Research is constantly evolving along with new techniques and guidelines. We would like to use this newsletter as a means to keep the research community aware of these changes.

Additional emails will be provided in a timely manner when they consist of the following issues:

- new federal regulations
- revised policy and procedures
- revised applications

Just in Time Research

One of the questions that have been asked of the HSRRC is, “how would it be possible to conduct a research study when time is of the essence?” No matter how fast the application can be completed and the research review conducted, there are circumstances when interviews and other research methods require immediate action. Through conversations and research within the IRB community we have found that there is a way to conduct this type of research. If you would like more information on applying for this type of research please contact the HSRRC office.

Crossed our radar

We also would like to offer the research community items that have “crossed our radar” and issues that other IRBs have reviewed and discussed. One such item is privacy issues and the internet. We are including a link below to Harvard Magazine and an article that addresses this issue, “EXPOSED The Erosion of Privacy in the Internet Era”.


COEUS Arriving Soon

COEUS is a web-based application designed to build a proposal online. The COEUS IRB Module is the latest addition to the suite of modules that make up the COEUS application.

The Human Subjects Office has begun training and implementing the IRB Module, and will open up the on-line application project to researchers. Until everyone is comfortable with this process, we will be running the new COEUS application and our old system side-by-side to avoid any difficulties.

We are confident that COEUS will provide a simpler and more efficient way for protocols to be submitted. We look forward to implementing this new process.

Student Subject Pools – OHRP Decisions

“OHRP has posted its January 8, 2010 letter to a commercial company, which provides a web-based system for managing student subject pools, in the belief that others may find the content to be useful. OHRP’s letter describes some acceptable alternative approaches for encouraging students to show up for scheduled appointments with investigators without imposing penalties on students who fail to show up.”

http://www.hhs.gov/ohrp/policy/correspond/OHRP20100108.html

As noted in the letter, “The following two options would not violate the requirements of HHS regulations at 45 CFR 46.116(a)(8).”
(1) Students who show up for an appointment as scheduled could be awarded a credit point, or some fraction thereof.

(2) Students who fail to show up for a scheduled appointment could have a decrease in the number of credits that can be earned through participation in research for a particular course, provided such students can still earn the same maximum number of credits by substituting an alternative non-research activity that involves a comparable amount of time and effort (see our guidance on this topic at http://www.hhs.gov/ohrp/informconsfaq.html#q9). For example, consider circumstances where students enrolled in a course can earn up to 3 extra credit points toward their final grade by participating in 3 separate studies (1 extra credit point per study). Under this option, if a student in the course fails to show up for an appointment for one study without cancelling by the specified deadline, the student is allowed to earn a maximum of 2 extra credit points by participating in two other research studies. However, the student must be able to earn a third extra credit point by completing an alternative non-research activity.

Please inform our office and the subjects, in the informed consent, which option you, will incorporate in your research.

This is the first edition of this newsletter and we welcome suggestions and comments.