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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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## E-mail us!

## FDA Requirements Regarding IRB Registration: July 1, 2009

In January, 2009, the Food and Drug Administration (FDA) posted a [final rule](#) (effective July 14, 2009) that will require institutional review boards (IRBs) to register through a system maintained by the Department of Health and Human Services (HHS). This registration system is the same system utilized by the HHS Office of Human Research Protections (OHRP) to maintain a list of IRBs which review federally funded research.

Any IRB reviewing clinical investigations regulated by the FDA must be registered in this system by September 14, 2009.

Please note that UHCMC IRB has two IRB committees, both of which are registered in this system. Anyone who requires documentation of this registration may search the OHRP website (<http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>) to confirm current registration status.

The IRB registrations numbers (IRB00000684 and IRB00001691), as well as the HHS Federal Wide Assurance (FWA) number (FWA00003937) can be found on the [IRB FAQ webpage](#), the [IRB Statement of Compliance](#) letter, the [IRB rosters](#) and the IRB protocol approval letter.

## Revisions to (N) Checklist

On June 15, 2009, the UHCMC IRB posted revisions on the website to the "CHECKLIST FOR NEW PROJECT INVOLVING HUMAN SUBJECTS (N)"

(<http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/NewProtocolN-June2009.doc>)

**Please utilize the most current version of the New Protocol Checklist when submitting a new protocol. Failure to utilize the most current version will result in delays in approval process.**

The following administrative revisions have been made to the New Protocol Checklist (N):

- Question 28b has been revised to request additional information about whether the research will involve the National Institutes of Health (NIH) Genome Wide Association Studies (GWAS) Program.
- Questions 29 regarding use of investigational drug has been revised to confirm if UHCMC Investigational Drug Services (IDS) is to be utilized as part of the study and to request a copy of the IDS Exemption Request Form.
- Question 29 has also been revised to request a copy of the IND/IDE correspondence affirming IND/IDE status from either the FDA or the Study Sponsor.
- Question 35 has been revised to correct the name of the Dahms Clinical research Unit (DCRU).

## New Policy: Quality Improvement Activities

On June 15, 2009, the UHCMC IRB posted a new policy: "Quality Improvement" Activities. This policy has been developed to clarify when quality improvement activities do or do not fall under the regulations for human subject protections which determines if IRB review and/or approval is needed. This policy reflects current Federal regulatory guidance disseminated by the Office of Human Research Protections (OHRP). The policy can be found at the following link:

[http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/IRBQuality\\_Improvement\\_4\\_2009.doc](http://www.uhhospitals.org/Portals/6/docs/research/irb/forms/IRBQuality_Improvement_4_2009.doc)

## Education Update

During the month of July, UHCMC Center for Clinical Research is sponsoring several education session including: "What You Need to Know About FDA Form 1572"; "The 10 Essential Documents Necessary in Conducting a Clinical Research Study" and "Registering Your Study in ClinicalTrials.gov". Registration for the sessions can be found at the following site. <http://ora.ra.cwru.edu/research/orc/education/onlinecalendar.cfm>