SOP#: RPS-1	**Folder and File Name Descriptions for Electronic Regulatory Files**
Version #: 2.1	**Next Review Date: 02/2023**
Approved Date: 02/2021	**Review Interval Period: Biennial**
NCI Clinical Director Signature:	

POLICY

Per the International Council for Harmonisation Good Clinical Practice Guidelines, essential documents allow for evaluation of the conduct of the study and quality of the study data. Center for Cancer Research (CCR) protocols must have these essential documents contained in a regulatory file using an electronic format. Each electronic regulatory file must have a consistent format, including naming of folders and files, to ensure required information is maintained and easily accessible.

PURPOSE

Describe how the electronic regulatory file is organized, which folders are included and how folders and files are named.

RESOURCE

- CCR Policies/Standard Operating Procedures
  - PM-6: *Guidelines for the Development and Maintenance of Regulatory Files/Binders*

PROCEDURES

Naming Standards/Directions

- Dating conventions: 4-digit year/2-digit month/2-digit day: YYYYMMDD
  - For dates of sponsor/IRB approval or outcome documents, use the decision date.
- In this SOP, the first level of subfolder is GREEN, followed by PURPLE.
- Folders will be listed separately by protocol under each PI.
- All saved documents should be final documents, not draft or working documents; and, should be saved in pdf format.

Regulatory File Format

CVs (and Licenses, if required)

- CVs (and Licenses)
  - Investigator Last Name _CV _signature date [YYYYMMDD]
  - Investigator Last Name _License _expiration date [YYYYMMDD]

For example:

- CVs (and Licenses)
  - Smith _CV _20170115
  - Smith _License _exp 20180930

Drug Accountability Records

- NIH number _DAR _date received [YYYYMMDD]

Data Safety Monitoring Board (DSMB)/Safety Monitoring Committee (SMC)/ Independent Monitoring Committee (IMC)

Create a sub-folder each for DSMB, SMC and/or IMC, as applicable.

Create a new folder for each submission and approval.

- DSMB
  - Date DSMB approved [YYYYMMDD] – DSMB
    - Outcome Letter: NIH number _DSMB Outcome Letter- [DSMB outcome] _decision date [YYYYMMDD]
- SMC
  - Date SMC approved [YYYYMMDD] – SMC
    - Outcome Letter: NIH number _SMC Outcome Letter- [SMC outcome] _decision date [YYYYMMDD]
- IMC
  - Date IMC meeting [YYYYMMDD] – IMC
    - Meeting Minutes: NIH number _IMC Meeting Minutes- [IMC outcome-Optional] _meeting date [YYYYMMDD]

For example:

- 20160601 – DSMB
  - 10C0025 DSMB Outcome Letter- Stipulations _20160601
  - 10C0025 DSMB Outcome Letter- Approval _20160701
- 20170601 – SMC
  - 10C0025 SMC Outcome Letter- Stipulations _20170601
  - 10C0025 SMC Outcome Letter- Approval _20170701
- 20180601 – IMC
  - 10C0025 IMC Meeting Minutes –_20180601

IND Safety Reports

Use this folder if receiving reports from a Sponsor or manufacturer for a study drug(s).

- Requirements:
  - Save all IND safety reports as pdf
  - Save the email/original notification of the IND safety report (i.e., when it was received from the Sponsor/manufacturer)
  - Document the PI review/assessment of the IND safety report

- Options:
  - The above documents may be saved together as a single pdf (i.e., merge all with the pdf of the safety report so that it is one document); independently within separate folders for each event; or, named clearly that all actions for the same report sort together.
  - By whatever method used, all reports/files should be named consistently within a study and sorted such that all information can be easily identified.

Example #1: PI acknowledges IND safety report review/assessment by initialing dating the IND safety report or via a separate email acknowledgement.

  - First save the email notification as a .pdf file and merge it with the .pdf file of the safety report that the PI reviewed/initialed; save as one document.
  - For the IND report name (use name on file as sent from manufacturer or sponsor).

Example #2: PI acknowledges IND safety report review/assessment by periodic signoff of multiple IND safety reports.

  - Generate a running list of IND safety reports received over a period of time (e.g., every quarter).
  - The PI acknowledges review/assessment of the entire listing of IND safety reports by signature on the list/memo.
  - The signed listing/memo is saved along with each of the applicable IND safety reports in a separate sub-folder for that period of time.
  - For the IND report name (use name on file as sent from manufacturer or sponsor).

