NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: RETENTION OF CLINICAL RESEARCH RECORDS	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT -OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-6
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. CRFs are not part of the medical record.

Clinical Research: Patient-oriented research that is conducted with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials and development of new technologies, but does not include in vitro studies that utilize human tissues that cannot be linked to a living individual.

Office of Clinical Research ("OCR"): The office responsible for coordinating the review, approval, and administration of industry sponsored clinical trials and clinical research.

Principal Investigator ("PI"): The individual whom the university designates to direct the scientific, technical, or programmatic aspects of sponsored clinical trials and clinical research. The PI is responsible and accountable to the university and the sponsor for the proper conduct of the project or activity. In addition to accepting the overall responsibility for directing the research or program activities, the PI also accepts responsibility for administrative/financial oversight of the award and for compliance with relevant university policies, federal regulations, and sponsor terms and conditions.

II. POLICY

The Principal Investigator, or faculty advisor if PI is a trainee, is responsible for ensuring that all records related to the conduct of the clinical trial such as regulatory documents and Case Report Forms (CRFs) are maintained with immediate accessibility for the longer of the following timeframes:

i. OHRP Requirements: 45 CFR 46 requires research records to be retained for at least **3 years** after the completion of the research.

ii. HIPAA Requirements: University Compliance and Integrity/Dept of HIPAA Privacy follows the Records management and Destruction Policy

Policies and Procedures | Office of Records Management | NSU (nova.edu)

iii. FDA Requirements: Any research that involved drugs, devices, or biologics being tested in humans must have records retained for a period of **2 years** following the date a marketing application is approved for the drug for the indication for which it is being investigated; or, if no application is to be filed or if the application is not approved for such indication, until 2 years after the investigation is discontinued and FDA is notified. ***Please note – this length of time can be much greater than 2 years.*** You should receive written confirmation from the sponsor and/or FDA granting permission to destroy the records. (21CFR312.62.c)

iv. VA Requirements: At present records for any research that involves the VA must be retained **indefinitely** per VA federal regulatory requirements. This could be subject to change if federal regulators establish a national policy setting a shorter period for retention.

v. Sponsor Requirements – per contract: If your study is sponsored you must ensure that you comply with any terms for record retention detailed in the contract with the sponsor. For example, a sponsor may require you to retain your research related documents for 20 years. Prior to agreeing to a contract that specifies how long records will be maintained you should ensure you will receive adequate funding to pay for the storage.

vi. NSU Records Retention Policy for Grants, Research, and Sponsored Programs (https://www.nova.edu/records/forms/secure/2022-nsu-record-retention-schedule-00926329-2.pdf), currently **2 years following** the date a marketing application is approved for the drug [or device] for the indication for which it is being investigated. If no application is to be filed, or the application is not approved for such indication, the records are to be retained by the Investigator for **2 years after** the investigation is discontinued and the FDA is notified of the same.

vii. Any clinical records considered part of a participant's medical record must be separately retained in the electronic health record as per NSU policy (https://www.nova.edu/records/ policies-and-procedures.html).

In Summary:

Research Records must be maintained **a minimum of three years** after the research

is completed and the study closed with the IRB.

Records may need to be kept longer if other requirements apply.

Researchers must comply with the longest applicable standard as described above.

After above retention period, record storage or destruction shall follow NSU's Record Management policy (https://www.nova.edu/records/forms/secure/records-and-destruction-policy.pdf).

III. SCOPE

This Policy applies to all clinical trials being conducted on NSU campuses.

IV. PROCEDURES

The location of the research records must be listed and accessible within a reasonable timeframe.

V. REFERENCES

- Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act (21 CFR) 21CFR312.62.c
- International Conference on Harmonization ICH, E6 Good Clinical Practice (GCP 3.4)

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.