TITLE: REGISTRATION OF CLINICAL RESEARCH ON CLINICALTRIALS.GOV	
POLICY OWNER: OFFICE OF CLINICAL RESEARCH	
FUNCTION: CLINICAL TRIAL MANAGEMENT	**POLICY CODE NO:** OCR-1
EFFECTIVE DATE: March 15, 2024	**REVIEW PERIOD:** ANNUALLY
REVISION DATE: June 6, 2024	

I. DEFINITIONS

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 or diagnostics) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Responsible Party: (1) the principal investigator (PI) of the Clinical Trial, or if a trainee PI, the faculty advisor for the Clinical Trial; or (2) the regulatory Sponsor of the Clinical Trial (as defined in section 50.3 of title 21, Code of Federal Regulations or any successor regulation)

II. POLICY

A. Purpose:

To provide guidance on identification of Clinical Trials to be registered on clinicaltrials.gov, and the process on how a study is registered.

B. Policy

NSU requires any Clinical Trial performed at NSU to be registered on clinicaltrials.gov by the Principal Investigator unless another Responsible Party has performed that registration and provided the NCT# (ClinicalTrials.gov unique identifier) to the Clinicaltrials.gov NSU Administrator at ocr@nova.edu. If registration is pending, written confirmation by Responsible Party is acceptable documentation.

All registered trials must be updated in a timely manner when study status changes and at least annually. Summary results must be submitted within 1 year of trial completion date.

The NSU Health financial team must include the NCT number on any routine costs charged to Medicare.

Financial Consequences of Non-Compliance: The College to which the Principal Investigator (PI) reports will bear the responsibility for resolution of any monetary penalties enacted against NSU due to the PI's non-compliance with Clinicaltrials.gov registration requirements. It is recommended that such penalties will be covered from indexes following the order below:

1. The research incentive (RI) index for the college/department to which the PI/PD is assigned.
2. If a balance remains after fully utilizing the RI index for the college/department, then additional funding will be provided by the departmental index used to cover restricted activities.
3. If no departmental index is available to cover other restricted activities, then a department operational index will be used.

III. PROCEDURES

A. The Office of Clinical Research (OCR) is available to support NSU faculty in the clinicaltrials.gov registration and maintenance for Clinical Trials being performed at NSU. The PI is responsible for making OCR aware of the study but Cayuse and IRB Manager processes are in place to assist with this in a timely manner.

B. It is the NSU PI's responsibility to register the Clinical Trial unless another Responsible Party has performed that registration and provided the NCT# (ClinicalTrials.gov unique identifier) to the Clinicaltrials.gov NSU Administrator at ocr@nova.edu . If the PI is a trainee, it is the faculty advisor's responsibility to supervise and ensure registration and maintenance of the record.

C. Research that does not qualify as a Clinical Trial but falls within the scope of ClinicalTrials.gov may be registered at the discretion of the PI.

D. Each College or functional unit, in accordance with this policy, may determine roles, expectations, and further processes at their discretion to support compliance with this policy and the policies of ClinicalTrials.gov.

E. A tutorial for how to register a Clinical Trial on clinicaltrials.gov is available at: https://prsinfo.clinicaltrials.gov/tutorial/content/index.html#/

F. If the NSU PI is unsure of whether the trial meets the requirements for registration under this policy, they should contact OCR for guidance.

G. OCR will review and monitor clinicaltrials.gov status for all open studies being performed at NSU facilities, providing feedback to PI if an update is required.

H. Either the PI or a designee must provide the NCT number both the NSU Health financial team supporting the trial at PFSBilling@nova.edu and Grants and Contracts team. This number will be used to facilitate Medicare billing as appropriate.

I. The PI will determine whether a study meets the definition of a Clinical Trial as described above. If there is ambiguity or disagreement by the IRB or other NSU entities as to whether or not the study qualifies as a clinical trial, the Dean of the PI's College (or their designee) will make the determination and will provide their decision in writing to the IRB and OCR.

IV. REFERENCES

https://prsinfo.clinicaltrials.gov/ACT_Checklist.pdf

https://classic.clinicaltrials.gov/ct2/manage-recs/resources#FDAAA2007

Final Rule for Clinical Trials Registration and Results Information Submission

V. COMPLIANCE CONTACT

If you would like further information on this NSU Policy, or have additional questions, please contact us via email to the Office of Clinical Research point-of-contact at ocr@nova.edu .

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.