Investigator Agreement (1572)

Refer to document as "FDA Form 1572" or "FDA 1572" for naming convention; save all forms for a study in a single folder, beginning with the form version date based on PI signature.

- 1572 (if IND study)
- Investigator agreement (if IDE or NSR device)

Document naming convention:

  - Date of PI signature [YYYYMMDD] - NIH number_Form 1572
  - OPTIONAL: Save the template/editable version of the document in addition to the signed copy, noting "_signed" in the file name for the signed/official copy

For example:

- FDA 1572
  - 20160115 – 10C0052 FDA 1572
  - 20160115 – 10C0052 FDA 1572 _signed
  - 20170601 – 10C0052 FDA 1572
  - 20170601 – 10C0052 FDA 1572 _signed

Investigator Brochure (and/or Package Insert, if applicable)

If more than one drug, create a folder for each drug; generally naming each folder(s) with the generic (not commercial/brand) name.

Within each drug, create a sub-folder for each IB version.

- Drug Name
  - Drug name _IB vX.x _IB version date [YYYYMMDD]
  - Save within the version sub-folder the IB and associated documents.

  For example:
  - Drug name _IB vX.x _IB version date [YYYYMMDD]
  - Drug name _IB vX.x _IB Summary of Changes [YYYYMMDD]
  - Drug name _IB vX.x _IRB Outcome Letter _IRB decision date [YYYYMMDD]
  - Drug name _IB vX.x _PI Signature Page _PI signature date [YYYYMMDD]

  For example:
- ABC-101 v8 _20160515
  - ABC-101 v8 _20160515
  - ABC-101 v8 Summary of Changes _20160515
  - ABC-101 v8 IRB Outcome Letter _20160521
  - ABC-101 v8 PI Signature Page _20160520

IRB Continuing Review or Progress Report

Each year of the CR or Progress Report should have its own subfolder; with the full approval date of the CR or acknowledgment of the Progress Report included in the folder name.

- Date IRB approved or acknowledged [YYYYMMDD] – CR

Optional: Create an Approval Package, NIH number_ CR_Approval Package _IRB decision date [YYYYMMDD] and include the following documents. Otherwise, save the following documents separately:

- IRB outcome letter(s):
  - For CR: NIH number _CR _IRB Outcome Letter- [IRB outcome] _IRB decision date [YYYYMMDD]
  - For Progress Report: IRB acknowledgment: NIH number _CR _IRB Acknowledgment - _IRB review date [YYYYMMDD]
- Progress Report Form: CR/Progress Report Submission Form _date submitted [YYYYMMDD]
- Review Response Submission Form(s) as applicable
- Study Application _date submitted [YYYYMMDD]

  For example:
- 20160601 – CR

  If no approval package is created, include as applicable:
  - 10C0025 CR/Progress Report Submission Form_20160501
  - 10C0025 CR IRB Outcome Letter- Stipulations_20160528
  - 10C0025 CR IRB Outcome Letter- Approval_20160601

- 10C0025 CR Review Response Submission Form(s) as applicable
- 10C0025 Progress Report IRB acknowledgement_20160601
- 10C0025 Study Application _20160501

IRB Membership and FWA

IRB Membership

Name the IRB in the file name

<u>Optional</u>: Additionally, sort rosters by folder per calendar year.

- Year
  - Roster date – [IRB Name] IRB Membership Roster

For example:

  - 20120501 – NCI IRB Membership Roster
  - 20120701 – NCI IRB Membership Roster
  - 20120901 – NCI IRB Membership Roster

OR:

- 2012
  - 20120501 – NCI IRB Membership Roster
  - 20120807 – NCI IRB Membership Roster

- 2013
  - 20130108 – NCI IRB Membership Roster

OR:

  - 20190901 – NIH IRBO Membership Memo

FWA

- Institution – FWA# expiration date [YYYYMMDD]

For example:

  - NIH FWA00005897 exp 20230716

IRB Other Submissions

Create a sub-folder for each type of other submissions (i.e., actions) submitted to the IRB, as applicable, including: Short Consent Forms, Participant Recruitment Materials, Miscellaneous Documents, Study Status Changes

Within each action sub-folder, save the approval packages/documents in date order, by the date of the IRB acknowledgment/approval, NIH #, and short description of the action.

