SOP#: RPS-20	**Preparation of Study Closure**
Version #: 2.2	**Next Review Date: 05/2024**
Approved Date: 05/2022	**Review Interval Period: Biennial**
NCI Clinical Director Signature:	Dahut, William (NIH/NCI) [E] Digitally signed by Dahut, William (NIH/NCI) [E] Date: 2022.05.06 10:00:11 -04'00'

POLICY

The study Principal Investigator (PI) is responsible for notifying the NIH Intramural IRB whenever an IRB-approved study will be closed, regardless of the reason for closure. Data collection and analysis for the study are not permissible after study closure.

IMPORTANT NOTES

A study may be closed when all research-related interventions/interactions with human subjects have been completed, including:

- follow-up visits or contact with all research participants;
- data or specimen collection and analysis as described in the IRB-approved protocol;
- all Sponsor reporting requirements have been met, monitoring is completed (including closeout visit or COV) and database is locked, if applicable;
- all manuscripts have been accepted for publication, as applicable; and
- plans are in process to post results on ClinicalTrials.gov

Study closures may occur for any of the following reasons:

- Completed: The study has concluded normally (e.g., as described in the protocol).
- Terminated (Premature Closure): The study has permanently stopped earlier than anticipated by the protocol (e.g., for cause or futility).
- Withdrawn: A study is stopped prior to enrollment of the first participant.

PURPOSE

To identify the actions necessary to confirm that a research study is ready to be closed with the IRB and to describe the process to submit the closure report to the IRB.

RESOURCES

- NIH Office of Intramural Research Policies & Guidance website
  - Policy 204 - *Levels of IRB Review and Criteria for IRB*
  - Policy 300 – *Investigator Responsibilities*

PROCEDURES

STEP 1: Determine if a Research Study Can Be Closed

PI is responsible for:

- Determining when a research study is to be closed.
- Determining the reason for the closure.
- Ensuring that all participating basic science laboratories have completed all specimen and data analyses per the protocol.
- Ensuring that all manuscripts associated with the protocol, including correlative analysis, have been accepted for publication.
- Determining with the participating labs that any leftover biospecimens have been either transferred to another study, used up, or destroyed as per the IRB approved protocol and per the individual participant informed consent form. Alternatively, samples may be securely retained in an identifiable format for future use.

  Note: It is preferred by IRB that samples not be transferred to another study for tracking. Future use of identifiable biospecimens or data will require IRB approval.
- Confirming with the research nurse coordinator that applicable study closure activities are completed.
- Informing all Associate Investigators and research support staff of study closure via email directly or with help of PSO Manager (refer to "Notice of Study Closure" in PSO share folder).
- Providing all requested information to the PSO Manager.

Research Nurse Coordinator is responsible for:

- Ensuring that there is documentation in the medical record for each participant as to the off-study date and the off-study reason.
- Ensuring that all participants have been taken off study with the Central Registration Office (CRO) or in the Patient Registration and Enrollment System (PRES).
- Confirming closeout visit/activities with the Sponsor, Coordinating Center, and/or monitor are completed, as applicable.

  Note: The closeout visit (COV) with the monitoring entity(ies) must be completed or confirmed/documented as not necessary prior to submission of request to IRB to close.

PSO Manager is responsible for:

- Confirming, with the PI, the decision to close the study.
- Confirming that publications are finalized, as applicable, and plans are in process to post results on ClinicalTrials.gov.
- Ensuring all documentation (e.g., regulatory correspondence) is filed appropriately, closeout visit documentation is filed, and Sponsor has confirmed approval to close the study with the IRB, if applicable.

- If a multicenter study:
  - If NIH is the coordinating center, closures from all participating sites must be confirmed and copies of IRB approval of closure from each site must be saved in the regulatory file.
  - If NIH is a participating site, and the database has been locked by the Coordinating Center/Sponsor, then the study may be closed at NIH if all the conditions above have been met. This can be done prior to final publication(s) if approved by the Coordinating Center/Sponsor.
- Confirming with CRO or PRES that all CCR study participants have been taken off study.

STEP 2: Gather Required Information/ Data

PSO Manager is responsible for:

- Working with the PI and Research Nurse Coordinator to collect the information/data needed for the IRB study closure application (refer to "Data Required for Study Closure" in PSO share folder).
- Preparing the Progress Report Form for Study Closure (i.e., an option under the Progress Report Submission Form) in iRIS.
- Requesting a Cumulative Inclusion Enrollment Form (CIER) and a termination memo from study coordinator to confirm the race and ethnicity information and to verify that all subjects have been taken off-study. If the study was not converted to PRES, the request can be made to the CRO via email. The address is "NCI Central Registration Office" in Global.
- Saving all communications pertaining to study closure in the electronic protocol file study closure folder.

STEP 3: Prepare Study Closure Form in IRIS

PSO Manager is responsible for:

- Completing the Progress Report Form for Study Closure.
- Entering the CIER information.
- Ensuring consistency between the request for data required for study closure and the iRIS fields.

STEP 4: Send for PSO QA

PSO Manager is responsible for:

- Sending the JIRA Task to PSO Director for QC.

STEP 5: Prepare Submission

PSO Manager is responsible for:

- Uploading required documents, as applicable.
- All participating site IRB closure documentation, for sites undergoing local IRB review, indicate “Other” as a type of document attachment, use attachment category “Outside IRB Document.”
- Any other relevant information regarding the closure of the study as determined by the PI and/or study sponsor.
- Assigning for signature as indicated in iRIS
    - Review that all relevant forms for the amendment have been completed or are in progress.

STEP 6: IRB Approval

PSO Manager is responsible for:

- Saving the following in the working files and the regulatory file:
    - IRB outcome letter - approval
    - Progress Report Form (study closure form)
    - Drug accountability log(s) for treatment studies, if applicable
    - Any attachments to the Study Closure submission in iRIS (if required by Sponsor)
- Handling additional notifications:
    - For studies involving CCR-sponsored INDs: PSO staff will notify the CCR sponsor of study closure.
    - If NIH is a participating site, IRB approval of study closure must be provided to the coordinating center.