Charles E. Schmidt College of Medicine
Clinical Trial Approval Request

Instructions: This form must be completed for all new prospective clinical trials. The Principal Investigator must complete sections 1-4 of this form and submit it to the main point of contact*. The main point of contact will forward to the Associate Dean of Clinical Research and Executive Vice Dean for appropriate signatures.

Important: This form needs to be submitted and granted **Pre-Approval** prior to confirmed site selection. The Principal Investigator should carefully review the protocol and identify all recruitment, staffing and resource needs, before being selected as a site. After site selection, the budget and staffing/resource plans must have full **Approval** *before* the site agrees to participate and before the contract can be sent to the Division of Research, Sponsored Programs.

Confidentiality Disclosure Agreement (CDA): Confidentiality Disclosure Agreements are processed by the Division of Research, Sponsored Programs. Please send CDA to the main point of contact* who will forward to Sponsored Programs. CDAs must be signed by an authorized FAU representative within the Division of Research, Sponsored Programs. Pre-Approval is not required to sign a CDA.

Site Selection Visit (SSV): Principal Investigators should obtain as much information as possible about the prospective trial during the Site Selection Visit, such as inclusion/exclusion criteria, staffing requirements, unblinded vs. blinded staff, additional medical equipment and/or procedures, recruitment support, targeted enrollment start date, etc. Before the site has been officially selected, the Principal Investigator must have completed the **Approval Request** and obtained **Pre-Approval** via signature of the Associate Dean for Clinical Research.

Site Selection: Principal Investigator should request the final protocol and contract/budget, as soon as possible after site selection, so that budget feasibility can be determined. Please forward the contract/budget to the main point of contact* listed below.

Approval: Once full **Approval** to initiate a new clinical trial has been obtained, please forward all study start-up materials to the main point of contact* who will submit initial regulatory documents to, and coordinate contract negotiations with the Sponsor and the Division of Research.

New Staff, Equipment, Facilities: The hiring of any new staff, purchase of large equipment, and agreements with new facilities should have full **Approval** and be coordinated with the appropriate COM departments.

New Staff: Catie Gouchenour (IMS), cgouchen@health.fau.edu (561) 297-0123
Sara Greene (BS), greenes@health.fau.edu (561) 297-2984
Questions regarding the hiring process can be directed to: comdeansoffice@health.fau.edu
COM Faculty Appointment Process for Compensated Positions
COM Staff Appointment Process for Compensated Positions

Equipment: Debra Bradley, dbradley@health.fau.edu (561) 297-2503
New Facilities: Bill Donelan, wdonelan@health.fau.edu (561) 297-4043

***Main point of contact:** Mary Lou Riccio, mriccio@health.fau.edu (561) 297-0161
***Funding information:** Jackie DeAquino, jdeaqui@health.fau.edu (561) 297-1206
Beth Swerdloff, swerdlof@health.fau.edu (561) 297-2723
***Business Operations:** Steven Bender, benders@health.fau.edu (561) 297-4814
***Sponsored Programs:** Myles Lathrop, lathropm@fau.edu (561) 297-4754
Tracy Vuong, tvuong1@fau.edu (561) 297-1289
***Research Integrity:** Donna Simonovitch, dsimonovitch@fau.edu (561) 297-1388
Elisa Gaucher, egaucher@fau.edu (561) 297-2318
***Associate Dean for Clinical Research:** James Galvin, MD, MPH, galvinj@health.fau.edu (561) 297-4793

Clinical Translational Research Unit

Charles E. Schmidt College of Medicine

Clinical Trial Approval Request

Section 1. Principal Investigator and Protocol Information

Investigator Name: _____ Date: _____

Protocol Info: _____

Sponsor/Funding Agency *Protocol No.* *Trial Phase*

Protocol Title: _____

Section 2. Staffing and Resource Information

Principal Investigator Effort Availability (FTE): _____ Number of Active Trials: _____

Study Physician (Name): _____ Effort Availability (FTE):_____

Study Coordinator (Name): _____ Effort Availability (FTE):_____

Complete Additional Staff, Facilities and Resource sections on page 2

Section 3. Participant Information

Briefly describe major participant inclusion/exclusion criteria:

Vulnerable Populations: ☐ Minority ☐ Cognitively Impaired ☐ Other Vulnerable (specify):

Identify source(s) for participants and size of potential pool. Include target enrollment number:

Section 4. Recruitment Information

Describe the recruitment plan:

_____

_____

_____

Principal Investigator Signature *Date*

Pre-Approval (prior to site selection)

_____

Associate Dean of Clinical Research Signature *Date*

Approval

☐ Budget Approval ☐ Staffing and Resource Plan Approval

_____

Associate Dean of Clinical Research Signature *Date* *Executive Vice Dean Signature* *Date*

Section 2. continued
Additional Staff

Investigator: Protocol No.:

List all the additional staff that are needed, time required, and effort availability. If using raters, please indicate the type of rating and that rater is certified.

Name:	Role:	Time Required (per visit):	Effort Availability (FTE):

Facilities

List all the facilities that will be used for this study.

Facility Name:	Subcontract Required?	Procedures to be conducted at this facility:
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	
	☐ Yes ☐ No	

New Resources Needed

Describe any new staff, facilities, or other new resources needed: