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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

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Master Agreements

The Office of Grants and Contracts (OGC) of the Center for Clinical Research and Technology is establishing a number of Master Clinical Trial Agreements (MCTA) and Master Confidentiality Agreements (MCDA) between University Hospitals Case Medical Center (UHCMC) and our clinical research sponsors, as part of our ongoing efforts to improve efficiency of execution of these agreements. By reducing the contract approval time for clinical trials, investigators will be able to enroll research participants earlier and have the opportunity to enroll more participants. MCTAs may also increase the possibility that UHCMC will be selected as a clinical research site.

Master Clinical Trial Agreements

A MCTA embodies agreed-upon terms and conditions between UHCMC and a sponsor which can then be used for future engagements with that sponsor. Typically, an addendum is attached for each new research study detailing specific information regarding the trial, such as the budget (coverage analysis), protocol, principal investigator, etc., and is signed by all the parties involved in the research. A MCTA streamlines the approval process and lessens negotiation time since it alleviates the need to negotiate the terms of the main agreement as these terms have already been established. Another potential benefit of having a MCTA in place is that some sponsors tend to waive the need for a Confidentiality Agreement, allowing the investigator to receive study information sooner to evaluate the research and determine level of interest in the study.

Master Confidentiality Agreements

Once a MCDA has been established between UHCMC and a sponsor, execution of the agreement will simply require the signatures of an authorized representative of UHCMC, the PI and the sponsor, which allows for a more efficient timeframe to receive the necessary trial information. MCDAs reduce turnaround time to a few days or less.

Currently Established Master Agreements

MCTA		MCDA
Bayer Pharmaceuticals	GlaxoSmithKline	Abbott
Biogen	Hoffman LaRoche	AstraZeneca
Cook	Novartis	Axcan
Dupont	Sanofi Aventis	US Endoscopy
EMD Serono	Schering Plough	Vertex

Who To Contact

The OGC is diligently working to negotiate additional master CTAs and CDAs. If you are aware of a sponsor looking to enter into such agreement, please contact any of the Grant and Contract Coordinators listed below.

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|------------------------|--|
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