University of Florida
IRB Investigator Guidelines
Approved Human Subjects Research Roles

Modified: November 2022

The University of Florida, UF Health, and the North Florida/South Georgia VAMC all have a mission to conduct and support human subjects research. The human research roles for which individuals may be eligible are determined by various regulatory groups within these institutions. The following is meant as a guide to determine those roles and any individual request to alter these guidelines must be approved by the Vice President for Research at UF. Approval as a Principal Investigator (PI) or study staff presumes compliance with all of the following applicable rules. Qualification to serve in a specific research role on a specific research protocol is determined by the IRB, eligibility is determined by the following:

General Rules:

1. What the IRB approves does not overrule the requirements of any other UF, UF Health, or VAMC organization or departmental rules.
2. All state or locally licensed, certificated, or registered individuals may not engage in a research intervention that is in conflict with their applicable state practice act.
3. Only properly credentialed individuals may engage in any greater-than-minimal risk study interventions or anything that requires credentialing, unless or until the individual becomes properly credentialed.
4. If not a U.S. citizen, that individual must have all proper visas, and complete the HR/volunteer onboarding process.
5. If researchers wish to take research data outside of UF, they must follow the University Intellectual Property policy and consult their departmental administration.
6. If someone belongs to more than one of the categories in the chart below, the category that allows the most research options prevails.
7. If working in a lab, individuals must obtain approval and training from Environmental Health & Safety (EH&S).
8. All appropriate IRB researcher training must be completed.
9. All investigators and study staff must be appropriately registered within myIRB and be listed in myIRB under the appropriate role with correct study functions.
10. If accessing protected health information (PHI), individuals must have completed the General HIPAA Awareness training as part of their job or position, or complete UF's Confidentiality Form.
11. If a non-UF researcher will have direct physical access in UF Health or VAMC patient care areas, that *individual* must complete all applicable clearances through UF, Shands, or VAMC Occupational Health.
12. For non-UF researchers that are not covered by another institution's Federal Wide Assurance (FWA), that individual and the PI of the UF study must complete and submit to the IRB an Unaffiliated Investigator Agreement (UIA) as part of their request to be included in the UF study.
13. Anyone who is eligible (see chart below) to obtain informed consent must be knowledgeable of the protocol and the research consenting process.
14. For incoming faculty that are have not yet started their employment with UF, please see the UF Investigator Guideline on External Faculty Joining UF.

Investigator type	Minimal Risk					Greater than Minimal Risk				
	PI	Evaluating Adverse Events	EPIC EMR Access	Access to data	Obtain Consent	PI	Evaluating Adverse Events	EPIC EMR Access	Acces s to data	Obtain Consent
1. UF Faculty (includes those that practice at the VAMC)										
a. UF Full time or part time compensated appointments										
b. UF Emeritus appointments										
c. UF Adjunct Faculty Appointments	Written approval from the Institutional Official or designee.					Written approval from the Institutional Official or designee.				
d. UF Courtesy Faculty Appointments, OPS lines			Proof of HIPAA Training					Proof of HIPAA Training		
e. +Visiting Faculty (domestic or foreign)			Case-by-case Basis					Case-by-case Basis		
2. UF\Shands Study Staff										
a. UF and Shands, full or part time employees						Case-by-case Basis	Case-by-case Basis			
3. UF\Shands Students – contingent on having a faculty mentor(N.B.: students cannot be PIs on international studies)**										
a. Fellows & Post Docs										
b. *Medical Residents										Case-by-case Basis

Investigator type	Minimal Risk					Greater than Minimal Risk				
	PI	Evaluating Adverse Events	EPIC EMR Access	Access to data	Obtain Consent	PI	Evaluating Adverse Events	EPIC EMR Access	Access to data	Obtain Consent
c. *Medical Students at UF										
d. *Graduate Students at UF										Case-by-case Basis
e. *Undergraduate Students enrolled at UF			Proof of HIPAA Training					Proof of HIPAA Training		
f. *High School Students enrolled at UF or within a UF sanctioned program (eg. CPet)										
4. External (non-UF or Shands) Faculty, Staff, or Students										
a. Volunteers (not faculty, staff or students of UF or Shands)										
b. +Visiting students currently enrolled at a non-UF college or university	Case-by-case Basis	Case-by-case Basis	Case-by-case Basis					Case-by-case Basis		
c. High School students (must be at least 16 years old)				De-Identified only					De-Identified only	
5. VAMC staff, students										
a. VAMC full or part time employees			To VA EMR only			Case-by-case Basis	Case-by-case Basis	To VA EMR only		
b. VAMC Without Compensation (WOC)			To VA EMR only				Case-by-case Basis	Case-by-case Basis	Case-by-case Basis	Case-by-case Basis
c. External VAMC faculty, staff or students			To VA EMR only					To VA EMR only		

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

+Must complete and submit a Visiting Researcher Agreement form located on the IRB-01 website.

Faculty mentor requirements

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. 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.

A faculty mentor must meet the criteria for *principal investigator* as outlined above. 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, a faculty mentor must agree to:

1. Meet with the student principal investigator on a regular basis to monitor the study progress,
2. Agree to be available, personally, to supervise the student principal investigator in solving problems should they arise during the course of the study,
3. Assure that the student principal investigator will promptly report significant or untoward adverse effects according to applicable policies,
4. Be available to the IRB should questions or issues develop, and
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 being added as the principal investigator or sub or co-investigator depending on the nature of the study.

UF students doing research outside of UF or UF Health as a means to complete a UF program, and the PI is not local:

1. Eligibility
    a. Enrolled UF student involved in research outside of UF or UF Health, or
    b. Enrolled UF correspondent student (defined as a non-local student enrolled in a UF distance learning class or program).

2. Protocol does not need to be submitted to a UF IRB, provided
    a. The research is minimal risk as defined by the federal regulations (Common Rule),
    b. A mentor at the student's external location site is listed as the PI on the research project,
    c. A non-UF local IRB has approved the research prior to the initiation of the research,
    d. Release of the data for UF student research purposes is governed by that local IRB.