Headline: IRB Announces Changes to Begin June 1, Toolkit Documents Updated and in New Location

May 19, 2020 -- The Institutional Review Board (IRB) staff has revised the toolkit documents to better align with best practices and compliance with the HHS Office for Human Research Protections (OHRP) and the Association for the Accreditation of Human Research Protection Programs (AAHRPP). The changes were made as part of the annual Human Research Protection Program Plan review.

Starting June 1, all initial studies submitted for IRB review must use toolkit document versions dated May 1. Initial studies in a Pre-Submission status not using the May 1 templates as of June 1 will be administratively discarded. Modifications to active studies should continue to use the toolkit document versions that were in place at the time of the initial study review.

While many of the toolkit documents only received minor revisions, there are several significant changes we would like to highlight:

1. **Administrative Check-in for studies not requiring continuing review under the revised 2018 common rule:** Expedited studies reviewed under the 2018 Common Rule are subject to an annual administrative check-in and Exempt studies are subject to an administrative check-in every three years. The IRB staff will send a comment using Huron IRB requesting a reply with basic information to verify the study is still ongoing and has not undergone unreported modifications nor experienced unreported events. See the revised HRP-103 Investigator Manual for additional details.
2. **Updated Identifiable Research Data Retention Requirements**. To align with Florida public record retention laws, IRB review will require all research data be retained for five fiscal years after study closure. See the revised Guidance-IRB-G2 Data Security Best Practices. https://ucf1.huronresearchsuite.com/IRB/sd/Doc/0/CM62L74MT88UKC445S29CLIG00/Guidance-IRB-G2-Data%20Security%20Best%20Practices.pdf
3. **Updated language regarding request for formal determinations of not human subjects research (NHSR) or study exemption:** The IRB is delegated the authority to make determinations of NHSR or study exemptions. Researchers should request formal determinations by applying through Huron IRB. See UCF Policy 4-202.2 Human Research Protection https://policies.ucf.edu/documents/4-202.pdf
4. **New Exempt Determination Request Form for Secondary Research**: Proposed studies only involving secondary research of identifiable private information or identifiable biospecimens should use the new template HRP-255SR. https://ucf1.huronresearchsuite.com/IRB/sd/Doc/0/8P5S0ASLBK8UKC445S29CLIG00/HRP-255-SR-FORM-%20%20Request%20for%20Exemption%20for%20Secondary%20Research.docx
5. **Additional Guidance Documents**: See
    a. Guidance-IRB-G4 CITI Training
    b. Guidance-IRB-G5 Quality Improvement Projects vs Research
    c. Guidance-IRB-G6 Not Human Subjects Research Status for Select Databases and Commercial Vendors
    d. HRP-430 Checklist Investigator Quality Improvement Assessment
6. **Toolkit document location:** Toolkit documents will no longer be available on the IRB website. Instead see:
    a. Guidance Documents and HRP-103 Investigator Manual, see Huron IRB>Library>General

https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=147773F5B21DBD429EC0FB75662BD9BC

b. Templates and Forms, see Huron IRB>Library>Templates
https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=294B1E5FDD6A8142A2AF57F5F7F197BF

c. Standard Operating Procedures, see Huron IRB>Library>Standard Operating Procedures
https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=147773F5B21DBD429EC0FB75662BD9BC

d. For Guidance Documents on use of the Huron System, see Huron Help Center>Guides
https://ucf1.huronresearchsuite.com/IRB/sd/Rooms/DisplayPages/LayoutInitial?container=com.webridge.entity.Entity%5BOID%5BE258B74E9300D14F8F4F7410463EB60D%5D%5D&tab2=147773F5B21DBD429EC0FB75662BD9BC

7. **Status of Exempt and Rely Upon Studies approved in iRIS:** UCF is transitioning iRIS to an archival state. If you have ongoing Exempt or Rely Upon studies that have not been transitioned to Huron IRB, please make plans to transfer these studies to Huron by August 30, 2020. Exempt studies previously approved in iRIS will be reviewed as a new study and each will require a new study application in Huron using the May 1 templates. Researchers with ongoing Rely Upon studies not already transferred to Huron are requested to contact the IRB at irb@ucf.edufor assistance.
8. **Rely Upon/External IRB:** Several changes to the External IRB process have been made. Researchers are asked to contact the IRB for new reliance requests or to request for the UCF IRB to be the central IRB in multi-site studies. In general, reliance agreements are only put in place for expedited studies unless there is a standing reciprocity agreement in place (Orlando Health, Nemours, Advent Health, and the SUS system). Note that Veteran's Administration regulations prohibit them from serving as the IRB of record for other institutions and UCF is not registered with the VA Office of Research Oversight as a reviewing body. UCF researchers with plans to collaborate with VA researchers should contact the IRB early in the process for more guidance.

Unit heads are asked to reiterate these changes with faculty members. Faculty advisors are asked to review this information with student researchers.

If you have questions about any of these changes, please contact the IRB office at irb@ucf.edu or contact me directly at debra.reinhart@ucf.edu