

In This Issue

- Identity Theft Program (new UH policy)
- NIH Challenge Grant Research protocol review
- Update protocols approved prior to June 2006
- Blood Draw Study Regulatory requirements

Quick Links

[University Hospitals](#)
[Center For Clinical Research](#)
[Office of Research Compliance](#)
[UHCMC IRB](#)
[UHCMC Grants and Contracts](#)
[William T Dahms Clinical Research Unit](#)
[Clinical Trial Listing](#)



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](#)

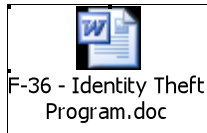
Contact Us

Office of Research Compliance
Lakeside 1400
11100 Euclid Avenue
Cleveland, Ohio 44106
216.844.5576

[E-mail us!](#)

Identify Theft Program (UH Policy F-36)

University Hospitals has developed a new policy regarding Identity Theft. This policy applies to University Hospitals and all of its wholly-owned entities (collectively, "UH") including all employees and others who provide services to or on behalf of UH. While it primarily applies to "clinical" interactions, this also impacts research personnel who will need to follow this policy when seeing research subjects during the course of an IRB approved research protocol or when subjects request research records. Persons seeking medical services or records from UH will be asked to provide a photographic identification (ID) at each encounter and when possible UH will retain a scan or photocopy in the patient's medical file. The attached policy describes the types of red flags and red flag situations and reporting procedures. In the next few weeks, an announcement regarding the availability of training will be disseminated.



IRB Submissions of NIH Challenge Grant Research Protocols

In order to ensure adequate time for review and approval prior to the beginning of the NIH funding cycle for the NIH Challenge Grants, the UHCMC Institutional Review Board (IRB) will request that all human subject research protocols that may result from NIH Challenge Grants are submitted to the IRB for review no later than July 31, 2009. Failure to comply with this request may result in a delay in review and approval. Additional information will be disseminated to those individuals who have applied for these grant opportunities.

Important Information for Protocols Approved prior to June 2006

Please review the UHCMC IRB [Protocol Submission Policy](#) to ensure that all sections and information can be found in your current protocol. Efforts are being made to ensure that all protocols are up to current standards. Protocols not containing all the necessary information and submitted for continuing review will cause a delay in the review and approval of the protocol by the IRB.

"It's Only a Blood Draw Study"

Research studies that involve the collection of blood for the sole purpose of conducting a research protocol (e.g., the blood draw has no clinical implication to the participant) must fulfill the regulatory requirements set forth by the institution and the IRB. Blood Draw study research protocols must contain all required elements as detailed in the UHCMC IRB policy "Protocol Submission Requirements" including a detailed plan for recruitment, how informed consent will be obtained and a Data and Safety Monitoring Plan.

Proper study documentation must also be maintained by the study staff as well. Study staff should maintain a research record for each participant which contains a log sheet to record the amount of blood collected for each subject, information to document the informed consent process, verification of subject eligibility and, and participant payment records (if applicable). A regulatory binder should also be maintained and should include all submission to and from the IRB, a staff signature and delegation log, signed and dated CV's or resumes of all research staff, screening and enrollment logs, and data and safety monitoring reports. Failure to maintain appropriate records can result in non-compliance investigations.