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The Clinical Coordinator

Clinical Research News You Can Use…

New Radiology Review Process

The Department of Diagnostic and Interventional Imaging (DII) has instituted a new departmental review process effective July 1, 2017.

It is important for DII to be aware of imaging being performed for research to ensure that imaging resources are available and billing occurs appropriately. All research protocols that involve the use of Radiology services (imaging, interpretation, reporting, processing, etc.) that are NOT being conducted for clinical care must obtain DII approval. Additionally, any studies that involve the non-routine use of Radiology (for example, the assessment of a new implant or device), non-routine imaging methods, or new/improved contrast methods also need departmental approval. This process applies to all UTHealth investigators utilizing imaging services at Memorial Hermann Hospital System, Memorial Hermann outpatient facilities, McGovern Medical School, and LBJ Hospital.

The DII departmental review form needs to be completed by the study team and sent to Dr. Usha Menon (usha.n.menon@uth.tmc.edu) for review and approval. The approved form should then be uploaded as a study document when submitting an Initial Review Application in iRIS.

The new form and supplemental instructions, including Dr. Menon's contact information, can be found at this link, as well as in the templates and forms section of the CPHS website.

A current CAP certificate is available on the CTRC website at this link.

UTHealth Good Clinical Practice (GCP) Corner

Topic: Informed Consent Process – TRUE or FALSE?

1. The written informed consent form should be signed and dated by the subject prior to initiating any study related procedures (i.e., fasting for screening lab work).
2. The subject should be given a copy of the signed informed consent.
3. The informed consent discussion and any re-consent process (as applicable) should be documented in a study note.
4. The informed consent discussion and written informed consent should include all the following (as applicable).

□ The trial involves research □ Prorated payment (if any) for trial participation □ Purpose of the trial □ Expected duration of subject's trial participation □ Study procedures □ Number of subjects involved in the trial □ Subject's responsibilities □ Who to contact regarding trial and for trial-related injury □ Potential risks □ Records identifying subject will be kept confidential □ Expected benefits/no intended clinical benefit □ Compensation/treatment in event of trial related injury □ Alternative treatment (if applicable) □ Subject may withdraw; PI may withdraw subject from trial □ Voluntary participation □ Use layman's terminology (6th-8th grade) □ Anticipated expenses to subject (if any) □ Randomization / Placebo possibility □ Study drug treatment plan and schedule of events

Answers: 1. True. **2.** True. **3.** True. **4.** True

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHealth's CPHS and AWC.
Date: July 20 and August 16, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (parking will be validated)
Free. Registration is required. Register here.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management, and network with administrators and staff from various research groups within UTHealth. More information here.
Date: August 9, 2017
Topic: FDA Presentation
Time: 11:30 am – 1:00 pm
Location: MSB 3.001
Lunch provided for the first 50 participants.
Free. Registration is not required.

Orientation for Clinical Research Staff

Objective: General overview of clinical trial research at UTHealth, including study start up processes and clinical trial management.
Date: August 29, 2017
Time: 9:00 am – 3:00 pm
Location: UCT 1505C (UCT parking will be validated)
Breakfast and lunch provided.
Free. Registration is required. Register here.

Clinical Research Education Program

Objective: Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. This three day program focuses on clinical trial management, good clinical practice, and efficient trial conduct.
Date: October 17 – 19, 2016
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
Register here.

The public ClinicalTrials.gov site at this link has a new look and enhanced searching capabilities.
Considering that ClincialTrials.gov can be a useful tool for recruitment,
these changes may help potential participants find your study! Details and images are at this link.

About the Clinical Trials Resource Center

It is the mission of the Clinical Trials Resource Center (CTRC) to provide a single portal of expertise and best practices for study teams in order to facilitate efficient, compliant, and ethical study conduct and management. The CTRC office is located at UCT 790. Please visit https://www.uth.edu/ctrc/ for more information.

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