Study Management
SM – 303.02

STANDARD OPERATING PROCEDURE FOR
Document Development and Change Control

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1. INTRODUCTION AND PURPOSE

Federal regulations require documentation of all study-related activities. This standard operating procedure (SOP) describes the steps Georgia CORE follows to fulfill all regulatory and clinical requirements for creating, collecting, reviewing, filing and storing study-related documents and records.

2. SCOPE

This SOP applies to the activities involved in establishing and maintaining the regulatory records for all clinical studies subject to investigational new drug (IND) regulations for

drugs and biologics and those which are IND exempt during all investigational phases of development.

3. APPLICABLE REGULATIONS AND GUIDELINES

The Code of Federal Regulations and the International Conference on Harmonization, Good Clinical Practice: Consolidated Guideline and selected program and guidance documents apply to this SOP (Appendix A).

4. REFERENCES TO OTHER APPLICABLE SOPS

GA-102 Sponsor Responsibility and Delegation of Responsibility
SS -204 Site Initiation Visit (SIV)
SM-304 Routine Monitoring Visits
SM-305 Closeout Visits
DM-401 Data Management
QA-601 Audits by Third Parties

5. ATTACHMENTS

A. Adapted Summary of International Conference on Harmonization (ICH) Essential Documents; Good Clinical Practice: Consolidated Guideline
B. Georgia CORE Regulatory Master File Structure

6. RESPONSIBILITY

This SOP applies to those members of Georgia CORE involved in clinical trials.

- Georgia CORE and all Georgia CORE Research Network Investigators and Subinvestigators are responsible for ensuring that complete and precise data are collected, documented, and maintained throughout the course of a clinical study involving human subjects.
- The Georgia CORE Designee (monitor) is responsible for verifying that the files are complete, accurate and securely maintained by the Research Network Investigator and Subinvestigators, and site research staff.
- Georgia CORE is responsible for terminating the participation of and discontinuing shipments of investigational product to any participating Georgia CORE Research Network Investigator or Subinvestigator who has failed to maintain or make available required records or reports of the study.

7. DEFINITIONS

The following definitions apply to this SOP (Appendix B):
Case Report Form (CRF)
Compliance (in relation to trials)
Confidentiality
Contract
Direct Access
Documentation
Essential Documents

Good Clinical Practice
Investigator
Inspection
Monitoring
Protocol
Protocol Amendment
Quality Assurance (QA)
Source Documents
Sponsor

8. PROCESS OVERVIEW

A. Collecting, filing and storing study-related documents and records
B. Monitoring the site(s) regulatory files

9. PROCEDURES

A. Collecting, filing and storing study-related documents and records

Georgia CORE Staff/ Consultants

For each study, create a Regulatory Master File (RMF) for documents created and used throughout the course of the study.

- The RMF may be a series of paper and/or electronic file folders and/or in a binder.
- If more than one system is used for a study, enter a note into the electronic file to document the location of any documents not maintained electronically. (Attachment A, Adapted Summary of ICH Essential Documents; Attachment B, Regulatory Master File Structure).

Maintain and update the RMF as necessary, adding appropriate documents as they are generated or received.

Retain copies of all original and revised documents (e.g., protocol, investigator's brochure, informed consent form). To ensure the current version is always used, save previous versions of documents in the archive section of each folder.

Ensure regulatory files are kept confidential and are stored in a secure, limited-access location.

Prior to site monitoring visits, review content of the RMF for completeness.

Ensure that files are organized and complete following the visit.

When the study is over, review the contents of the RMF for completeness by comparing with the adapted summary of the ICH Essential Documents and the RMF structure

document. In addition to the documents maintained in the RMF during the course of the study, the following documents will be included after study closure or termination:

- Investigational product(s) accountability forms
- Documentation of investigational product destruction, if applicable
- Audit certificates and reports/FDA inspection reports
- Final study closeout monitoring report(s)
- Treatment allocation and decoding documentation, if applicable
- Final study reports sent to the respective IRB(s)
- Clinical study report

Archive the RMF in appropriate storage containers.