<u>Note</u>: When the IRB Other Submission is approved with the initial protocol or with a protocol amendment, a separate IRB outcome letter will not be generated. In these cases, include a copy of the approval letter that corresponds to the action with which the Other Submission was approved.

For example:

- Miscellaneous Documents
  - Date IRB approved [YYYYMMDD] – NIH number _Study Drug Diary _document version date [YYYYMMDD]
    - Document: NIH number _Study Drug Diary _document version date [YYYYMMDD]
    - IRB Outcome Letter: NIH number _IRB Outcome Letter- [IRB outcome] _IRB decision date [YYYYMMDD]

For example:

- 20160801 – 10C0025 Study Drug Diary _v20160615
  - 10C0025 Study Drug Diary _20160615
  - 10C0025 IRB Outcome Letter- Approval _20160801

- Study Status Changes

  If status is changed during CR, save copy of CR Form and IRB Outcome letter
  - Date IRB acknowledged [YYYYMMDD] - NIH number _IRB Study Status- [Status update]

  For example:
  - 20100301 - 10C0025 IRB Study Status- Recruiting
  - 20100901 - 10C0025 IRB Study Status- Suspended

IRB Protocol and Consents

Each IRB action should have its own subfolder; with the full approval date of the action included in the folder name.

- Date IRB approved [YYYYMMDD] – Initial Approval or Amendment [Letter, if applicable] Protocol and/or Consent(s)

Optional: Create an Approval Package: NIH number_Approval Package _IRB decision date [YYYYMMDD] and include the following documents. If no approval package is created, save the following documents separately:

- IRB outcome letter(s): NIH number_ Initial/Amendment [Letter] _IRB Outcome Letter- [IRB outcome] _IRB decision date [YYYYMMDD]
- Approved consent(s) as downloaded from iRIS: Consent: [NIH number].[OPS assigned footer #] [Cohort Name] [clean Consent] [consent version date [YYYYMMDD]
- If other consents, save each separately using unique consent number/name (e.g., Standard, Healthy, Spanish, Minor, Volunteer, Donor, etc.)
- Protocol: NIH number Initial/Amendment [Letter] _Protocol _protocol version date [YYYYMMDD]
- Cover Memo: NIH number _ Amendment [Letter] _Cover Memo _protocol version date [YYYYMMDD]
- Initial or Amendment Form: NIH number Initial/Amendment [Letter] _IRB Submission Package _IRB submission date [YYYYMMDD]
- Review Response Submission Form(s) as applicable
- Study Application (if changes were made in the application): NIH number _ Initial/Amendment [Letter] _Study Application_date submitted [YYYYMMDD]

- Protocol Signature Page: NIH number _Protocol Signature Page v.[protocol/amendment version date]_ signed, if applicable

For example:

- 20100601 – Initial Approval
  - o If created, 10C0025 Initial Approval Package _20100601
  - o If no approval package is created, include as applicable:
    - 10C0025 Initial IRB Outcome Letter- Stipulations _20100528
    - 10C0025 Initial IRB Outcome Letter- Approval _20100601
    - 10C0025 1. Consent Standard 20100515
    - 10C0025 2. Consent Spanish 20100515
    - 10C0025 Initial Protocol _20100515
    - 10C0025 Initial Review Form _20100515
    - 10C0025 Review Response Submission Form(s) 20100530
    - 10C0025 Study Application_20100515
    - 10C0025 Protocol Signature Page v.20100515 _signed, if applicable

For example

- 20100901 – Amendment Protocol and Consents
  - o If created, 10C0025 Amendment Approval Package _20100901
  - o If no approval package is created, include as applicable:
    - 10C0025 Amendment IRB Outcome Letter- Stipulations _20100828
    - 10C0025 Amendment IRB Outcome Letter- Approval _20100901
    - 10C0025 1. Consent Standard 20100815
    - 10C0025 2. Consent Spanish 20100815
    - 10C0025 Protocol_20100815
    - 10C0025 Cover Memo _20100815
    - 10C0025 Amendment Form _20100815
    - 10C0025 Review Response Submission Form(s) 20100830
    - 10C0025 Study Application_20100815
    - 10C0025 Protocol Signature Page v.20100815 _signed, if applicable

