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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

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

Confidentiality / Non-Disclosure and Material Transfer Agreements:

A confidentiality/non-disclosure agreement (CDA/NDA) is a contract between two or more parties for the exchange of confidential information. A material transfer agreement (MTA) is an agreement for the transfer of material (e.g., chemicals, biologics, cell lines, animals, and organs) for use in research. **How to process:** submit all CDA's/NDA's/MTA's and other related agreements in electronic Word format (or PDF if Word format is not available) to Stephen Behm, Director Technology Management. Please include a company contact, and indicate whether UHCMC will be receiving or providing the confidential information. For additional information please contact Stephen Behm at: (216) 844-1415 or Stephen.Behm@uhhospitals.org



Please be sure to use the current versions of all IRB documents, including the informed consent template. The templates are located on the University Hospitals Research internet page: <http://www.uhhospitals.org/tabid/1298/Default.aspx>

When IND or IDE Is Required

The US Food and Drug Administration (FDA) enforce the Food, Drug and Cosmetic Act (FD&C Act) and other laws and regulations governing the use of drugs, biologics, and devices for treatment and in research studies. Investigators are responsible for determining whether research in which they are engaged requires an IND or IDE and, if so, for securing the necessary approvals. An investigator who is unsure whether IND or IDE requirements apply may consult with the Center for Clinical Research and Technology by contacting Stephen Behm, Director Technology Management, at: (216) 844-1415.

Sponsor: A person who takes responsibility for and initiates a clinical investigation. (This is often a pharmaceutical, biotechnology, or medical device company).

Investigator: An individual who actually conducts a clinical investigation.

Sponsor-Investigator: An individual (not a company) who both initiates and conducts an investigation and complies with all the obligations of both a sponsor and an investigator.

IND: Investigational New Drug (IND) Application is required when a sponsor intends to conduct a study with an investigational new drug or the sponsor intends to conduct a study with an approved drug but in a new indication, dose form, or dose range that is not covered under the current labeling. The main purpose of an IND Application is to provide the data showing that it is reasonable to begin tests of a new drug on humans. For additional information on INDs, please contact the US FDA Center for Drug Evaluation and Research (CDER) website at: www.fda.gov/cder/regulatory/applications/ind_page_1.htm

IDE: An Investigational Device Exemption (IDE) allows the investigational device to be used in a clinical study in order to collect safety and effectiveness data required to support a premarket approval (PMA) application or a premarket notification [510(k)] submission to the FDA. Use of an investigational device also includes clinical evaluation of certain modifications or new intended uses of legally marketed devices. For additional information on IDEs, please visit the US FDA Center for Devices and Radiological Health (CDRH) at: www.fda.gov/cdrh/devadvice/ide/index.shtml

216.844.5576

[E-mail us!](#)

Research Education Series: Mark Your Calendars

An education session, "Creating and Managing Clinical Trial Budgets" will be held on **Friday, April 4, 2008**, from 12:00 - 1:00 a.m. in Lakeside 1400 Conference Room. This education session, will review, define, and discuss the components of a clinical trial budget, examine the process for developing technical and professional costs and describe the components of managing clinical trial budgets to include: discussion and negotiation; payment schedules; and billing and reconciliation.

Research Education Registration Page

If you are interested in attending an Educational Session or obtaining Continuing Research Education Credits (CRECs) please visit the following web link:

<http://ora.ra.cwru.edu/research/orc/education/onlinecalendar.cfm>