

Researcher Responsibilities

Researchers must comply with all UF policies and procedures*(see below) as well as all applicable federal*, state, and local laws regarding the protection of human subjects in research, including, but not limited to the following:

1. Obtaining IRB approval **prior** to involving any human subjects (including their data or tissue) in research studies.
 - o Only the IRB may determine if research is exempt from Federal regulations (investigators may not make the final determination of exemption).
2. Ensuring that only qualified personnel conduct the study according to the approved Protocol, and in compliance with each individual's scope of practice.
3. Insuring the rights and welfare of each research subject, and that the subject's rights and welfare must take precedence over the goals and requirements of the research.
4. Implementing no changes in the approved Protocol or Informed Consent Form without prior Institutional Review Board (IRB) approval, except in an emergency, if necessary to safeguard the well-being of human subjects.
5. Ensuring that anyone obtaining informed consent has read the protocol and has sufficient knowledge of all information provided in the informed consent document.
6. Obtaining legally effective informed consent from human subjects or their legally responsible representative before any research-related screening or intervention commences and using only the currently approved, stamped Informed Consent Form, when applicable.
7. Providing each subject enrolled in the study a copy of the IRB-approved informed consent document at the time of the consent, unless the IRB has specifically waived this requirement.
8. Unless specified otherwise, all signed informed consents and other research related documents (including but not limited to paperwork submitted to and approved by the IRB) should be retained throughout the study and for an additional three years after the study is completed/closed with the IRB.
9. Promptly reporting any injuries or unanticipated problems to the IRB in writing within 5 working days of occurrence or discovery of occurrence.
10. Reporting progress of approved research to the appropriate IRB, as often as and in the manner prescribed by the IRB on the basis of risks to subjects, but not less than once per year. This includes submitting a closure report to the IRB once the research is completed.
11. Completing investigator training as required by the Institutional Review Board.
12. 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.

13. 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 (or investigator-sponsor responsibilities, where appropriate), including those described at:
 - 21 CFR 312: Investigational New Drugs
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr312_00.html
 - 21 CFR 812: Investigational Device Exemptions
http://www.access.gpo.gov/nara/cfr/waisidx_00/21cfr812_00.html
14. 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 of this change prior to the absence.
15. 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. These changes must be sent in writing to the IRB by submitting either a formal revision or a Continuing Review/Study closure report. This notification must be submitted in advance (prior to the termination of employment).
16. No research investigator will seek to obtain research credit for, or use data from, patient interventions that constitute the provision of emergency medical care without prior IRB approval. A physician may provide emergency medical care to a patient without prior IRB review and approval, to the extent permitted by law (see Section 116[f]). However, such activities will not be counted as research nor the data used in support of research.

* All investigators should review and be familiar with:

- The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research:
<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>
- The U.S. Department of Health and Human Services (DHHS) regulations for the protection of human subjects at 45 CFR 46:
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>
- As well as all pertinent instructions on the IRB-03 web site:
<http://www.hscj.ufl.edu/irb/>