Student Research

Modified: January 2017

Background:

To insure that all human subjects’ research is conducted by experienced investigators, the following outlines the role of faculty mentors and what roles various categories of students can assume when conducting human research.

Q: Is a faculty mentor required for all student research?

Yes. 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:

- meet with the student principal investigator on a regular basis to monitor the study progress;
- agree to be available, personally, to supervise the student principal investigator in solving problems should they arise during the course of the study;
- assure that the student principal investigator will promptly report significant or untoward adverse effects according to applicable policies;
- be available to the IRB should questions or issues develop;
- 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.

Q: Is the role a student can assume in the conducting of a human research project dependent on the type of student and the risk level of the research?

Yes, the following is a guideline. The IRB makes the final decision on what role(s) a student can assume:
Approved roles for UF\Shands students involved in human subjects research:

<table>
<thead>
<tr>
<th>Student Type</th>
<th>Minimal Risk</th>
<th>Greater Than Minimal Risk</th>
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<tbody>
<tr>
<td></td>
<td>PI</td>
<td>SS</td>
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<tr>
<td>Volunteer</td>
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<td>Undergrad</td>
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<td>Graduate</td>
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<td>Doctoral or Resident</td>
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<td>Post-Doc Fellow</td>
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**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

Q: Is the role a student can assume different if the research is conducted at the VAMC?

Yes, no student may be the principal investigator of any research conducted at the VAMC regardless of risk.