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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 or contact Carol Fedor, Clinical Research Manager at (216) 844-5524

Contact Us

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Exempt Research

The Federal regulations allow certain research activities involving human subjects to be exempt from IRB full or expedited review [see 45 CFR 46.101(b)(1-6); 45 CFR 46.401(b); and 21 CFR 56.104(d)]. The [IRB Exemption Determination Form](#) lists the permitted exemption categories and the IRB (or investigators) may not create new categories of exempt research. Only the IRB may determine which activities qualify for an exempt review. The final determination of applicability will be made by namely the IRB Chair, Vice-Chair, designated IRB member or Senior IRB staff member who is familiar with the regulations. Investigators do not have the authority to make an independent determination that research involving human subjects or their medical information is exempt.

Continuing review is not required for research that has been determined to be exempt. However, all research determined to be exempt, will be awarded an expiration date of six years from the time the exemption was approved.

Proposed changes to an exempt study after initial IRB approval must be submitted to the IRB as a new "Request for Exemption" application. Certain changes may disqualify the research from exempt status (i.e., recruiting prisoners); therefore all changes in the research plan must be reported to the IRB for review and approval prior to implementation. Please note, changes in research staff or persons accessing or using the data during the conduct of the research, must also be formally submitted to the IRB office. These changes do not require a new exemption application to be submitted, unless determined otherwise by the IRB Chair.

If the proposed research involves Protected Health Information (PHI), HIPAA regulations still apply, even if the IRB has determined that the research qualifies for IRB Exemption, or if the IRB has determined the activity is not human subject research. Investigators must submit an Authorization Form or a request for a waiver of HIPAA Authorization for review and approval in addition to their Exemption application.

Investigators requesting a determination of exemption are required to be certified in Human Subjects Protections through the [Case CREC \(Continuing Research Education Credit\) Program](#).

HIPAA Authorization Template Language: Important Reminder

At this time, all NEW research protocols submitted to the UHCMC IRB and RPB for review must use the new HIPAA Authorization language template. In addition, the UHCMC IRB and RPB are requiring that investigators use the new template instead of making changes to the old template. Please visit the following website for additional guidance: [Research HIPAA](#).

Center for Clinical Research (CCR) Resources: The Office of Technology Management

The Office of Technology Management is a component of the CCR to assist researchers with all aspects of the creation, protection and commercialization of Intellectual Property generated by the University Hospitals community. Intellectual property can include patents, copyrights, trademarks, and trade secrets, with the first two of most importance in our setting.

Through the Office of Technology Management, we can assist with properly documenting the concept or idea, evaluating the patent landscape and marketplace for competing technologies, filing the necessary patent or copyright paperwork to protect the idea, identifying potential industry partners and negotiating agreements to commercialize the technology, through licenses, start-ups, or other vehicles. Through these activities we work to ensure that the idea receives the maximum market exposure and is able to impact the largest number of patients, bridging the gap between the discovery and healing components of our mission. Contact us today for help with a specific concept or to discuss ways in which we might be able to help support your activities.

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