## 1 PURPOSE

The purpose of this document is to describe the procedures related to close-out of a clinical research protocol.

## 2 REVISIONS FROM PREVIOUS VERSION

2.1 Version 1.0, 19Sept2024: Initiation of new SOP

## 3 POLICY

N/A

## 4 RESPONSIBILITIES

4.1 Principal Investigator (PI)

- 4.1.1 Review the project's financial status with the CRU Director or Sponsored Research Administrator
- 4.1.2 Ensure that affiliate sites/subcontractors have submitted or will submit all required deliverables, reports and invoices, if applicable.
- 4.1.3 Plan for updates and changes to payroll, transitioning either to a renewal period or to award expiration
- 4.1.4 Submit final report to IRB
- 4.1.5 Meet sponsor's deadline(s) for final reports
- 4.1.6 Submit required final invention report, if applicable
- 4.1.7 Review the final financial report
- 4.1.8 Ensure retention of the project records for the required period of time, as specified in applicable regulations or sponsor correspondence/contract
- 4.1.9 Submit study results http://clinicaltrials.gov (if applicable)
- 4.1.10 Ensures all activities have been completed by the CRP(s) as outlined in this SOP

4.2 Clinical Research Professional (CRP)

- 4.2.1 Ensure all subject study visits or subject transfer processes have been completed per sponsor and IRB.
- 4.2.2 Ensure all data collection forms have been completed, submitted to sponsor (if applicable), and filed in appropriate subject research binder
- 4.2.3 Ensure completion of all action items, resolution of data queries and data lock (if applicable)
- 4.2.4 Ensure all used and/or unused IP is collected from all subjects, inventoried, and returned to sponsor or destroyed.
- 4.2.5 Ensure regulatory binder is current and complete and ready for archiving
- 4.2.6 Assist PI in preparing all study files for storage in a secure location

## 5 PROCEDURE

5.1 All subject study visits or subject transfer process must be completed per

sponsor and IRB instructions prior to initiating study close-out activities

5.2 Study close-out activities should not occur without approval from the sponsor (if applicable) and PI

5.3 Review and ensure all regulatory documentation is current, complete, and filed correctly in the regulatory binder

5.4 Review and ensure all subject research files are complete (data collection forms, labs, etc.)

5.5 Review and ensure all data queries have been resolved and all data collection forms have been signed by the PI (where applicable)

5.6 Ensure a close-out letter has been obtained from the sponsor (if applicable) and filed in the regulatory binder

5.7 Ensure a plan is in place to appropriately follow up on on-going adverse events as required per protocol

5.8 Notify ancillary departments/colleges and third-party vendors involved in the conduct of the study of study closure

5.9 Review and confirm that all IP has been returned or destroyed at the site as specified by the sponsor. File copies of study packing slips and shipment receipts in the regulatory binder

5.10 Ensure return or destruction of all other study-related materials (i.e. unused study lab kits, data collection forms, recruitment materials) as instructed by the sponsor

5.11 Ensure that any equipment on loan has been returned, and file the appropriate shipping return documents in the regulatory binder

5.12 Ensure final subject payments have been distributed

5.13 Ensure final payment is received from funding sponsor

5.14 Confirm requirements for data retention and storage per applicable regulations and per sponsor, if applicable

5.15 Notify the IRB that the study is complete by submitting Final/Termination Report, if applicable

5.16 Confirm study results have been submitted to http://clinicaltrials.gov (if applicable)

5.17 Documentation

5.17.1 Complete study close-out checklist, suggested

## 6 MATERIALS

6.1 Templates

6.1.1 Study Close-Out Checklist

## 7 REFERENCES

7.1 21 CFR 312.62

7.2 ICH E6 Section 4.9.5

## 8 SIGNATURES

Prepared by: Judyta Kociolek Date: 05 Nov 2024

Judyta A. Kociolek, MSN, RN
Director of CRU Operations

Approved by: Date: 05 Nov 2024

Peter J. Holland, MD
CRU Medical Director