

November 2011 HSPO Update

New Policy – Security and Integrity of Human Research Data

In January 2012 the IRB will implement a new standard operating procedure regarding the security and integrity of human research data. At that time, all new human research study applications and ongoing studies at the continuation review will require a plan for data security and integrity. The IRB will review the plans to ensure that they fulfill the requirements, and the Research Quality Assurance Office will monitor the plans as part of routine approval reviews. This new IRB policy is available on the IRB website at <http://www.pennstatehershey.org/irb>, under Investigator Resources.

One of the resources available to investigators to meet these requirements is the REDCap software. REDCap is a secure, web-based application that supports data capture and management for research studies, is designed to quickly build and manage research data, and provides tools to ensure appropriate access, data validation and de-identification. REDCap software and support is currently available at no cost to the project budget. For more information on REDCap, contact redcap@hmc.psu.edu or visit the site at <http://pennstatehershey.org/sites/ctsi/for-researchers/ctsi-programs/clinical-research/redcap/>

More information about this policy and the REDCap system will be presented at the Dec. 15, IRB seminar (details below). The session will be recorded and available on Mediasite. If you have questions, please contact the HSPO at 717-531-5687.

IRB Education Policy

Effective January 1, 2012, the institution's Protection of Human Research Subjects education requirement will be applicable to all research studies involving human subjects, including all studies that meet the exemption category. Previously the requirement was applicable to research meeting the convened review and expedited research categories, and for exempt studies conducted to meet medical student research requirements. With this change the education requirement will apply to all research that meets the definition of human subjects research. The revised education policy is available on the IRB website, under [Educational Resources](#).

IRB Seminars and Workshops

Payer Coverage Analysis

December 6, 2011

9:00 – 10:00 a.m., Room C1857

Learn about the coverage analysis process conducted to determine the qualifying Medicaid coverage status for items and services provided to research subjects over the course of a research study. This program has been approved for category 1CME credits, continuing nursing education contact hours, and CEUs. [E-mail](#) or call 531-5687 to register.

IRB Policy for Data Security and Integrity

December 15, 2011

12:00 – 1:00 p.m., Lecture Room B

Learn about the new requirements for security and integrity of human research data, what's required for IRB submissions, and how the REDcap system can be used to manage data for research studies. This program has been approved for category 1CME credits, CEUs, and an application is pending for continuing nursing education contact hours. [E-mail](#) or call 531-5687 to register.

IRB Process Overview for Researchers

Thursday, January 19, 2012

9:00 – 11:00 a.m., Room C1830

This 2-hour workshop provides an in-depth summary of the ethical and regulatory requirements for IRB review of human research, the IRB submission process, investigator responsibilities and requirements for ongoing research. This program has been approved for category 1CME credits, continuing nursing education contact hours, and CEUs. Pre-registration is required for this workshop to ensure adequate materials. [E-mail](#) or call 531-5687 to register

If you have any questions about this HSPO Update, contact the HSPO at 531-5687 or at hspo@hmc.psu.edu.