Nova Southeastern University
Office of Clinical Research
3300 S. University Drive
Fort Lauderdale, FL, 33328-2004

INIM Protocol Approval Record

For Non-Federally Funded Human Subject Research

INSTRUCTIONS

1. Complete Section I to determine whether this form is required.
2. **Complete this form prior to Clinical Trial Agreement negotiations.**
3. The Principal Investigator (PI) is responsible for the completion of this form, including **obtaining all personnel and Deans' signatures**.
4. Once completed, this form must be electronically forwarded to the Office of Clinical Research ocr@nova.edu

Section I – Research Questions

1. Please describe the type of study in detail below, including study population, study design, what you will be testing, and what outcomes are being measured.

   _____

2. Has this study already been registered on Clinicaltrials.gov?

   ☐ No ☐ Yes, NCT# _____

SECTION II – Protocol

PI: _____

College / Center / Department _____

Phone ext. _____ Email_____ Cell phone _____

Protocol Title: _____

Proposed Start Date: _____ End Date: _____ Duration: _____Year(s) / _____Month(s)

Instrument of Award: ☐ Contract ☐ Sub Contract

External Sponsor: _____

Address: _____

Contact Person _____ Phone _____ Email _____

Date of Executed CDA _____

Section III- Staffing

***Note for Dean Wallace and Alfredo: Nancy Klimas' effort must be allocated to clinic time because her research time is fully allocated.**

Instructions: The individual members of the Project Staff, as well as the Dean of College or Dept. Chair for the faculty or staff member's primary appointment must sign this section. If the PI is a Dean or Dept. Chair, then his/her supervisor must sign this section.

Name	**Role**	**% Effort** Nancy Klimas' effort must be allocated to clinic time	**College/Dept**	**Personnel Signature**	**Dean/Dept. Chair or Supervisor (if applicable as described above) Signature**

***The PI and all individuals on the study team will receive a separate Conflict of Interest email via Cayuse. Please monitor your Clutter and Junk email just in case.**

Section IV – Finance and Budget - Approximate

Total Direct Funding _____

Total Indirect Funding _____

Total Project Funding _____

Business Representative Signature

Section V – Location/Space

Will the study be conducted at NSU?

☐ **No** ☐ **Yes**

If yes, where will the study be conducted? (please be specific)

Building/Room # _____

Does this location also serve non-research patients? (i.e. Dental, Medical, Psychology, Physical Therapy, Optometry, Audiology, SLP, etc.)

☐ **No** ☐ **Yes**

Has the space been authorized for use for the duration of the study?

☐ **No** ☐ **Yes**

If yes, by whom? _____

Will any College or Clinic equipment be utilized for the study?

☐ **No** ☐ **Yes**

Has use of the equipment been authorized for use by the study?

☐ **No** ☐ **Yes**

If yes, by whom? _____

***College space and equipment is to be approved by the Dean, and NSU Health space and equipment should be approved by Leonard Pounds, Vice President NSU Health.**

Section VI - Commitments

Instructions: PI should initial each statement.

_____I agree to conduct the study in accordance with the current protocol and will only make changes in the protocol if approved by the regulatory sponsor (if applicable) and IRB, except when necessary to protect the safety, rights, or welfare of subjects.

_____ I agree to personally conduct or supervise the described investigation(s).

_____ (If applicable) I agree to inform any patients, or any persons used as controls, that the investigational product are being used for investigational purposes and I will ensure that the requirements relating to obtaining informed consent in 21 CFR Part 50 and Institutional Review Board (IRB) review and approval in 21 CFR Part 56 are met.

_____ (If applicable) I agree to report to the sponsor adverse experiences that occur during the investigation(s) in accordance with 21 CFR 312.64. I have read and understand the information in the investigator's brochure, including the potential risks and side effects of the investigational product.

_____I agree to ensure that all associates, colleagues, and employees assisting in the conduct of the study are informed about their obligations in meeting the above commitments.

_____I agree to maintain adequate and accurate records in accordance with 21 CFR312.62 and to make those records available for inspection in accordance with 21 CFR 312.68

_____I will ensure that an IRB that complies with the requirements of 21 CFR Part 56 will be responsible for the initial and continuing review and approval of the clinical investigation. I also agree to promptly report to the IRB all changes in the research activity and all unanticipated problems involving risks to human subjects or others. **Additionally, I will not make any changes in the research without IRb approval, except where necessary to eliminate apparent immediate hazards to human subjects.**

_____ I agree to comply with all other requirements regarding the obligations of clinical investigators and all other pertinent requirements in 21 CFR Part 312.

SECTION VII - Principal Investigator

I certify that:

- the above information and content of the proposal are true, accurate and complete
- that the budget reflects all appropriate expense items
- and that the project will be performed in compliance with university and sponsor policies, if funded.
- I certify that I will obtain all necessary approvals. For example, human subjects or biosafety, if applicable to my project, prior to initiating any research activities.

_____ _____

Signature, Principal Investigator **Date**

SECTION VIII - Dean of PI's College

I certify that:

- Personnel, space, and facilities are available to conduct/support the project as proposed and PI/ research personnel are appropriately qualified to conduct the work.
- The project is appropriate to the goals and objectives of the College Unit
- The budget is approved.
- The sponsor's restriction or disallowance of F&A recovery for this submission, if applicable, is approved.

_____ _____

Signature, Dean, Unit Director, or authorized delegate as applicable **Date**