Guidelines for PI Qualifications & Student Roles

After working with the three UF IRB’s (IRB-01, 02, 03), faculty stakeholders, and research deans in affected colleges, the Office of Research developed guidelines to better define the qualifications needed to be a Principal Investigator (PI) of a human subjects research project. These guidelines were set forth by Dr. David Norton, the Vice President of Research, on July 15, 2015 to specifically address the role that students can play in overseeing human subject research. The University must ensure that PIs are suitably qualified and accountable for all aspects of research projects, and that other investigators/staff are qualified to fulfill their requested roles. The IRBs designate as Principal Investigator the person who either conducts and/or oversees the entire protocol. The PI is also the person held accountable by the University and IRBs to insure all human subjects’ regulations and any financial issues are addressed. A PI often delegates some of the research activities to students, study coordinators or others, the P.I. remains accountable for the protocol.

The table summarizes who can and cannot be a PI. Please refer to the complete guidelines found on the IRB-01 website at http://irb.ufl.edu/wp-content/uploads/studentpolicy1.pdf for more information.

<table>
<thead>
<tr>
<th>ALLOWED to be a PI</th>
<th>NOT ALLOWED to be a PI</th>
</tr>
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<tbody>
<tr>
<td><strong>UF Faculty (FT/PT)</strong></td>
<td>~Adjunct appointments only with written approval ~Emeritus appointments</td>
</tr>
<tr>
<td><strong>UF Graduate Students/Residents</strong></td>
<td>~Minimal risk studies ONLY (chart reviews, surveys, educational research) with documentation of a faculty mentor ~Decided by reviewers on a “case-by-case basis”</td>
</tr>
<tr>
<td><strong>UF/Shands Staff (FT/PT)</strong></td>
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<tr>
<td><strong>NF/SG VHS Staff (FT/PT)</strong></td>
<td>Individuals designated as “Without Compensation” WOC appointments</td>
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- UF Undergrads
- Volunteers
- Individuals unaffiliated with UF, Shands, or NF/SG VHS
- Correspondent Students
- Affiliated individuals but are conducting their research as a private citizen
- Not qualified to conduct research
- Restricted/banned to conduct research by IRB/regulatory agency
PI Responsibilities

Principal Investigators are ultimately responsible for the conduct of their research. Though research responsibility may be delegated to research staff, researchers must maintain oversight and retain ultimate responsibility for the conduct of those to whom they delegate responsibility.

The University of Florida IRBs are responsible for oversight of its research and for ensuring that faculty and staff are in compliance with UF policies and procedures as well as all applicable federal, state, and local laws regarding the protection of human subjects in research. In summary, PIs are responsible for the following:

- Completing investigator training as required by the Institutional Review Board.
- Obtaining IRB approval prior to involving any human subjects (including their data or tissue) in research studies. This includes approval from the VA Research & Development (R&D) Committee before initiating research at the VA and all ancillary reviews (RAC, radiation review, biosafety, etc.).
- Apply for continuing review/renewal of your IRB approved projects prior to the expiration date.
- Ensuring that only qualified study staff conducts the study according to the approved Protocol, and in compliance with each individual’s scope of practice.
- Ensuring the rights and welfare of each research subject
- Implementing no changes in the approved Protocol, Informed Consent Form or other IRB approved study related documents without prior Institutional Review Board (IRB) approval, except when it is necessary to safeguard the well-being of human subjects.
- You are responsible for notifying all parties about the approval of your research projects, including your co-investigators and study team.
- Promptly reporting all reportable events (major deviations/noncompliance, serious & unexpected adverse events, unanticipated problems) to the IRB within 5 working days of occurrence or discovery of occurrence.
- Promptly reporting any interim reports (e.g., Data Safety and Monitoring Board reports).
- Reporting progress of approved research to the appropriate IRB. This includes submitting a closure report to the IRB once the research is completed or terminated.
- Research investigators will advise the IRB and the appropriate officials of this Institution and other institutions of the intent to admit human subjects who are involved in research protocols. When such admission is planned or a frequent occurrence, those institutions must possess an applicable OHRP-approved Assurance prior to involvement of such persons as human subjects in those research protocols.
- If conducting research involving products regulated by the Food and Drug Administration (FDA), the investigator will comply with all applicable FDA regulations and fulfill all investigator responsibilities.
- Reporting the emergency use of an approved test article to the IRB within 5 working days.
- Submitting paperwork/myIRB proposals in accordance with IRB Submission Acceptability Standards.
- If unavailable to conduct or direct this research personally, as when on sabbatical, leave, or vacation, to: (1) arrange for a co-investigator to assume research related responsibilities in the researcher’s absence, and (2) to notify the IRB in writing/designate a PI Proxy.
- In the event that employment with the university is discontinued, to do one of the following with each approved/active study prior to leaving the university: (1)
transfer the study to a new principal investigator or (2) close the project.

**INFORMED CONSENT**

- Ensuring that anyone obtaining informed consent has read the protocol and has sufficient knowledge of all information provided in the informed consent document.
- Obtaining legally effective informed consent from human subjects or their legally responsible representative before commencement of research-only screening/procedures.
- Providing each enrolled subject a copy of the IRB-approved informed consent document at the time of the consent, unless the IRB has specifically waived this requirement.

**RESEARCH RECORDS**

- Must be retained after completion of the research. Researchers must comply with the longest applicable standard according to current institutional policies.
- UF & Shands researchers must retain research records throughout the study and for a minimum of three additional years depending if any of the following are involved: HIPAA, medical treatment, patents, or Contractual language with a sponsor.
- For research involving the VA, records must be retained indefinitely until VA Regulations establish a shorter retention period.
- Lastly, research data is the property of the institution and you must comply with all institutional requirements before destroying, copying, or transferring any research data.

Please refer to [http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html](http://irb.ufl.edu/irb01/researcher-information/researcherresponsibilities.html) for a complete list of PI responsibilities.

**True or False**

Dr. Dustin Robinson will be going on sabbatical in New Zealand for the month of August. Simone Gofunckle may be added as a PI Proxy since she is a graduate nurse, has completed all required IRB training, and has worked as a research coordinator for years.

**mvIRB Helpful Hints**

1. When you are searching for behavioral questionnaires or funding sources from the drop down lists in myIRB, please remember to use “%” as a search wildcard before the item you are searching (e.g., %American Cancer Society).
2. Please check the “Yes” box to “Will you be using CTSI resources?” in Q2.0 of the Requested Review Type smart form page if you will be using REDCap.

**IRB Education Opportunities**

~ July Brown Bag Series ~
Broad Building, Room 104
Noon - 1:30 PM
July 8, 2015

“IRB-01 Updates”

By
Tiffany Danielle Pineda, BA
Education Coordinator, IRBs
IRB-01 Board Member
University of Florida

The objectives are:

- For participants to understand the new IRB-01 discretionary policy
- For participants to understand the myIRB study conversion process
- For participants to understand the retrospective chart review submission process

RSVP: Tiffany Danielle Pineda
tiffany.danielle@ufl.edu

Brain Teaser answer: False
PI Proxies must be Co-Investigators and have the level of expertise and ability to act as a PI.