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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

## Contact Us

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

## E-mail us!

## Am I conducting research involving human subjects?

All activities that have the potential to involve humans, living or deceased, or specimens/data obtained from humans must receive a determination from the UHCMC Center for Clinical Research (CCR) regarding the nature of the activity and the type of review required.

Any investigator who believes an activity does not constitute "*human subject research*" as defined by either Department of Health and Human Service (DHHS) regulations or Food & Drug Administration (FDA) regulations [when use of drug, device or biologic is requested] must fill out a "ACTIVITY DETERMINATION FORM (DET)". This form, along with an attached summary of the project activities, will be used by a designated representative of the CCR to determine whether or not the activity qualifies as "human subject research".

If the activity is deemed to not qualify as "research" or to involve "human subjects" (both as defined by either the Department of Health and Human Services or by the Food and Drug Administration), the investigator will receive an affirmation from the CCR designee indicating such and noting that the project may proceed as planned.

If the activity is thought to qualify as "research" or to involve "human subjects", then the investigator may be asked either for additional clarification pertaining to the activity or to re-submit the project for IRB review.

**PLEASE NOTE:** Only a designated representative of the UHCMC CCR may make the final determination as to whether a project does **OR** does not qualify under the Federal regulations as "human subject research". An UHCMC investigator may not make this determination on his or her own.

Additional information regarding non human subject research determinations may be found in the UHCMC policy "[Purpose and Scope, Section A. Human Subject Research/Non-Human Subject Research Determination](#)". **The required determination form (DET) and DET FAQ is attached** and will be found on the UHCMC IRB website under "[Forms and Templates](#)" in the near future.

## Protocol Version Dates

Please note that all protocols submitted to the UHCMC IRB for review should contain a version date (in either the header or the footer of each page). This version date should be changed each time the investigator submits a new version of the protocol to the IRB for review and approval. Protocols submitted without this version date will be returned for revision, which can delay the review for the project.

## New Requirements for Clinical Trial Registration

In the Food and Drug Administration Amendments Act of 2007, Congress significantly expanded the scope of clinical trials that must be registered in [ClinicalTrials.gov](http://ClinicalTrials.gov), as well as the number of specified data elements that must be posted. The expanded clinical trial registration responsibilities fall on sponsors of clinical trials and on the principal investigators of such trials. **Some of these requirements must be met by December 26, 2007 and necessitate prompt compliance by responsible parties.**

NIH posted its initial Guidance on these provisions on November 16 at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-014.html>. Trials that must be registered generally include Phase 2 - 4 trials of drugs and biologics (controlled clinical investigations other than Phase 1 investigations of a product subject to FDA regulation) and trials of devices (controlled trials with health outcomes, other than small feasibility studies and pediatric post-marketing surveillance). NIH states in its guidance that it encourages registration of all trials, regardless of whether required under applicable law, and AAMC lends its support to this recommendation.

Registration responsibilities are technical in nature but in general fall on the sponsor of a clinical trial or on the principal investigator if certain key conditions are met. The NIH Guidance, and its underlying references, must be consulted for specifics, but it is especially important to note that **principal investigators have the responsibility to determine whether they are obligated to register their trials in accordance with the law.** Principal Investigators are encouraged to consult with their sponsored research office and other appropriate institutional offices, and for NIH funded trials, with the funding institute, to determine the extent of their responsibilities.

**Please refer to the attached document for additional information and specific UHCMC IRB guidance.**