NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: INDUSTRY SPONSORED STUDY CLOSURE	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT - OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-4
EFFECTIVE DATE: JULY 01, 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE: N/A	

I. DEFINITIONS

Case Report Forms ("CRF"): A printed, optical, or electronic document designed to record all of the protocol required information [e.g., study data] to be reported to the sponsor on each trial subject. CRFs standardize the collection of study data and help to ensure that the medical, statistical, regulatory and data management needs of the study are met.

Protocol: The document that describes the objectives, design, methodology, statistical considerations and plan for the conduct of the study. A protocol for an industry-sponsored study is usually prepared by the sponsor and ensures the safety of the trial subjects and integrity of the data collected.

Contract Research Organization (CRO): A company hired by the company Sponsor or research center Sponsor to take over certain parts of running a clinical trial, including designing, managing, and monitoring the trial, and analyzing the results. Also called CRO.

Regulatory Binder: The Regulatory Binder or Investigator Site file (ISF) contains essential documents. The requirement to maintain a set of essential documents within a Regulatory Binder comes from International Conference on Harmonization Good Clinical Practice (ICH GCP). GCP guidance defines essential documents as:

> "…those documents which individually and collectively permit evaluation of the conduct of the clinical trial and the quality of the data produced. These documents serve to demonstrate the compliance of the investigator, sponsor, and monitor with the standards of Good Clinical Practice and with all applicable regulatory requirements".

Residual Balance: The remaining unspent funds left in a sponsored project account following the closeout of a fixed amount award.

II. POLICY

A clinical study should be closed at NSU when all NSU study activities are complete. This means that:

1) enrollment of participants, interventions, follow-up, and data collection are all complete,
2) all data collected is analyzed to the point that participants' records will no longer be required,
3) the Industry Sponsor has confirmed no further subject data is required,
4) and all financial reconciliation has been completed.

To close a study, several steps must be taken to properly close out the project. Once a study is closed, no further research related activities can occur.

III. SCOPE

This Policy applies to all University employees and students.

IV. PROCEDURES

A. Finalize Study Data

Either the PI/University or the sponsor/CRO will notify the other Party of intention to close the study. All study documentation must be complete prior to the sponsor/CRO locks the study database.

The PI should be responsive to the sponsor/CRO during database review for accuracy. Any queries from the sponsor/CRO must be resolved before study closure is initiated.

For industry sponsored clinical research, the PI is responsible for the submission of all technical reports, CRFs, and other agreed upon deliverables to the sponsor/CRO.

B. Test Article Reconciliation

At the completion of the study, the PI must return all remaining investigational product, supplies, and/or equipment to the sponsor as per the Clinical Trial Agreement, if applicable.

C. Study Close Out Visit

A study Close-out Visit is a visit which may be arranged by the sponsor/CRO of the research study to ensure that all necessary aspects of the study closure have been addressed, to include organization and completion of documentation and reporting. The study monitor will ensure that everything is legible, well organized and will remain intact and be accessible in the future as needed for regulatory reasons.

Study close out visits include, but are not limited to:

- Confirming that all CRFs have been completed and submitted;
- Verifying that a signed informed consent form is on file for each study participant;
- Confirming completion of all study logs (IP Accountability Log, Delegation of Authority Log, Subject Enrollment/Screening Log, etc.)
- Review of Regulatory Binder Essential Documents

- Conducting final investigational product reconciliation

D. Notification of Study Closure to IRB

Upon receipt of written confirmation from the sponsor that a study may be closed, the PI or his/her designee shall initiate study termination with the Institutional Review Board (IRB) (https://www.nova.edu/irb/policies-procedures/1-3-investigator-responsibilities-v2023-08-10.pdf). The PI shall submit all final reports to the IRB and if applicable, documentation of IRB closure to the industry sponsor.

E. Closure of Study Banner Account

After receiving written confirmation from the sponsor that a study may be closed and from the IRB that the IRB protocol has been closed, the PI must notify Contracts and Grants Accounting of study closure. Contract and Grant Accounting (CGA) will complete a final budget vs actual report (BAR), reflecting any pending adjustments necessary. The PI and College Business Representative will address the adjustments and notify CGA once resolved. CGA will complete the closeout process and notify the PI, the College Representative and the Office of Clinical Research once the index has been officially closed in the Banner financial system.

The internal NSU process of financial reconciliation should be as follows:

1. The PI or designee should review and confirm that all performed study activities have been invoiced and payment received.
2. The PI or designee should confirm that no further study activities will be performed.
3. The PI or designee should provide to the Office of Clinical Research (OCR) an updated study budget based on actual subjects accrued, length of study, personnel effort, actual expenditures, and revenue received. OCR will assist the PI/designee in developing the budget amendment.
4. The Office of Clinical Research will then submit the amended budget to the Budget Office, who will update the Banner Index budget.
5. Contracts and Grants Accounting will perform an account reconciliation based on the amended budget and provide to the PI and Office of Clinical Research.
6. Once all queries and concerns have been reconciled, CGA will proceed with closing the research index following FOP Policies #127.9 and #127.13. Any residual balance will be addressed as per OSP-47 “FINANCIAL DISPOSITION OF RESIDUAL FUNDS” https://www.nova.edu/osp/policies/forms/closing_fixedamount.pdf
7. Closeout should be complete within 120 days of study closure by Sponsor or per FOP policy.

F. Maintenance of Records

The PI will maintain records for the longer of: (i) the retention period required in the clinical

trial agreement, or (ii) the applicable NSU Records Retention Policy.

V. REFERENCES

- Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act (21 CFR)
- International Conference on Harmonization ICH, E6 Good Clinical Practice (GCP) Guideline
- US Food and Drug Administration ("FDA") Form 1572

VI. ENFORCEMENT

All employees having roles or responsibilities covered under this policy are expected to be thoroughly familiar with the policy and its procedures and obligations as they pertain to the employee's role. Failure to comply with this policy may result in disciplinary action pursuant to all applicable university policies and procedures.