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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
216.844.5576

E-mail us!

Helpful Tips: Investigational Pharmacy Services

For any study using investigational drugs, the drugs should be stored in and dispensed from Pharmacy Services in accordance with the University Hospitals Policy CP-7 "Investigational Drugs". Pharmacy Services will dispense investigational drugs only in accordance with the protocol approved by the IRB. Pharmacy Services dispenses the doses, maintains a record of drug utilization, and provides copies of these records to the investigators as required for reporting drug use. Pharmacy Services is also available to investigators during study monitoring visits.

Importance of Maintaining Current Research Personnel Information

Changes in research personnel (additions or deletions), must be submitted to the IRB as an **Amendment**. It is essential that the personnel listed in the protocol are consistent with the personnel documenting in the research record(s). In particular, the individuals who are obtaining consent must be added to the protocol prior to consenting research participants.

Principal Investigators and research personnel who obtain consent must have current Human Subjects Protection Certification (CITI).

Common Non-Compliance Finding: Options in the Informed Consent Documents

Informed consent documents may include additional "options" for participants such as storage and/or future use of research samples including blood or tissue. If your informed consent document contains these "options", please ensure that the options are documented correctly. All check boxes, necessary initials and dates, must be completed by the participant. In cases where the option selections are incomplete, the data/specimen collected not be used. Please review these options carefully with the participant to ensure that the document is complete.

New Education Session: Mark Your Calendars

A newly developed education session, "Non-Human/Non-Research Determinations" will be held on **Wednesday, February 6th**, from 10:00 - 11:00 a.m. in Lakeside 1400 Conference Room. This education session will prepare Investigators and research staff in completing the newly revised IRB forms.

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 complete the " **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".

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>

Attention: An updated version of the University Hospitals Laboratory Services Values is available. Please be certain to include the most recent version in your regulatory binder. For more information, contact the Office of Research Compliance.