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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) here at UHCMC, send an email to:

clinicalresearch@uhhs.com
or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Contact Us

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Inclusion of Illiterate, non-English speaking subjects, and pregnant women and fetuses in research studies

The University Hospital Case Medical Center Institutional Review Boards (UHCMC IRBs) have reviewed our policies in connection with the process of seeking accreditation of its Human Research Protection Program with the accreditation body AAHRPP (Association for the Accreditation of Human Research Protection Programs). As a result, we want to provide further guidance for addressing the inclusion of illiterate and non-English speaking subjects; and pregnant women and fetuses in research studies. While many research studies may not directly target these populations, there is the potential for inclusion of someone from one of the above referenced in a research protocol if the individual meets all other inclusion criteria.

Beginning February 19, 2007, the following items must be appropriately addressed in initial and continuing review protocol submissions to secure UHCMC IRB approval.

Illiterate subjects; non-English speaking subjects; and pregnant women and fetuses.

- To comply with the ethical principles of the Belmont Report, illiterate and non-English speaking subjects cannot be unfairly excluded from research without good reason. As a result, the UHCMC IRBs will review all submissions (both initial and at continuing review) to ensure that their inclusion/exclusion is justified, based on the type of research and the potential benefit to subjects.

- In addition, if a study wishes to collect data from pregnant women and fetuses, as they are a vulnerable population, their inclusion must be described and fully justified; and comply with 45 CFR 46 Subpart B.

Please visit the following website for the complete announcement and additional guidance ([Vulnerable Populations](#)). If there are any questions, please contact the UHCMC IRB Office or the UHCMC Office of Research Compliance.

NEW: HIPAA Authorization Template Language

As you are aware, the Health Insurance Portability & Accountability Act (HIPAA) was enacted April 14, 2003. This regulation, also known as the "Privacy Rule", establishes conditions under which researchers and investigators may have access to and use an individual's PHI to for research purposes. This regulation indicates that signed authorization must be obtained unless the Institutional Research Privacy Board (RPB) has otherwise designated that this is not necessary.

In a continued effort to implement quality improvement processes within our human research protection program, the UHCMC Research Privacy Board (RPB) has revised the HIPAA Authorization template language that must be used as the basis to obtain written authorization to use and disclose PHI for research purposes. These changes were based on current guidance in the Federal regulations regarding research and the [Privacy Rule](#), as well as on feedback from UH research investigators. It is believed that these collective efforts will greatly simplify the language in the HIPAA authorization documents and that such changes will be welcomed by investigators.

To assist with this transition, the UHCMC Center for Clinical Research will hold two educational sessions: **March 15, 2007 (3-4 PM), and March 16, 2007 (12-1 PM)**. Seating is limited therefore please RSVP to [Cristina Ferrazzano Yaussy](#) if you plan to attend.

Beginning **April 1, 2007** all NEW research protocols submitted to the UHCMC IRB and RPB for review must use the new HIPAA Authorization language template. Please visit the following website for the complete announcement and additional guidance: [Research HIPAA](#).