UF Prepares for AAHRPP Accreditation

What it means to you (Investigators & Research Staff)

By Galline P. McCaslin, MS, CCRP
AAHRPP Project Coordinator

In the recent years, a number of major research universities have achieved or are in the midst of applying for accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The primary purpose of AAHRPP accreditation is to strengthen an institution’s protections for research participants. As one of the leading public research universities in the nation, UF is also making plans to pursue accreditation through AAHRPP. We have already begun the accreditation application process and are now preparing for the subsequent site visit.

As part of the UF research community, the process of achieving accreditation will mean two things to you:

- **First**, the process of applying for accreditation will bring evaluators on campus to examine UF’s human participant study review process from top to bottom. Researchers, research teams, and various units will be selected and examined for their compliance to federal regulations, including the reporting of all projects involving human subjects. The AAHRP review team will randomly select research projects from all 3 IRBs files to determine whether reviews and status are in compliance with Federal regulations.

- **Second**, the AAHRPP team will investigate researcher education and knowledge of federal regulations regarding their research specialties. Members of the AAHRPP team will interview university officials, department chairs and/or unit heads, and a random selection of faculty in order to evaluate campus-wide knowledge of human research protection issues. Accreditation will be dependent not just on the actions of UF’s HRPP, but also on an evaluation of whether researchers and officials are cognizant of their responsibilities for the protection of human subjects.

It is important to remember that the protection of human subjects is a **shared** responsibility and we are pursuing accreditation Together!
The Office of Research has developed a new Human Research Protection Program (HRPP) website that provides important information about our program, including new institutional HRPP Policies. In addition, the UF IRBS have drafted a series of Investigator Guidelines that compliments their recently revised polices and regulatory guidances, to better assist the UF research community in the protection of human subjects.

Please refer to the UF HRPP web page at http://research.ufl.edu/hrpp.html for more information.

To learn more about AAHRPP, please visit http://www.aahrpp.org/

If you have any questions regarding UF’s HRPP and/or AAHRPP accreditation, please contact Gailine McCaslin in the Office of Research at (352) 273-3407 or gailinemccaslin@ufl.edu

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1. Does your research study include the use of an investigational drug or investigational device? Does your research propose to use a marketed drug or device in a manner not indicated in the FDA approval for that product? Has the IRB directed you to the FDA to find out if an IND/IDE is required? Help is here. IND/IDE assistance is available through the CTSI. Contact Sheila Austin, Regulatory Knowledge and Support, at sheila.austin@ufl.edu or (352)273-8702 for more information.

2. Many studies are making use of third-party software to implement online surveys and other forms of data collection. The protocol or Study Description SmartForm page in myIRB (for exempt research) should describe what software or vendor is being used to implement the study; if sensitive or identifiable information is being obtained from individuals; and the system’s privacy protections should be explained (i.e., are IP addresses of respondents collected, then destroyed, or not monitored at all?). Before submitting your study, it is important to ensure that the software has been or can be approved.

   a) Please refer to the Information Security in Research link on the IRB-01 website to access information about software applications and for a list of software applications and their approved uses.

   b) Both REDCap (approved for PHI and human research) and Qualtrics (approved for human research as long as PHI is not collected) are listed. Survey Monkey, however, is not on the list of approved etools, and it will not be approved by the UF IRBs for online survey research; it is not secure and the vendor keeps the data.

   c) If you want to use software that is not listed as approved on the software list, you will need to go through an online risk assessment process or “intake” via the UF IT Management System. Please refer to https://security.ufl.edu/it-workers/risk-assessment/ for more information.