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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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POLICY UPDATE: Investigational Drugs and Devices

Please be advised that the University Hospitals Case Medical Center Institutional Review Board (IRB) will be posting two (2) updated policies: **Investigational Devices Used in Research** and **Investigational Drugs or Biologics Used in Research**. These policies describe the required procedures necessary for conducting research with an investigational agent (drugs, device, or biologic). The policies identify the items to be submitting to the IRB for review and approval; management of investigational agents; and required training for investigators who are conducting investigator initiated protocols as well as other required elements.

Educational sessions led by Dr. Joseph Gibbons, IRB Chair, are being held on January 23, 2009 at 11:00 in Lakeside 1400 and a repeat session on January 30, 2009, at 11:00 in Lakeside 1400. Attendance is strongly encouraged. Additional information regarding these policy updates will follow. Please register at <http://ora.ra.cwru.edu/research/orc/education/onlinecalendar.cfm>

Things to consider: IRS Decreases Mileage Rate for 2009

Many research protocols and informed consent documents indicate that participants will be reimbursed for mileage. There are several approaches to reimbursing participants including a flat amount per visit or an amount based on mileage. Please be advised that if you chose or have chosen to use the option based on mileage, and are going to reimburse participants per the IRS rate, it is strongly recommended that you **do not** indicate the specific amount but just reference the "standard business mileage rate". This will prevent you from needing to change the protocol and informed consent document every time the IRS changes the rate.

Please be reminded that if your current informed consent documents reference the 2008 mileage rate, the protocol and informed consent document must be change.

Guidance from the FDA: Data Retention When Subjects Withdraw from FDA Regulated Clinical Trials

The Food and Drug Administration (FDA) has clarified its position requiring that data from clinical trial participants be retained if the person discontinues participation or is withdrawn from the study. The FDA guidance notes that clinical studies data is submitted to the FDA in support of research applications for a new product approval, and it is critical that FDA have a complete and accurate data set. The agency believes that incomplete study databases could compromise the scientific validity of investigations and jeopardize the FDA's ability to analyze the study and, eventually, to safeguard the public health. Comments on the guidance may be submitted at any time.

The following are key points regarding FDA's policy on the withdrawal of subjects from a clinical investigation, whether the subject elects to discontinue further interventions or the clinical investigator terminates the subject's participation in further interventions:

- When a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
- An investigator may ask a subject who is withdrawing whether the subject wishes to provide continued follow -up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the subject would distinguish between stud y-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
- If a subject withdraws from the interventional portion of the stud y, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the investigator must obtain the subject' s informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). In accordance with FDA regulations, IRB approval of informed consent documents would be required (21 CFR 50.25, 56.1 09(b), 312.60, 312.66,812.100).
- If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator must not access for purposes related to the stud y the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review stud y data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

For more information go to <http://www.fda.gov/OHRMS/DOCKETS/98fr/FDA-2008-D-0576-gdl.pdf>