Label storage containers clearly and completely.

Document inventory of storage containers.

Store in a secure location for the required period of time.

B. Monitoring site regulatory files

Georgia CORE Staff/ Consultants	At the site initiation visit, routine monitoring visits, and site closeout visit, review the participating site's regulatory file(s) to ensure they contain the appropriate documents, completed as applicable. (Attachment A, Adapted Summary of ICH Essential Documents).

10. History of Changes

Version Number	Section Number	Modification	Approval Date
303.00	All	Original Version	
303.01	3	Updated references and federal guidelines	09 March 2012
303.01	All	No changes necessary	01 July 2014
303.01	All	No changes necessary	17 March 2017
303.02	All	Edit for clarity	30 June 2020

ATTACHMENT A:
Adapted Summary of International Conference on Harmonization (ICH) Essential Documents: Section 8 of ICH, Good Clinical Practice: Consolidated Guideline (Appendix B)

"The minimum list of essential documents which has been developed follows. The various documents are grouped in three sections according to the stage of the trial during which they will normally be generated: 1) before the clinical phase of the trial commences, 2) during the clinical conduct of the trial, and 3) after the completion or termination of the trial. A description is given of the purpose of each document, and whether it should be filed in either the investigator/institution or sponsor files, or both. It is acceptable to combine some of the documents, provided the individual elements are readily identifiable.

Trial master files should be established at the beginning of the trial, both at the investigator/institution's site and at the sponsor's office. 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 documents are in the appropriate files.

Any or all of the documents addressed in this guideline may be subject to, and should be available for, audit by the sponsor's auditor and inspection by the regulatory authority(ies)." P. 41 'Essential Documents for the conduct of a clinical trial' Summary of International Conference on Harmonization (ICH) Good Clinical Practice: Consolidated Guideline (Appendix B).

A. Before the Clinical Phase of the Trial Commences

During this planning stage the following documents should be generated and should be on file before the trial formally starts.

	Title of Document	Purpose	Location of Files: Research Network/ Site	Location of Files: Sponsor
1	**INVESTIGATOR BROCHURE**	To document that relevant and current scientific information about the investigational product has been provided to the investigator.	X	X
2	**SIGNED PROTOCOL, AMENDMENTS, IF ANY, & SAMPLE CRF**	To document investigator and sponsor agreement to the protocol/amendment(s) and CRF.	X	X
3	**INFO. GIVEN TO TRIAL PARTICIPANT**		X	X
	- INFORMED CONSENT FORM(S)	To document the informed consent(s); including all applicable translations.	X	X
	- ANY OTHER WRITTEN INFORMATION	To document that subjects will be given appropriate written information (content and wording) to support their ability to give fully informed consent.	X	X
	- ADVERTISEMENT FOR PARTICIPANT RECRUITMENT (if used)	To document that recruitment measures are appropriate and not coercive.	X	X
4	**FINANCIAL ASPECTS OF THE TRIAL**	To document the financial agreement between the investigator/institution and the sponsor for the trial.	X	X
5	**INSURANCE STATEMENT** (where required)	To document that compensation to subject(s) for trial-related injury will be available.	X	X
6	**SIGNED AGREEMENT BETWEEN INVOLVED PARTIES**	To document agreements. e.g.: investigator/institution and sponsor	X	X
7	**DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF INSTITUTIONAL REVIEW BOARD (IRB) OF THE FOLLOWING:** - protocol and any amendments - informed consent form(s) - any other written information to be provided to the subject(s) - advertisement for subject recruitment (if used) - subject compensation (if any) - 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). Also include any other relevant correspondence with the IRB.	X	X

