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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

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Revised Policy: "Exempt Human Research" - Amendment Clarification

The Institutional Review Board (IRB) policy that pertains to review and approval of "exempt" research, under the Federal regulations pertaining to human subject protections, has been revised to provide clarifications regarding amendments to protocols that have been previously approved as "Exempt" by the University Hospitals Case Medical Center (UHCMC) IRB.

If an investigator makes changes to a protocol that was previously determined as "exempt" under the Federal regulation, the investigator will need to re-submit the protocol to the IRB to verify that the protocol still qualifies as "exempt". Investigators should submit the following to the IRB for review: 1) new Exemption checklist, 2) a copy of the previously approved exempt protocol, 3) a "tracked changes" version (with the change clearly indicated) and 4) a "clean" version with the changes incorporated into the text. In addition, the investigator must provide a memorandum which references the previously approved IRB Exemption number (e.g., EM-08-01) and a summary of the change that is being made.

A designated representative of the UHCMC IRB will review the protocol and the proposed changes. If the protocol continues to qualify as "exempt" under the Federal Regulations, the investigator will receive a notice of approval from the IRB. NOTE: the IRB Exemption number and the expiration date will not change. If the change to the protocol alters the research in a way in which it will no longer qualify as "exempt" under the Federal Regulations, the investigator will be notified and instructed about how to proceed.

Update Regarding Expiration of HSP Certification

It is your responsibility to ensure that you maintain your Human Subjects Protections (HSP) Certification by obtaining continuing research education credits (CRECs). Recertification is required every three (3) years, and is achieved by obtaining, at minimum, twelve (12) CREC. The majority of individuals currently active in the HSP Certification Program are due for renewal by September 1, 2010. The UHCMC Center for Clinical Research and Technology and Case Office of Research Compliance are collaborating to provide an array of opportunities for individuals to fulfill the CREC requirements over the next year. The opportunities will include not only in-person classroom education sessions, but hands-on workshops and online presentations. Announcements regarding these opportunities are forthcoming.

Converting Sponsor Provided ICF into UHCMC Acceptable ICF

In order to help facilitate the creation of informed consent forms (ICFs), industry sponsors of clinical research often provide investigators with ICFs. The primary intention of the sponsor is to minimize the time needed for sites to create the ICF, as well as expedite the review and approval, and subsequently the start of the trial. However, it is important to note that in order to comply with UHCMC IRB requirement, these sponsor templates should not be used verbatim, but rather incorporated into the UHCMC IRB consent format.

The UHCMC [Informed Consent Language and Tutorial](#) should be used as the building block for the development of an ICF that will meet the UHCMC IRB requirements. This template can be saved as a Word document which can be edited to incorporate information provided in the Sponsor's ICF template. All UHCMC IRB required sections are provided in the Informed Consent Language Tutorial, and any non-applicable sections can be deleted. The order and section headers should not be altered.

Please be aware that the ICF language provided by industry sponsors may be technical and often requires substantial revisions prior to IRB approval. In addition, the Sponsor ICF often provides extra information about the FDA and HIPAA Authorization that is redundant with information already present in the UHCMC templates. Study staff should use the Sponsor's ICF template as a guide when drafting the UHCMC ICF according to UHCMC IRB requirements. These should be done whenever possible before initial submission to the IRB to avoid unnecessary delays in review. Assistance is available; please contact the IRB Administration Office at 216.844-1529.