

Memorandum

To: University Research Community
From: Andrés G. Gil, Vice President for Research
Subject: Upcoming Changes to the IRB Approval Process
Date: November 20, 2012

The Office of Research Integrity (ORI) is in the process of implementing several changes to streamline the FIU IRB approval process and to strengthen the human subject research program. The following changes will go into effect on January 2, 2013:

Online Paperless IRB Protocol Submission Process

- A new TOPAZ Electronic Protocol Application System is being deployed, which will allow investigators to submit their protocols electronically online. More information is available at the following web page: <http://research.fiu.edu/compliance/topaz/index.html>

New Principal Investigator Requirements

- Students will no longer be permitted to serve as Principal Investigators on IRB protocol submissions. For all new protocols and/or renewals, student researchers will need to be listed as Co-Investigators or Key Personnel.

New IRB Online Training Requirements

- The NIH PHRP IRB Training Course certificates will no longer be accepted by the FIU IRB. The new course required is the CITI IRB Training Course, which is more thorough and comprehensive.
- This CITI IRB Training Course will apply for all new IRB submissions, and when adding new personnel onto existing IRB-approved protocols.
- Researchers will need to complete the CITI IRB Training Refresher Course every three years. The CITI training system will send notice when the Refresher Course is due.
- Researchers accessing protected health information (PHI) will also be required to complete the CITI Health Information Privacy and Security (HIPS) Training.

New Informed Consent Requirements

- Researchers will be required to use the FIU Informed Consent Templates when developing their consent documents (available from the FIU IRB website).
- In some circumstances, researchers will still be permitted to use an external consent document when the research is conducted off-site in collaboration with another institution's IRB.

If you have any questions about these upcoming changes, please contact Christopher Grayson, Director of Research Integrity at 305-348-8379 or via email at graysonc@fiu.edu.