

**POLICY: Principal Investigator and Student Roles in Human Research**

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**1. PURPOSE**

- 1.1. This policy establishes the categories of individuals who may be a Principal Investigator on a human subject’s research study overseen by a UF IRB and the role UF students can play within those research studies.

**2. POLICY**

- 2.1. In order to insure the protection of research subjects and regulatory compliance, only the individuals listed below may serve as the Principal Investigator (PI) on projects overseen by a UF IRB.
- 2.2. The University of Florida may grant exceptions to the following on a case-by-case basis. Research must be within the PI’s scope of expertise or the project must include co-investigators who provide sufficient expertise.
- 2.3. When an individual is a faculty or staff person, but is conducting the research as a student, then the student rules apply for that individual, as it relates to the protocol being submitted.
- 2.4. Academic titles and definitions are based on UF Regulation 7.003 <http://regulations.ufl.edu/wp-content/uploads/2012/09/7003.pdf>.

**3. RESPONSIBILITY**

- 3.1. The IRB chair, members and office staff are all responsible for carrying out these procedures.

**4. PROCEDURE**

- 4.1. The following are allowed to serve as the Principal Investigator on human subjects research studies submitted to UF IRBs
  - 4.1.1. UF faculty with full time or part time compensated appointments
    - 4.1.1.1. Adjunct appointments may only be a PI with written approval from the Institutional Official or designee.
    - 4.1.1.2. Excludes courtesy appointments, OPS lines, or visiting faculty
  - 4.1.2. UF faculty with emeritus appointments
  - 4.1.3. UF residents or graduate students; with the following limitations:
    - 4.1.3.1. Minimal risk studies only (such as chart reviews, surveys, educational research)
      - 4.1.3.1.1. Provided there is documentation of a faculty mentor (see description below)
    - 4.1.3.2. Excludes international research regardless of risk. A faculty mentor must be PI.
  - 4.1.4. UF fellows or Postdoctoral Associates; with the following limitations:
    - 4.1.4.1. Minimal risk studies only (such as chart reviews, surveys, educational research)
    - 4.1.4.2. Greater than minimal risk studies on a case-by-case basis
    - 4.1.4.3. There is documentation of a faculty mentor (see description below)
    - 4.1.4.4. Excludes international research regardless of risk. A faculty mentor must be the PI.

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- 4.1.5. UF staff (full time or part time)
- 4.1.6. Shands staff (full time or part time).
- 4.1.7. North Florida/South Georgia Veteran’s Health System staff (full time or part time) as indicated by NF/SG VHS requirements.
  - 4.1.7.1. Excludes individuals designated as “Without Compensation” (WOC) appointments.
- 4.2. The following individuals are prohibited from serving as the Principal Investigator on human subjects research studies submitted to UF IRBs:
  - 4.2.1. UF undergraduate students
  - 4.2.2. Volunteers
  - 4.2.3. Individuals who are not affiliated with UF, Shands, or the NF/SG VHS
  - 4.2.4. Any correspondent student (defined as a non-local student enrolled in a UF run distance learning class or program)
  - 4.2.5. UF Faculty with Courtesy/Honorary/Affiliated Clinical/Industry appointments
  - 4.2.6. Individuals who are only affiliated with UF, Shands, or the NF/SG VHS as volunteers.
  - 4.2.7. Individuals who may be affiliated with UF, Shands, or the NF/SG VHS but are conducting their research outside of that affiliation (e.g. as a private citizen or other affiliation).
  - 4.2.8. Anyone deemed insufficiently qualified by the IRB or institution, for the research being submitted.
  - 4.2.9. Anyone restricted from serving as a PI by the institution or a UF IRB.
  - 4.2.10. Anyone banned or similarly prohibited from engaging in Human Subjects Research by a regulatory agency.
- 4.3. Faculty Mentor Requirements:
  - 4.3.1. A faculty mentor is required for all students conducting human subject’s research; the mentor must approve the application prior to submission to the IRB.
  - 4.3.2. A faculty mentor is considered the responsible party for the legal and ethical performance of the project, helping to ensure that all research procedures comply with federal, State and University policies pertaining to the protection of human subjects.
  - 4.3.3. A faculty mentor must meet the criteria for “Principal Investigator” as outlined above.
  - 4.3.4. The University of Florida may grant exceptions to this requirement on a case-by-case basis. As faculty mentor for the students involved in conducting human subjects’ research that faculty mentor certifies that the student investigator serving as the Principal Investigator of the submitted protocol is knowledgeable about the regulations and policies governing research with human subjects and has sufficient training and experience to conduct the study in accord with the approved protocol. In addition
  - 4.3.5. A faculty mentor is responsible to:
    - 4.3.5.1. Meet with the student principal investigator on a regular basis to monitor the study progress;
    - 4.3.5.2. Agree to be available, personally, to supervise the student principal investigator in solving problems should they arise during the course of the study;
    - 4.3.5.3. Assure that the student principal investigator will promptly report significant or untoward adverse effects according to applicable policies;

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- 4.3.5.4. Be available to the IRB should questions or issues develop;
- 4.3.5.5. Arrange for an alternate faculty mentor to assume responsibility during periods of absence (e.g., sabbatical leave or vacation), and advise the IRB by letter of such arrangements; and
- 4.3.5.6. Being added as the principal investigator or sub or co-investigator depending on the nature of the study.

**5. ADDENDUM**

5.1. Approved roles for UF students involved in human subjects research:

	Minimal Risk				Greater Than Minimal Risk			
	PI	SS	PHI	Consent	PI	SS	PHI	Consent
Volunteer	Red	Green	Red	Red	Red	Green	Red	Red
Undergrad	Red	Green	Green	Green	Red	Green	Green	Red
Graduate	Yellow	Green	Green	Green	Red	Green	Green	Yellow
Doctoral or Resident	Yellow	Green	Green	Green	Red	Green	Green	Yellow
Post-Doc Fellow	Yellow	Green	Green	Green	Yellow	Green	Green	Yellow

Code: PI = can assume the role as the Principal Investigator  
 SS = can assume the role as a member of the study staff (eg. Sub-investigator, coordinator, etc.)  
 PHI = can have access to Protected Health Information (reference to the Privacy Office link)  
 Consent = can obtain informed consent from a study subject

Color Key	
	Not allowed
	Decided on a case-by-case basis
	Allowed