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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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Study Closure for Lack of Response

The University Hospitals Case Medical Center (UHCMC) Institutional Review Board (IRB) Administration Office routinely conducts quality assurance reviews of the IRB files to ensure that the record is complete and up to date. When the IRB Administration Office identifies a submission which has been reviewed (either administratively or by a fully convened meeting of the IRB) and requires **a series of modifications prior to submitting the research for final approval**, and there is no record of a timely response from the study team to address the necessary revisions, the IRB Administration Office will administratively close and archive the study unless the requested changes are submitted within the required time period.

For submission reviewed at a fully convened meeting of the IRB, the investigator has 90 days from the time of the IRB meeting at which the protocol was considered to respond in writing to the changes requested by of the IRB. If the investigator does not respond in writing within 60 days from the time of the IRB meeting, a reminder letter will be sent. If the investigator does not respond in writing in 90 days, the protocol will be closed by the IRB. A written notice of study closure for lack of response will be sent to the investigator and placed in the protocol file.

A protocol that has been closed cannot be reopened. Once a protocol is permanently closed all research activities must cease, including data analysis (unless the data is de-identified). To resume research activities a new protocol must be approved by the IRB.

If there are unusual circumstances that prevent a timely response to requested changes, the principal investigator must request an extension of time to respond.

It is recommended that investigators review all protocols to ensure that any requests from the IRB have been addressed, and a response has been returned to the IRB so as to avoid administrative closure of the protocol by the IRB

iRIS™ Electronic IRB System Implementation

In 2009, the UHCMC IRB Administration office will begin the transition to an electronic IRB document submission, review and maintenance system called "iRIS". The iRIS™ electronic system from iMedRIS™ will allow for protocol submissions, research-related documents, board/committee meetings and review records to all be managed electronically. This is a collaborative project involving both UHCMC and Case Western Reserve University; including the Case Cancer IRB and the Institutional Animal Care and Use Committee (IACUC).

The software configuration process, which kicked off in Fall 2008, has begun by translating all current UHCMC IRB forms, templates and submission guidelines into the iRIS system.

Beta testing of the iRIS system at UHCMC is slated to begin in April 2009 with potential roll-out to all research areas in the Fall or Winter of 2009. Prior to this implementation, the Center for Clinical Research and Technology (CCRT) will hold multiple informational and training sessions, both in-person and via the UH Oracle Learning Management System (LMS).

Updates regarding the progress of this transition and proposed implementation dates will be disseminated to the local research community as more information becomes available.