	Title of Document	Purpose	Location of Files: Research Network/ Site	Location of Files: Sponsor
8	**IRB COMPOSITION**	To document that the IRB is constituted in agreement with GCP.	X	X
9	**REGULATORY AUTHORITIES AUTHORIZATIONS/APPROVALS/ NOTIFICATIONS OF PROTOCOL** (where required)	To document appropriate authorization/approval/notification by the regulatory authority(ies) has been obtained prior to initiation of the trial in compliance with the applicable regulatory requirement(s).	X	X
10	**CURRICULUM VITAE (CV) AND/OR OTHER RELEVANT DOCUMENTS EVIDENCING QUALIFICATIONS OF INVESTIGATOR(S) AND SUB-INVESTIGATOR(S) FORM FDA 1572**	To document qualifications and eligibility to conduct trial and/or provide medical supervision of subjects. Include CVs, medical licenses and financial disclosures. A copy of the signed original FDA Form 1572 Statement of Investigator listing the name of the investigator and any sub-investigators, if applicable as submitted to the IRB.	X	X
11	**NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/ LABORATORY/TECHNICAL PROCEDURE(S) AND/OR TEST(S) INCLUDED IN THE PROTOCOL**	To document normal values and/or ranges of the tests.	X	X
12	**MEDICAL/LABORATORY/TECHNICAL PROCEDURES /TESTS** - certification or - accreditation or - established quality control and/or external quality assessment or - other validation*	To document competence of facility to perform required test(s), and support reliability of results.	X	X
13	**SAMPLE OF LABEL(S) ATTACHED TO INVESTIGATIONAL PRODUCT CONTAINER(S)**	To document compliance with applicable labeling regulations and appropriateness of instructions provided to the subjects.		X
14	**INSTRUCTIONS FOR HANDLING OF INVESTIGATIONAL PRODUCT(S) AND TRIAL-RELATED MATERIALS** (if not included in protocol or Investigator Brochure)	To document instructions needed to ensure proper storage, packaging, dispensing and disposition of investigational products and trial-related materials.	X	X
15	**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.	X	X
16	**CERTIFICATE(S) OF ANALYSIS OF INVESTIGATIONAL PRODUCT(S) SHIPPED**	To document identity, purity, and strength of investigational product(s) to be used in the trial.		X

	Title of Document	Purpose	Location of Files: Research Network/ Site	Location of Files: Sponsor
17	**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.	X	X **
18	**MASTER RANDOMIZATION LIST**	To document method for randomization of trial population.		X **
19	**PRE-TRIAL MONITORING REPORT**	To document that the site is suitable for the trial (may be combined with #20).		X
20	**TRIAL INITIATION MONITORING REPORT/TRAINING LOGS**	To document that trial procedures were reviewed with the investigator and the investigator's trial staff (may be combined with #19) and any ongoing training.	X	X

B. During the Clinical Conduct of the Trial

In addition to having on file the documents in section A, the following should be added to the files during the trial as evidence that all new relevant information is documented as it becomes available.

	Title of Document	Purpose	Located of Files: Research Network Site	Located of Files: Sponsor
1	**INVESTIGATOR BROCHURE UPDATES**	To document that investigator is informed in a timely manner of relevant information as it becomes available.	X	X
2	**ANY REVISION TO:** - protocol/amendment(s) and CRF - informed consent form - any other written information provided to subjects - advertisement for subject recruitment (if used)	To document revisions of these trial related documents that take effect during trial.	X	X
3	**DATED, DOCUMENTED APPROVAL/ FAVORABLE OPINION OF IRB OF THE FOLLOWING:** - protocol amendment(s) - revision(s) of: - informed consent form - any other written information to be provided to the subject - advertisement for subject recruitment (if used) - any other documents given approval/favorable opinion - continuing review of trial*	To document that the amendment(s) and/or revision(s) have been subject to IRB review and were given approval/favorable opinion. To identify the version number and date of the document(s).	X	X
4	**REGULATORY AUTHORITY(IES) AUTHORIZATIONS/APPROVALS/ NOTIFICATIONS WHERE REQUIRED FOR:** - protocol amendment(s) and other documents	To document compliance with applicable regulatory requirements.	X	X
5	**CVs FOR NEW INVESTIGATOR(S) AND/OR SUB-INVESTIGATOR(S)** **FORM FDA 1572**	(see A #10). Also updated CVs, medical licenses, and Form FDA 1572 as required.	X	X
6	**UPDATES TO NORMAL VALUE(S)/RANGE(S) FOR MEDICAL/LABORATORY/ TECHNICAL PROCEDURE(S)/TEST(S) INCLUDED IN THE PROTOCOL**	To document normal values and ranges that are revised during the trial (see A #11).	X	X