- 20100901 – Amendment - Protocol Only
  - o If created, 10C0025 Amendment Approval Package _20100901
  - o If no approval package is created, include as applicable:
    - 10C0025 Amendment IRB Outcome Letter- Stipulations _20100828
    - 10C0025 Amendment IRB Outcome Letter- Approval _20100901
    - 10C0025 Protocol_20100815
    - 10C0025 Cover Memo _20100815
    - 10C0025 Amendment Form _20100815
    - 10C0025 Review Response Submission Form(s) 20100830
    - 10C0025 Study Application_20100815
    - 10C0025 Protocol Signature Page v.20100815 _signed, if applicable

- 20100901 – Amendment - Consent Only
  - o If created, 10C0025 Amendment Approval Package _20100901
  - o If no approval package is created, include as applicable:

- 10C0025 Amendment IRB Outcome Letter- Stipulations _20100828
- 10C0025 Amendment IRB Outcome Letter- Approval _20100901
- 10C0025 1. Consent Standard 20100815
- 10C0025 2. Consent Spanish 20100815
- 10C0025 Cover Memo _20100815
- 10C0025 Amendment Form _20100815
- 10C0025 Review Response Submission Form(s) 20100830
- 10C0025 Study Application_20100815

- 20100901 – Amendment – Translated Consents
  - o If created, 10C0025 Amendment Approval Package _20101001
  - o If no approval package is created, include as applicable:
    - 10C0025 Amendment IRB Outcome Letter- Stipulations _20100928
    - 10C0025 Amendment IRB Outcome Letter Spanish Consent - Approval _20101001
    - 10C0025 Affected Patients Spanish Consent Certification(s) of Accuracy _20200915
    - 10C0025 Amendment Form _201000925
    - 10C0025 Affected Patients Spanish Consent _20200910
    - 10C0025 Review Response Submission Form(s) 20100928
    - 10C0025 Study Application_20100925

IRB (Key) Study Personnel List

Each IRB action for approval of a Study Personnel List should have its own subfolder; with the full approval date of the action included in the folder name.

Initial Study Personnel or KSP List

- Date IRB approved [YYYYMMDD] – Initial KSP List
  - o IRB Outcome Letter – include as applicable:
    - If a separate Study Personnel (or KSP) outcome letter:
      - ♦ NIH number _Study Personnel (or KSP) List _IRB Outcome Letter- Approval _IRB approval date [YYYYMMDD]

    Note: When the initial Study Personnel List is approved with the initial protocol or with a protocol amendment, a separate IRB outcome letter will not be generated. In these cases, include a copy of the approval letter that corresponds to the action with which the list was approved.
  - o 10C0025 Initial Review Form _20100515
  - o Study Personnel List: NIH number _Study Personnel (or KSP) List _version date [YYYYMMDD]

Revised Study Personnel or KSP List

- Date IRB approved/acknowledged [YYYYMMDD] – Revised KSP List
  - o IRB Acknowledgement email: NIH number _Study Personnel (or KSP) List _IRB Outcome - Acknowledged _IRB acknowledgement date [YYYYMMDD]
  - o OPS Packet: NIH number _Study Personnel (or KSP) List _OPS Packet- Acknowledged _acknowledgement date [YYYYMMDD]

- Amendment Form: NIH number Amendment [Letter, if applicable] _IRB Submission Package _IRB submission date [YYYYMMDD]
- Study Personnel List: NIH number _Study Personnel (or KSP) List _version date [YYYYMMDD]

For example:

- 20160601 – Initial
  - 10C0025 Initial IRB Outcome Letter- Approval _20100601
  - 10C0025 Initial Review Form _20100501
  - 10C0052 Study Personnel List _20160515

- 20160801 – Revised
  - 10C0052 Study Personnel List IRB Outcome- Acknowledged _20160901
  - 10C0052 Study Personnel List OPS Packet- Acknowledged _20160901
  - 10C0025 Amendment Form _20100501
  - 10C0052 Study Personnel List _20160815

Lab Normals and Certifications

Save normals and certifications from NIH and all outside labs used by patients.

Identify/save pertinent laboratory files for the applicable year(s) from the central regulatory folder.

