

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. 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@fau.edu (561) 297-1206

Beth Swerdloff, swerdlof@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