	Title of Document	Purpose	Located of Files: Research Network Site	Located of Files: Sponsor
7	**UPDATES OF MEDICAL/LABORATORY/ TECHNICAL PROCEDURES/TESTS** - certification or - accreditation or - established quality control and/or external quality assessment or - other validation (where required)	To document that tests remain adequate throughout the trial period (see A #12).	X	X
8	**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.	X	X
9	**CERTIFICATE(S) OF ANALYSIS FOR NEW BATCHES OF INVESTIGATIONAL PRODUCTS**	To document identity, purity, and strength of investigational product(s) to be used in the trial.		X
10	**MONITORING VISIT REPORTS**	To document site visits by, and findings of, the monitor.		X
11	**MONITORING LOG**	To document each visit from the sponsor, the log sheet is signed and dated by all sponsor personnel and the purpose of the visit is noted.	X	
12	**RELEVANT COMMUNICATIONS OTHER THAN SITE VISITS** - letters - meeting notes - notes of telephone calls	To document any agreements or significant discussions regarding trial administration, protocol violations, trial conduct, adverse event (AE) reporting.	X	X
13	**SIGNED INFORMED CONSENT FORMS**	To document that consent is obtained in accordance with GCP and protocol and dated prior to participation of each subject in trial. Also to document direct access permission (see A #3).	X	
14	**SOURCE DOCUMENTS**	To document the existence of the subject and substantiate integrity of trial data collected. To include original documents related to the trial, to medical treatment, and history of subject.	X	
15	**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.	X copy	X orig.
16	**DOCUMENTATION OF CRF CORRECTIONS**	To document all changes/additions or corrections made to CRF after initial data were recorded.	X copy	X orig.

	Title of Document	Purpose	Located of Files: Research Network Site	Located of Files: Sponsor
17	**NOTIFICATION BY ORIGINATING INVESTIGATOR TO SPONSOR OF SERIOUS ADVERSE EVENTS AND RELATED REPORTS**	Notification by originating investigator to sponsor of serious adverse events and related reports in accordance with ICH Guideline 4.11, Safety Reporting.	X	X
18	**NOTIFICATION BY SPONSOR AND/OR INVESTIGATOR, AND IF NEEDED, TO REGULATORY AUTHORITIES AND IRB(S) OF UNEXPECTED SERIOUS ADVERSE DRUG REACTIONS 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 in accordance with ICH Guideline 5.17, Adverse Drug Reaction Reporting and ICH Guideline 4.11.1, Safety Reporting and of other safety information in accordance with ICH Guidelines 5.16.2, Safety Information and 4.11.2, Safety Reporting.	X*	X
19	**NOTIFICATION BY SPONSOR TO INVESTIGATORS OF SAFETY INFORMATION**	Notification by sponsor to investigators of safety information in accordance with ICH Guideline 5.16.2, Safety Information.	X	X
20	**INTERIM OR ANNUAL REPORTS TO IRB AND AUTHORITY(IES)**	Interim or annual reports provided to IRB in accordance with ICH Guideline 4.10, Safety Reporting and to authority(ies) in accordance with ICH Guideline 5.17.3, Adverse Drug Reaction Reporting.	X	X
21	**SUBJECT SCREENING LOG**	To document identification of subjects who entered pre-trial screening.	X	
22	**SUBJECT IDENTIFICATION CODE LIST**	To document that investigator/institution keeps a confidential list of names of all subjects allocated to trial numbers on enrolling in the trial. Allows investigator/institution to reveal identity of any subject.	X	
23	**SUBJECT ENROLLMENT LOG**	To document chronological enrollment of subjects by trial number.	X	
24	**INVESTIGATIONAL PRODUCTS ACCOUNTABILITY AT THE SITE**	To document that investigational product(s) have been used according to the protocol. This includes sponsor investigational drug shipping inventory and investigational drug dispensing log.	X	X
25	**SIGNATURE SHEET**	To document signatures and initials of all persons authorized to make entries and/or corrections on CRFs.	X	X
26	**RECORD OF RETAINED BODY FLUIDS/ TISSUE SAMPLES (IF ANY)**	To document location and identification of retained samples if assays need to be repeated.	X	X

C. After Completion or Termination of the Trial

After completion or termination of the trial, all of the documents identified in Sections A and B should be in the file together with the following

	Title of Document	Purpose	Location of Files: Research Network Site	Location of Files: Sponsor
1	**INVESTIGATIONAL PRODUCT(S) 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 subjects, returned by the subjects, and returned to sponsor or destroyed at the site.	X	X
2	**DOCUMENTATION OF INVESTIGATIONAL PRODUCT DESTRUCTION**	To document destruction of unused investigational products by sponsor or at site.	X***	X
3	**COMPLETED SUBJECT IDENTIFICATION CODE LIST**	To permit identification of all subjects enrolled in the trial in case follow-up is required. List should be kept in a confidential manner and for agreed upon time.	X	
4	**MONITORING LOG**	To document each visit from the sponsor, the log sheet is signed and dated by all sponsor personnel and the purpose of the visit is noted.	X	X
5	**AUDIT CERTIFICATE** (if available)	To document that audit was performed.		X
6	**FINAL TRIAL 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.		X
7	**TREATMENT ALLOCATION AND DECODING DOCUMENTATION**	Returned to sponsor to document any decoding that may have occurred.	X	X
8	**FINAL REPORT BY INVESTIGATOR TO IRB WHERE REQUIRED, AND WHERE APPLICABLE, TO THE REGULATORY AUTHORITY(IES)**	To document completion of the trial.	X	X
9	**CLINICAL STUDY REPORT**	To document results and interpretation of trial.	X*	X

* if applicable/required
** third party if applicable
*** if destroyed at the site

ATTACHMENT B:
Georgia CORE Regulatory Master File Structure

Study Folder Guidelines

- Site folder and site document nomenclature = Site name, PI surname, date(dd, mm, yyyy)
- If a folder or sub-folder is not relevant for a specific study, a note to file will be placed in the folder stating that it is not relevant for the study with author's name and date
- When a document is maintained as a hardcopy only, a note to file will be made in the appropriate electronic folder designating the location of the hardcopy document.
- Executed documents = (scanned document with signatures and dates, executed date = last signature date)
- Archive folders = includes original versions (if no longer in use), all interim versions, all red-lined documents once associated version is implemented. If an archive folder is not already established and one is needed, create one.
- Correspondence related to a specific topic, e.g. Related to agreement negotiation will be placed in the like titled study folder, in this case in the Agreement folder
- Regulatory files are to be kept confidential and stored in a secure, limited-access location. Electronic files are maintained on a secure server.

Study Name _____Action Plan

- Georgia CORE action/operations plan(s)
- Sponsor action/operations plan(s)

Agreement/Budget

- Archive: Agreement and Budget templates
- Confidentiality Agreement template (if applicable to this study)
- Georgia CORE agreement and budget with Sponsor – final executed Agreement
- Georgia CORE Master Clinical Research Agreement and Budget Addendum study specific template for sites
- Site specific sub-folders
  - Archive: Site Specific Agreement and Budget
  - Current executed Confidentiality Agreement for participating sites, if applicable
  - Current executed Master Clinical Research Agreement and Budget Addendum for participating sites

Audits

- Audit certificate (if available)
- Audit process template
- Audit report
- Site specific sub-folders
  - Results of site-specific audit for a study
  - Site-specific action plan in response to audit
  - Site-specific audit action plan update reports

Case Report Form (CRF) and Data Correction Form (DCF) Templates

- Archive: CRF templates and Data Correction form templates
- CRF templates – e.g. Pre-study, registration, treatment cycles, off treatment, pathology reports, record of retained body fluids/tissue samples (if applicable)
- DCF Templates, if applicable
- Site-Specific sub-folders
  - Archive: CRF and DCFs documents
  - Completed CRF forms such as: Pre-study, registration, treatment cycles, off-treatment, pathology reports, record of retained body fluids/tissue samples (if applicable)
  - Completed DCF, if applicable