Include a copy also of the Laboratory Log (required for CCR-sponsored studies; optional for all others); with a notation also of the last date updated when received by the team.

- Laboratory Certificates
  - Lab Name Certificate Type _expiration date [YYYYMMDD]

  For example:
  - DLM CAP certificate _20200311
  - DLM CLIA certificate _20210208
  - NCI LP CAP certificate _20200716
  - NCI LP CLIA certificate _20200711

- Laboratory Normal Values
  - NIH Normal Value – Lab test/panel Name_start/effective date [YYYYMMDD]

  For example:
  - NIH Normal Value – CBC with Diff_20090203
  - NIH Normal Value – Acute Care Panel_20140209

Monitoring

Create the following sub-folders:

- Monitoring Visit Log
- Monitoring Visits

Within the Monitoring Visits folder, create a new sub-folder for each monitoring visit. In the sub-folders, save the relevant notification, correspondence, and final documents as listed below.

- Date of monitoring visit [YYYYMMDD] – Type of visit [e.g., Site Initiation, RMV]
- Document examples:
    - NIH # _Visit notification email/letter _notification date [YYYYMMDD]
    - NIH # _Monitor report _report date [YYYYMMDD]
    - NIH # _Site/team response (if applicable)_response date [YYYYMMDD]

For example:

- 20161001 – Site Initiation Visit [SIV]
    - 10C0052 SIV Notification _20160901
    - 10C0052 SIV Agenda _20161001
    - 10C0052 SIV Minutes _20161015
    - 10C0052 SIV Attendance Record _20161015
- 20161201 – Site Monitoring Visit [SMV]
    - 10C0052 SMV Notification _20161101
    - 10C0052 SMV Follow-Up Letter _20161215
    - 10C0052 SMV Study Team Response _20161220
- 20170101 – EC-IC Review (Eligibility Check/Inclusion Criteria Review)
    - 10C0052 EC-IC Review _20170101
    - 10C0052 EC-IC Study Team Response _20170115

Notes to File

The purpose of this folder is to document unusual events that occur, provide clarification on matters discussed, etc., during the course of a clinical trial. All notes to file should be included in this file; they may also be saved within the pertinent folder to which they apply (e.g., information regarding filing CVs/licenses in the regulatory file).

For example: include a Note to File that regulatory documents will be maintained electronically and not also on paper for industry sponsors/representatives.

For example:

- 20160901 – 10C0052 NTF- Electronic Regulatory Files
- 20161001 – 10C0052 NTF- Omission of Laboratory Director CVs
- 20161001 – 10C0052 NTF- Drug Accountability Reconciliation Forms (DARFs)

Institutional Biosafety Committee (IBC)

- Date approved [YYYYMMDD] – IBC number _Action Name*

*Initial Submission or Registration, Amendment [Letter], Annual Review, Adverse Event, Inactivation or Termination

    - If available:
        - Approval Package: NIH number _IBC [Action Name] Approval Package _IBC approval date [YYYYMMDD]

- o If no approval package available, include as applicable:
  - IBC Submission: NIH number _IBC [Action Name] Submission _IBC submission date [YYYYMMDD]
  - IBC Approval: NIH number _IBC [Action Name] Approval Letter _IBC approval date [YYYYMMDD]

For example:

- 20100601 – IBC RD-10-XI-00 Initial Registration
  - o If available: 10C0025 IBC Initial Approval Package _20100601
  - o If no approval package available, include as applicable:
    - 10C0025 IBC Initial Submission _20100501
    - 10C0025 IBC Initial Approval _20100601
- 20110601 – IBC RD-10-XI-00 Annual Review and Report
  - o If available: 10C0025 IBC Annual Review Approval Package _20110601
  - o If no approval package available, include as applicable:
    - 10C0025 IBC Annual Review Submission _20110501
    - 10C0025 IBC Annual Review Approval _20110601
- 20110901 – IBC RD-10-XI-00 Amendment Review
  - o If available: 10C0025 IBC Amendment B Approval Package _20110901
  - o If no approval package available, include as applicable:
    - 10C0025 IBC Amendment B Submission _20110801
    - 10C0025 IBC Amendment B Approval _20110901
- 20110901 – IBC RD-10-XI-00 Safety Report to FDA
  - o If available: 10C0025 IBC FDA Safety Report Approval Package _20110901
  - o If no approval package available, include as applicable:
    - 10C0025 IBC FDA Safety Report Submission _20110801
    - 10C0025 IBC FDA Safety Report Approval _20110901

Genomic Data Sharing (GDS) Plans

- Date approved [YYYYMMDD] – GDS number _Action Name

Include in this folder all GDS plans and IC Memos for the study.

