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

## Education Updates!

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## Contact Us

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## **IRB UPDATES: Revised policies and procedures**

As part of the University Hospitals Case Medical Center Institutional Review Board's (UHCMC IRB) process of quality improvement and self-assessment, many of the current policies, procedures and forms/templates are being reviewed and revised accordingly. Many of the revisions are administrative in nature. However, in the coming months there will be some new processes and procedures presented to the research community. These are being done to ensure appropriate maintenance of the highest Human Research Protection Program (HRPP) standards under AAHRPP accreditation. The research community will be made aware of any changes, revisions or clarifications through a) this newsletter (*Research Collaboration Corner*), b) separate e-mail correspondence sent by the Center for Clinical Research and Technology to all members of the research community; and c) through the "[IRB News and Updates](#)" page on the UHCMC IRB's website (<http://www.uhhospitals.org/tabid/1294/Default.aspx>).

Below is a list of some of the recent changes:

- Revisions to the IRB's "[Frequently Asked Questions](#)" webpage to organize the text. (<http://www.uhhospitals.org/Research/InstitutionalReviewBoard/FrequentlyAskedQuestions/tabid/3862/Default.aspx>)
- Addition of a "[Statement of Compliance](#)" available on the IRB website: Written documentation that the UHCMC IRB meets all required regulations pertaining to human subject protections, including Department of Health and Human Services (DHHS) 45 CFR 46 and Food and Drug Administration (FDA) 21 CFR 50 and 56, in addition guidelines established under Good Clinical Practice (GCP) and the International Conference on Harmonization (ICH), is now available for dissemination on the IRB website. (<http://www.uhhospitals.org/tabid/1294/Default.aspx>)
- "[Protocol Submission Requirements](#)" policy (revision): All methods of data collection for research purposes must be articulated in the IRB approved protocol. The policy was revised to provide additional guidance to address when study procedures require the use of UH clinical electronic documentation systems (e.g., Physician Portal). ([http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/Jan\\_09/IRBPolicyProtocolSubmissionRequirements\\_0209.doc](http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/Jan_09/IRBPolicyProtocolSubmissionRequirements_0209.doc))
- "[Other Vulnerable Populations](#)" policy (revision): More information regarding the IRB's expectations for inclusion and exclusion of these individuals has been added to the policy, including additional clarification about the inclusion of persons who do not speak English. ([http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/jan\\_09/IRB\\_Policy\\_Other\\_Vulnerable\\_Populations\\_12\\_2008.doc](http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/jan_09/IRB_Policy_Other_Vulnerable_Populations_12_2008.doc))

## **Investigator Certification Reminder:**

As a reminder to the research community, the UH IRB follows the Case requirements for human subject protection certification training. Information regarding the policy on "[Certification in Human Subject Protections](#)" can be found on the UH IRB Policy and Procedure website. Certified investigators and research staff members (key personnel and especially individuals obtaining informed consent) must earn 12 CRECs every three (3) years to maintain their certification in human subjects' protections. ([http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/jan\\_09/IRB\\_Policy\\_Certification\\_HumanSubjects\\_Protections\\_7\\_2007.doc](http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/jan_09/IRB_Policy_Certification_HumanSubjects_Protections_7_2007.doc))

**IMPORTANT NOTE:** Case no longer sends emails to currently certified research personnel to provide reminders to about CREC expiration and the need to become re-certified. Individual research personnel must keep track of individual CREC status to ensure continued certification. CREC status may be accessed through the Case [SPIDERWEB](#) database using a Case Network ID and password (<https://ora.ra.cwru.edu/spiderweb/>).