Clinical Study report

- Final Clinical Study report, if available
- Interim Clinical Study report, if available

Communications Plan

- Archive: Communications Plan
- Current Communications Plan

Contact list

- Archive: Contact list
- List of Sponsor, Georgia CORE administration and staff, site (Investigator(s), Sub-investigators, and other key site research staff and WIRB contacts with phone numbers, e-mails, and addresses

Communications: Other than site visits

- Georgia CORE: Georgia CORE/Sponsor letters, meeting notes, notes of phone calls, e-mails (documenting any agreements or significant discussions regarding trial administration, protocol violations, trial conduct)
- Site specific sub-folders: Site specific letters, meeting notes, notes of phone calls, e-mails (documenting any agreements or significant discussions regarding trial administration, protocol violations, trial conduct)
- Study newsletters
- Study wide: Study wide letters, meeting notes, notes of phone calls, e-mails (documenting any agreements or significant discussions regarding trial administration, protocol violations, trial conduct)

Drug/Device Management

- Certificates of analysis of investigational product(s) shipped (initial and new batches), if applicable
- Drug or device information for this study including instructions for handling of investigational product(s) and trial related materials (if not included in protocol or investigator brochure)
- Sample of label(s) attached to investigational product containers

- Site specific sub-folders
  - Completed shipping invoice/receipt of drug records form
  - Completed inventory log
  - Completed dispensing log
  - Completed record of disposition and/or return of unused or damaged study drug
  - Completed storage area temperature log, if applicable
- Templates for drug/device management specific to this study
  - Archive
  - Dispensing log template
  - Inventory log template
  - Record of disposition and/or return of unused or damaged study drug
  - Shipping Invoice/Receipt of drug records templates
  - Storage Area Temperature Log, if applicable

FDA Form 1572

- Site specific sub-folders
- Template

Financial analysis

- Financial tracking - dashboard
- Invoices
  - Georgia CORE
  - Site Specific sub-folders
    - Payments
      - Georgia CORE
      - Site Specific sub-folders
    - Templates
      - Archive
      - Invoice

Financial disclosure

- Financial disclosure template
- Investigator financial disclosures – signed and dated

IND Safety Reports

- Correspondence regarding IND safety reports
- IND safety report distribution tracker
- IND safety letters
- IND safety report template, if originated from Georgia CORE
- Medwatch reports
- Study wide IND safety reports and associated letters to IRB

Informed Consent

- Multi-site Templates
  - Approved HIPAA template if not included in informed consent
  - Archive: Informed Consent and HIPAA templates

- Informed Consent template(s) – current approved templates for each type of consent form(s)

- Site specific Template sub-folders
  - Approved HIPAA template if not included in informed consent
  - Archive: Informed Consent and HIPAA templates
  - Informed Consent template(s) – current approved templates for each type of consent
  - form(s)

Investigator Brochure

- Archive: Investigator Brochure drafts, if applicable
- Correspondence re Investigator Brochure
- Investigator Brochure
- Investigator Brochure updates

Investigator Meeting

- Investigator meeting documents and correspondence
- Safety meeting documents and correspondence

IRB

- IRB tracker
- Central IRB
  - Approval/re-approval letters (of protocol, protocol amendments, consent forms, and revised consent forms)
  - Archive
  - Copies of approved subject recruitment and information materials at study wide level
  - Correspondence with IRB
  - IND exemption letters (request and approval), if applicable
  - IRB membership list including their affiliations and terms of office or letter stating the IRB meets all requirements
  - Submission template form(s)
  - Submitted documents
- Local IRB – Site Specific sub-folders
  - Approval/re-approval letters (of protocol, protocol amendments, consent forms and revised consent forms)
  - Archive
  - Copies of approved subject recruitment and information materials at study wide level
  - Correspondence with IRB
  - IND exemption letter, if applicable
  - IRB membership list including their affiliations and terms of office or letter stating the IRB meets all requirements
  - Submission template form(s)
  - Submitted documents
  - Site-specific folders

