirms the observations recorded.
- Documentation of CRF corrections:
  - **Purpose:** To document all changes/additions or corrections made to CRF after initial data were recorded.

Policies/Guidances: Located in the CHOP policy
ORC Making Corrections to Research Case Report Forms
ORC Eligibility Documentation Guidance and Eligibility Checklist

ADDITIONAL AUDIT SUPPORT

- ORC Quality Assurance (QA) Monitoring Team provides guidance and support for audit preparation and management.

- Center for Childhood Cancer Research (CCCR) (Oncology only) provides guidance and support for audit preparation and management.

- **Policies/Guidances:** Located in the CHOP policy library under ORC
  - ORC Site Inspections by Regulatory Agencies

CONTRACTS/AGREEMENTS/FINANCIAL DOCUMENTS

- The IDE Sponsor is responsible for ensuring that contracts/agreements/financial documents are current and the trial is in compliance.
- Update the following documents if/when applicable protocol amendment:
  - Contact Clinical Trial Finance Management (CTFM) to review protocol amendments for budget changes
  - Contact research contracts to review protocol amendments if it impacts the Clinical Trial Agreement (CTA)
  - Contact Supply Chain and Office of Technology Transfer (OTT) for Business Associate Agreements
  - Transfer of Obligations
  - Confidential Disclosure Agreement

CONTRACTS/AGREEMENTS/FINANCIAL DOCUMENTS

What would go in this section?

- Financial Disclosures
- Clinical Trials Agreements (CTAs)
- Transfer of Obligations
- Confidential Disclosure Agreement

Contact CHOP Office of Compliance and Privacy via email COI@chop.edu for information on:

- Conflict of Interests
- Business Associate Agreements

Policies/Guidances: Located in the CHOP policy library

- COI Standard Operating Policies
- Conflict of Interest Policy

FINANCIAL DISCLOSURES

- The IDE Sponsor is responsible for ensuring collection and reporting of financial disclosures for marketing applications and also to report it to the FDA.
- Anyone who is directly involved in the treatment or evaluation of research subjects and their spouses and dependent children would complete this. Questions include:
  - Compensation that could be affected by study outcome
  - Proprietary interest in the tested product (patent, trademark, copyright, or licensing agreement)
  - Equity interests in the sponsor (i.e. ownership interests, stock options, or other financial interests who value cannot be determined through reference to public prices)
  - Any equity interest in a publicly held company that exceeds $50,000
- When is this done?
  - Required prior to study initiation (at CHOP this is completed electronically)
  - Update annually up to 1 year after trial completion

CHOP RESOURCES: *PRE-STUDY*

CHOP Resources	
Office of Collaborative and Corporate Research Contracts (OCCRC)	• Confidential Disclosure Agreements • Material Transfer Agreements • Clinical Trial Agreements • Intellectual property management and technology commercialization • Contact: techtransfer@chop.edu
Clinical Research Support Office (CRSO)	• Research Staffing Core • Clinical Trials Financial Management • Oncore Clinical Trial Management System Support • RedCap Support • Recruitment Enhancement Core (REC) • IND/IDE Support

CHOP RESOURCES: *PRE-STUDY*

CHOP Resources	
CHOP Institutional Review Board (IRB)	IRB webpage (https://irb.research.chop.edu) for • Protocol templates • Informed consent templates
Clinical Trials Financial Management (CTFM)	• Prepares "Pricing Requests" for "Patient Care" costs for non-industry proposals for grants and budget proposals. • Can review finalized protocols and informed consents for billable procedures and submission (upon request). • Reviews protocol amendments, upon request, for budget implications • Contact: CTFM@chop.edu
Sponsored Projects and Research Business Management	• Grants/Award management, negotiation and subcontracting Budget creation support • Institutional approvals and signatures • Contact Brent Bell at bellb@chop.edu, 267-425-0509 • Find your Pre- and Post- Award team at https://sprbm.research.chop.edu/ or email stokes@chop.edu

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BIOSTATISTICAL SUPPORT

- **CHOP Biostatistics and Data Management Core (BDMC)**
  - Free consults and PhD statisticians for percent effort
  - Visit: https://www.research.chop.edu/biostatistics-data-management/contact

- **Westat**
  - Free consults from BS/PhD statisticians
  - Other services available

OTHER RESOURCES

Other Resources	
Translation and Language Services Program	
Interpreter Services	Visit: https://www.chop.edu/services/language-services
CHOP Shipping Core	Contact: researchshippingcore@chop.edu
Supply Chain	Contact: supplychain@chop.edu

CLOSING A STUDY

CLOSING OUT A STUDY

- Notify ORC of Plans to Close Study
- Final Monitoring Visit
- Close the study with the IRB
- ClinicalTrials.gov
- Notify other regulatory bodies
- Device Accountability
- Device Destruction
- Blinding/Decoding Documentation
- File the Final Subject ID List
- Records Maintenance
- Notify FDA – Close Out/Withdrawal Submission

FDA CORRESPONDENCE

- Close-Out/Withdrawal Report
  - To document the results and interpretation of trial
  - Detailed report of entire study and results
  - Notify FDA of next plan or withdrawal of IDE

  For templates, forms, and guidance please reach out to INDIDE@chop.edu

IRB AND OTHER REGULATORY GROUPS

- IRB Correspondence
  - Close the study with the IRB
- Other Regulatory Approvals
  - Close the study with all other regulatory bodies
- Research Procedures
  - Ensure all samples are maintained/batched for analysis in accordance with the study protocol.

SUBJECT TRACKING, DATA AND SAFETY MANAGEMENT

- Subject tracking and recruitment
  - Completed subject ID Code List should be filed
- Data collection and management
  - Final versions of applicable documents should be filed
- Safety management and reporting
  - Final versions of applicable documents should be filed.
  - If trial stopped due to safety prompt notification to the IRB and FDA is required

MONITORING, REGISTRATION, SUBJECT CASE HISTORIES

- Final trial close-out monitoring report should be filed:
  - To document that all activities required for trial close-out are completed, and copies of essential documents are held in the appropriate files
  - A final close-out of a trial can only be done when the monitor has reviewed both investigator/institution and sponsor files and confirmed that all necessary essential documents are in the appropriate files.

- Clinical trials.gov registration
  - If applicable, post trial results ***within 12 months of primary completion date***
  - Contact ORC mailbox: ORC@chop.edu

- Subject case history template
  - Maintain in accordance with CHOP Record Retention Policy, up to 10 years after the age of 18.
  - CHOP Policy No. A-3-9: Retention and Destruction of Records

EXTERNAL AUDIT SUPPORT, CONTRACTS & AGREEMENTS

- External Audit Support
  - If a 510(k) or PMA is submitted and the trial supports the labeling of the device, the FDA will inspect records prior to approval.

- Contracts/Agreements/Financial Documents
  - Check all contracts/agreements to ensure all key stakeholders are informed according to contract.

NEXT STEPS FOR SPONSOR

- Finish Training
  - CITI GCP
  - CHOP Modules
- Create TMF/Regulatory Binder
  - File all essential documents
  - Create any SOPs
- Identify, train and delegate appropriate staff
  - Document training and delegation
- Obtain all regulatory approvals
  - IRB, FDA, others
- Schedule ORC Pre-Trial Monitoring Visit

REFERENCES

- ICH E6 Section 8 Essential Documents for the conduct of a clinical trial
  - http://ichgcp.net/8-essential-documents-for-the-conduct-of-a-clinical-trial

Gregory M Podsakoff, M.D.

Digitally signed by Gregory M Podsakoff, M.D.
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