NSU | NOVA SOUTHEASTERN UNIVERSITY Florida	
POLICY TITLE: INITIATING AN INDUSTRY SPONSORED STUDY	
POLICY OWNER: DIVISION OF RESEARCH & ECONOMIC DEVELOPMENT - OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-3
EFFECTIVE DATE: JULY 01, 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE: N/A	

I. DEFINITIONS

Authorized Official: An individual who has been specifically designated by the Board of Trustees as authorized to sign agreements on behalf of the university. The Vice President, Division of Research is a Nova Southeastern University Authorized Official.

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

Clinical Research: Patient-oriented research that is conducted with human subjects for which an investigator (or colleague) directly interacts 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.

Clinical Trial: A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes (42 CFR 11.10(a); 81 FR 65139, 65140-41).

Delegation of Authority Log: This document identifies all personnel involved in the study, their specific responsibilities, the time period for which the authority is delegated and their signatures and initials, and is signed and dated by the PI.

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.

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.

Sponsor: Pursuant to FDA regulations, a Sponsor is a person who takes responsibility for and initiates a clinical investigation. The Sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization. The Sponsor does not actually conduct the investigation unless the Sponsor is a Sponsor-investigator. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a Sponsor, not a Sponsor-investigator, and the employees are investigators.

Sponsor-Investigator: Pursuant to FDA regulations, a Sponsor-Investigator is an individual who both initiates and conducts an investigation, and under whose immediate direction the investigational drug is administered or dispensed. The term does not include any person other than an individual. The requirements applicable to a Sponsor-Investigator under this part include both those applicable to an Investigator and a Sponsor.

POLICY

Before any clinical research project funded by an external for-profit entity is undertaken, the PI must contact the Office of Clinical Research (OCR). OCR must provide guidance to the PI on NSU processes to initiate administrative onboarding of the new project.

On-boarding includes reviewing the resources available for the study and an internal cost assessment. Study approval requires both College and Division of Research legal approval.

II. PROCEDURES

Initiating a Study

A. Confidentiality Disclosure Agreement (CDA) / Nondisclosure Agreement (NDA)

Prior to lengthy discussions between the PI and external entity or initial NSU review, OCR would facilitate the execution of a CDA/NDA between the funding entity (whether Industry Sponsored or Investigator-Sponsored) and the University. For Industry Sponsored Clinical Trials, the Industry Sponsor would initiate a CDA/NDA if it so desires. For Investigator Sponsored Clinical Trials where industry provides funding, NSU will initiate a CDA/NDA. The PI must forward it to the Nova Southeastern University's Office of Clinical Research at ocr@nova.edu for review, negotiation, and Authorized Official signature. Once executed, OCR will provide the executed CDA/NDA to the PI, Sponsor, and retain a copy in OCR.

After the CDA/NDA has been executed, the Sponsor should provide the complete protocol, draft Clinical Trial Agreement, draft Informed Consent and draft proposed budget to the PI

and OCR. PI should forward these documents to OCR if Sponsor did not provide to OCR.

B. Feasibility Assessment

For any clinical research project, whether developed by an industry Sponsor or initiated by a University PI, the PI must assess whether the proposed study is a good fit for Nova Southeastern University and his/her research team based on the following criteria:

- Ready access to the eligible patient population
- Necessary facilities and services to conduct the trial
- Time and availability of qualified research team members
- Sufficient budget to cover all costs.

The PI should request the complete study protocol and proposed budget from the Sponsor. An internal feasibility assessment should then be performed by the PI, utilizing guidance from College, OCR, and potential collaborators as needed. OCR has a feasibility checklist for optional use in guiding the feasibility assessment

https://www.nova.edu/ocr/forms/protocol-feasibility-assessment-checklist.pdf

C. Pre-Study Site Qualification Visit

When a Sponsor approaches a PI about participating as a site in the trial, the Sponsor may send a form to evaluate whether the PI and University are set up to conduct the trial. The form typically inquires as to currently competing studies, patient population access, availability of qualified research team members and necessary facilities, and any history of FDA inspections.

Many industry Sponsors also conduct site qualification visits to determine if the investigator and clinical site have the resources in place to conduct the trial. During this visit, the Sponsor will discuss the fundamentals of the protocol including responsibilities, study objectives and eligibility criteria, Institutional Review Board and informed consent requirements, and documentation- and record-keeping practices.