Laboratory certification and normal ranges

- Laboratory certification/licenses and updates
  - Archive
- Laboratory normal ranges for site and updates
  - Archive

Monitoring Visits

- Templates
  - Agenda
  - Monitoring log
  - Monitoring visit report (PSSV, SIV, Interim, Termination)
  - Archive
- Site Specific sub-folders
  - Interim Visit
    - Interim report(s), documents and related correspondence
  - Pre-Study Site Visit (PSSV)
    - PSSV agenda, report, documents and related correspondence
  - Study Initiation Visit (SIV)
    - SIV agenda, report(completed checklist), documents and related correspondence
  - Termination Visit
- Termination Visit report, documents, and related correspondence
  - Documents (completed) such as:
    - Outcome events log
    - Protocol Deviation log
    - Screening log
    - Signature/Delegation of duties log – completed copy from site
    - Training/Education log
    - Treatment Allocation and Decoding Documentation, if applicable

Protocol and Protocol Proposal

- Archive
- Current Protocol
- Current Protocol Synopsis (Summary)
- Correspondence related to the protocol documents
- Protocol signature page and/or Investigator protocol acceptance form template, if applicable
- Randomization Plan, if applicable (accessible to sponsor or third party only)
- Regulatory authorities' authorizations/approvals/notifications of protocol (where applicable) including copies of submissions such as the Investigational New Drug (IND) submission
- Research Concept Proposal (RCP), if applicable
  - Georgia Core Scientific Review Committee Evaluations, if applicable
  - RCP related correspondence

Protocol Feasibility (Site Solicitation Feedback)

- Correspondence related to protocol feasibility
- Protocol Feasibility Form, if applicable

- Protocol Feasibility Responses, if applicable
- Site Solicitation Feedback template
- Site Solicitation Responses from sites

Safety Reports

- Site specific sub-folders, where applicable
  - Safety reports and letters and correspondence

Serious Adverse Events

- Site specific sub-folders, where applicable
  - Completed SAE report forms and related correspondence

Site Selection

- Invitations
  - Invitation Template
  - Potential Investigator Qualification form template
  - Specific site invitations
- Responses
  - Potential Investigator Qualification forms completed by sites
  - Specific site response letters
- Site Selection Tracker

Study Specific Unique Forms

- Site specific sub-folders
  - Personal Data Consent Form – signed and dated
  - PI Acceptance Form – signed and dated
  - Protocol Acceptance Form – signed and dated
- Templates
  - Personal Data Consent Form template
  - PI Acceptance Form template
  - Protocol Acceptance Form template

Serious Adverse Events

- Serious Adverse Event (SAE) form template(s)

Site Assessment Form Template

- Site assessment form template(s)

Subject recruitment

- Site specific sub-folders, if necessary
  - Subject recruitment documents (including advertisements) and correspondence
- Study-wide: Subject recruitment documents (including advertisements) and correspondence

Template Forms for use by Investigators- not specific to other folders

- Archive: Template forms
- Decoding procedures for blinded trials, if applicable
- Investigator Manual Contents
- Protocol Deviation log
- Screening log
- Signature/Delegation of Duties log

- Site Visit log
- Specimen Shipping form, if applicable

- Subject Enrollment log
- Subject Identification code list, if applicable
- Training/Education log
- Outcome Events log

Template letters – not specific to other folders

Separate Folders (i.e., not study specific)

Investigator Curriculum Vitae

- Current Investigator CV – signed and dated
- Archive: Investigator specific sub-folders
- Expired Investigator CVs
  - Investigator Curriculum Vitae Tracker
- Tracker includes CV version date submitted to IRB for each study, the corresponding expiration date and what studies the investigator is participating in

Investigator License

- Archive: Investigator specific sub-folders
- Expired Investigator licenses
- Current Investigator License
- Investigator License Tracker
- Tracker includes License expiration date