- Upon approval of the GDS plan, save the document:
  - o NIH number _GDS Plan_CCR_GDS[PLAN#]- approved _approval date [YYYYMMDD]
- Upon approval of the Institutional Certification Memo (IC), save the document:
  - o NIH number IC Memo_CCR_IC[IC#]- approved _approval date [YYYYMMDD]

Reportable Events

Include in this folder all reportable event forms to the IRB and when applicable to the drug manufacturer(s), or study sponsor (e.g., SAEs/serious adverse events, events of special interest, deviations, non-compliances, etc.).

- Events to IRB

  Create a sub-folder for each event, save within that folder all information received and/or submitted; include initial and follow-up submission, queries, RCRC correspondence and communications/determinations, OHSRP/IRB reports to OHRP and FDA, etc.:

    o Upon return of the reviewed action from the IRB, save the review documentation:

      ▪ NIH number _iRIS reference number_Abbreviated event name

  For example:

      ▪ 10C0025 _234567 _Stroke
      ▪ 10C0025 _244578 _Wrong dose

- Events to Manufacturer

  Create a sub-folder for each event, save within that folder all information received and/or submitted; optionally sub-divide each folder for the initial, follow-up submission, queries, etc.:

    o [Date of event] – NIH number _Event name and/or Subject #

      ▪ NIH number _Event name/Subject # _submission date [YYYYMMDD]

- Events to Sponsor

  Create a sub-folder for each event, save within that folder all information received and/or submitted; optionally sub-divide each folder for the initial, follow-up submission, queries, etc.:

    o [Date of event] – NIH number _Event name and/or Subject #

      ▪ NIH number _Event name/Subject # _submission date [YYYYMMDD]

Publications

Include in this folder all publications (e.g., abstracts, letters to the editor, peer-reviewed journal publications) for the study.

For ease of tracking, suggest filing publications by date and/or continuing review period (i.e., to easily track/identify information already reported to IRB).

Radiation Safety

Radiation Safety Committee submission

NOTE: The RSC number below refers to the "Radiation Authorization No./Number."

- Date approved [YYYYMMDD] – RSC number _Action Name*

  *Initial Submission or Application, Amendment [Letter], Triennial Review, Closure or Termination

    o If provided:

      ▪ Approval Package: NIH number _RSC [Action Name] Approval Package _RSC approval date [YYYYMMDD]

- o If no approval package provided, include as applicable:
    - RSC Submission: NIH number _RSC [Action Name] Submission _RSC submission date [YYYYMMDD]
    - RSC Approval: NIH number _RSC [Action Name]- Outcome [Stipulations, Approval, etc.] _RSC approval date [YYYYMMDD]

For example:

- 20100601 – RSC 2166 Initial Registration
    - o If provided: 10C0025 RSC Initial Approval Package_20100601
    - o If no approval package provided, include as applicable:
        - 10C0025 RSC Initial Submission_20100501
        - 10C0025 RSC Initial Approval_20100601
- 20110601 – RSC 2166 Amendment Review
    - o If provided: 10C0025 RSC Amendment B Approval Package _20110601
    - o If no approval package provided, include as applicable:
        - 10C0025 RSC Amendment Submission_20110501
        - 10C0025 RSC Amendment Approval_20110601
- 20130601 – RSC 2166 Triennial Review
    - o If provided: 10C0025 RSC Triennial Review Approval Package _20130601
    - o If no approval package provided, include as applicable:
        - 10C0025 RSC Triennial Review Submission _20130501
        - 10C0025 RSC Triennial Review Approval _20130601

Radiation Exposure Worksheet

Save worksheet used to calculate total radiation exposure for imaging.

