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Questions, Comments, Suggestion?

If you have questions, comments or have a suggestion about how we can improve our human research protection program (HRPP) at UHCMC, send an email to: clinicalresearch@uhhs.com or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Education Updates!

[Click Here](#)

Contact Us

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[E-mail us!](#)

Anti-kickback Laws and Informed Consent Language

The Federal Anti-kickback Law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health care program business, including Medicare and Medicaid, can be held accountable for a felony. (<http://oig.hhs.gov/fraud/docs/safeharborregulations/safefs.htm>).

Many times a research sponsor will inform subjects that they are paying for the conduct of the study. Please note that the Sponsor does not pay the Principal Investigator (PI) directly, as receiving the payment personally could be viewed as violating the Anti-kickback Statute. Rather, payment is made to the institution, who then distributes the funds appropriately according to the study's research budget. If you wish to include this information as a statement in an informed consent form, use the following:

CORRECT: "University Hospitals Case Medical Center is being paid to conduct this study."

NOT: "Dr. John Smith is being paid by Sponsor X to conduct this study."

Reference UH Policy and Procedures: C&E-14 – The Federal Anti-Kickback Statute and Stark Law.

Exemption Request submission form update -

Effective Monday June 16, 2008

A new Exemption Request Form (version 06/08) has been created for use. This new form combines the 2 previously required forms: "Exemption Determination Form" and "Request for Exemption". Please note that all exemptions must receive Department Research Review Committee/Department Chairperson review prior to submission to the IRB. A signature block for this approval has been added to page 6 of the new form.

Please note that per [UHCMC IRB policy](#), projects which are approved as "Exempt" will be awarded an expiration date of six (6) years from the time the exemption was approved. If the research is ongoing for six years the investigator must resubmit the research for review as a new protocol.

Transferring CITI Credits from Former Institutions

Successful completion of the Collaborative IRB Training Initiative (CITI) course is the only way to enter the Case Western Reserve University's Continuing Research Education Credit (CREC) Program. If a new faculty member or key personnel has completed the CITI course through their former institution, there is a possibility that some of the completed courses can be transferred to their current institution [The CREC Program provides documented training in the protection of human participants in research that is conducted at University Hospitals Case Medical Center, The MetroHealth System, and Case Western Reserve University. In some instances, researchers from the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSCDVAMC) and The Cleveland Clinic may also participate in the CREC Program.] If the credits are non-transferable, you will be required to retake the basic training. Qualifying courses are determined by the University of Miami, the creator of the CITI program.

New faculty members and key personnel who have documented training in the protection of human subjects in research from their former institution have one year from their hire date in order to obtain "Core" CREC certification. New faculty members without such documentation will need to complete the "Core" CREC Certification before their IRB privileges are granted.

Please contact the UHCMC Office of Research Compliance for step-by-step instructions for determining if credits can be transferred. Once an investigator has successfully completed the training, CITI will notify Case directly. For further information on the CREC program and a link to the program, please see: <http://ora.ra.cwru.edu/research/orc/crec/index.cfm>.

UHCMC HIPAA Policy Revision: Education Update

All research studies enrolling patients or collecting Protected Health Information (PHI) must abide by the Health Insurance Portability and Accountability Act (HIPAA). The UHCMC research HIPAA policy has recently been revised. Valerie Wiesbrock and Kelly Roberts will provide an overview of the important changes to the policy. Education sessions have been scheduled for July 11, 2006 and July 16, 2007 at 10:00 in Lakeside 1400. [Register here.](#)