D. Protocol Approval Record Review

Following the determination that the study is feasible, the PI is responsible for completing the OCR Protocol Approval Record (*https://www.nova.edu/ocr/forms/protocol-approval-record.pdf*), obtaining approval and signature from the Dean of his/her college, and returning to OCR. By signing the form, the PI agrees to conduct the clinical research study in compliance with the protocol and all applicable federal regulations, institutional policies, and any sponsor agreement. The PI should provide their best estimate of which personnel will participate in the study and receive approval of the planned effort from the personnel's College.

Once the PAR is signed, the PI must forward the completed Protocol Approval Record (PAR) form to the Office of Clinical Research at ocr@nova.edu.

E. Conflict of Interest Review

Upon receipt of the PAR and/or budget outlining anticipated study personnel, OCR will provide the list of study personnel to the Research Compliance Manager. The Research Compliance Manager will send an ad hoc compliance query from Cayuse to each personnel. Each study team member is responsible for completing the Conflict of Interest disclosure questions.

Prior to finalizing the CTA, OCR will confirm with the Research Compliance Manager that COI disclosures have been obtained for all personnel. The Research Compliance Officer will alert OCR if any management plan is deemed necessary.

F. Liability Review

OCR will submit a protocol synopsis to NSU's insurance carrier to confirm that compensation to subject(s) for trial-related injury will be available. NSU Risk Management will review and approve or work with OCR to address any concerns.

G. Negotiation of Budget and Clinical Trial Agreement

After receipt of the protocol and Sponsor-proposed budget, the PI should develop an internal NSU budget for the study that details all of the costs of performing the study. This includes a list of:

- one-time fees such as start-up annual and closeout costs. The PI should reference the NSU Research Fee Standards for guidance (attach once approved).
- Schedule of events with study and standard of care activities identified and costs / Sponsor reimbursement attributed to each activity at each relevant time point.
- Study personnel and projected effort attributed to the study
- Banner Index budget, preferably with a benchmark payment guide

It is recommended that the PI use the Clinical Trial Budget template provided by OCR.

The PI must identify in the Schedule of Events any standard of care activities that will be billed to insurance or participant as "SOC" and provide to NSU Health's Director of Revenue Cycle and Contracting & Credentialing before the study begins screening for patients.

The PI must provide the budget, a list of NSU staff who should have access to the study Banner account, and the signed PAR to OCR. OCR will review the budget for completeness and compliance with NSU policies, and then negotiate the clinical trial agreement and related documents (eg protocol, budget, informed consent) with the Sponsor.

After execution of the clinical trial agreement and notice of IRB protocol approval, OCR will complete final processing with the Central Finance Office to establish a Banner account for the underlying study.

H. Institutional Review Board Review (IRB) and Approval

Federal regulations require that research projects involving human subjects, including clinical trials, be reviewed by an IRB. For information on the IRB submission process, click on the following link. https://www.nova.edu/irb/index.html

I. Internal Study Approval Meeting

Once the CTA is executed, IRB protocol is approved, and a Banner index has been assigned, OCR will lead a study approval meeting where the contractually obligated details of the study are reviewed with the PI, the relevant study team members, the College Business Representative, CGA accountant, College HR representative, and the research pharmacy/lab when appropriate.

J. Sponsor's Site Initiation Visit

A Site Initiation Visit (SIV) or Study Start-Up is an organized meeting to discuss the new protocol before the research project is ready to screen and enroll potential patients. It also serves as training for the protocol of interest. All members on the study (everyone listed on the Delegation of Authority Log and IRB approved) should attend the meeting. The study team members should have reviewed the protocol prior to this meeting. The study start up meeting should lay the ground work for the study and allow all team members to ask any questions they may have prior to accrual.

Prior to study enrollment, the study monitor on behalf of the sponsor will conduct a Site Initiation Visit (SIV) to provide the principal investigator and the study team training on the protocol, procedures, processes and monitoring plan.

III. REFERENCES

- Title 21 of the Code of Federal Regulations, the Federal Food, Drug, and Cosmetic Act (21 CFR)
- The International Conference on Harmonization ("ICH") Guideline for Good Clinical Practice (GCP)
- US Food and Drug Administration ("FDA") Form 1572
- 42 CFR §50.604

IV. SCOPE

This Policy applies to all University employees.

V. 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.