- Date created [YYYYMMDD] – Radiation Exposure Worksheet
    - o NIH number _ Radiation Exposure Worksheet Initial _creation date [YYYYMMDD]
    - o NIH number _ Radiation Exposure Worksheet Amended _creation date [YYYYMMDD]

For example:

- 20200515 – Radiation Exposure Worksheet
    - o 19C0076 Radiation Exposure Worksheet Initial _20200515
- 20200630 – Radiation Exposure Worksheet
    - o 19C0076 Radiation Exposure Worksheet Amended _20200630

Correspondence – Manufacturer (and/or Sponsor)

*Only include correspondence that is not directly related to an IRB action (**if related, please file with that action**). Correspondence should be named with date first.*

For example:

- Correspondence Date [YYYYMMDD]-NIH number _Short description of correspondence

If there are multiple correspondence around the same topic, consider creating a sub-folder for that topic using the date of initial correspondence in the sub-folder name.

Study Closure

- IRB Submission Package: NIH number _Closure _IRB Submission Package- submission date [YYYYMMDD]
- IRB Outcome Letter: NIH number _Closure _IRB Outcome Letter- [IRB outcome] _IRB decision date [YYYYMMDD]
- Any attachments to the Study Closure submission in iRIS (if required by Sponsor)

For example:

- 10C0025 Closure IRB Submission Package _20180501
- 10C0025 Closure IRB Outcome Letter- Approval _20180601

Study Logs (and/or Manuals)

Include study-specific logs (see below) and/or manuals (e.g., pharmacy, laboratory) within this folder. Logs are maintained by the study coordinator in paper form and sent to the protocol manager periodically (and prior to monitor/audit visits) for uploading into the regulatory file.

Optional: Create sub-folders for each type of log and/or manual, or type of information. Provide the study team with templates of the logs as noted (i.e., asterisk "*").

Important: **Be sure that no names, medical record numbers, etc. are listed on the following logs.**

- Screening and Enrollment Log*
- Delegation of Tasks/Authority and/or Site Signature Log*
- Deviation Log*

Note: The following logs are added to the file at the time of study closure:

- Final Enrollment Log – include only those participants that signed the study-specific consent and enrolled in the study; do not include those that only screened for the study
- Record of Samples Log, if applicable

Training

Maintain all HSP, GCP and PI training certificates here. Also save records of any nursing in-service or other protocol-specific training (e.g., study initiation, amendment, sponsor training).

The file name should include the last name of the person training, date of training, and type of training.

Optional: Create sub-folders for each type of training (e.g., IRB [HSP/GCP], protocol, eCRF, etc.).

For example:

- GCP and HSP Training – *Update as needed. Should remain current while the study remains open*
  - [Staff member name]
    - [Staff member name] _GCP Training _expiration date [YYYYMMDD]
    - [Staff member name] _Biomed 101 Training _expiration date [YYYYMMDD]

- Protocol Training
  - Initial Protocol
    - SIV Meeting _Attendance Log _meeting date [YYYYMMDD]
    - If not at SIV meeting:
      - ♦ [Staff member name] _Protocol v[version date] _training date [YYYYMMDD]
  - Amendment

    <u>Note:</u> Insert training log/documentation and/or individual training acknowledgments, as applicable, per protocol version.
    - NIH # Notification Email _date sent [YYYYMMDD]
    - Add read receipts

Other Documents/Folders

Multi-Center Documents

For multi-site studies where CCR serves as the Coordinating Center for enrolling sites and/or where outside collaborators/companies are involved in the research, add a separate folder for each site/sub-site taking part on the study.

Within each site folder, set-up subfolders similar to the above as applicable to the activities being conducted at the site.

For example:

At a minimum for enrolling sites where CCR serves as the Coordinating Center and where the site/center is seeking local IRB review (*Applies to studies where CCR is the IND sponsor only):

- CV and Medical License – PI
- CVs – Sub-Investigators
- Financial Disclosure Forms*
- Investigator Agreement (1572)*
- IRB Membership Roster and FWA
- Investigator Brochure – Receipt/Signature Pages*
- IRB Documents – <u>Note:</u> Create sub-folders regarding IRB activities as applicable to the site (e.g., Amendments, CRs).
- Notes to File
- Correspondence – Site
- Study Closure
- Study Logs – <u>Note:</u> Create sub-folders as applicable (e.g., Screening/Enrollment, Delegation, etc.). Additionally, a "Study Contact List" should be collected and maintained.
- Training