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The Clinical Coordinator

Clinical Research News You Can Use

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COVID-19 Preparedness – Clinical Research

The most important consideration is to ensure the safety of participants enrolled in clinical research studies. Research studies that involve in-person contact with research participants at all UT Physician clinics, Memorial Hermann locations, and Harris Health System locations should not enroll any new participants. This decision is intended to minimize exposure of patients, participants, and research staff. Additionally, we want to be mindful of the availability of PPE and other clinic and hospital resources and prioritize patient care.

Research studies that do not involve in-person contact with participants (such as research studies that only involve online surveys, telephone calls, or chart reviews, etc.) may continue to enroll participants. Requests for emergency use/compassionate use/single patient use may continue to be submitted as usual.

Suspension of new enrollment does not apply to critical research studies, such as research related to COVID-19 or ARDS and other critical and essential research studies.

Requests for consideration to continue new enrollment should be submitted to the IRB as a change request. Please address the following issues in the 'rationale' section of the change request:

- Does the research involve in-person contact with participants?
- Is this research related to the pandemic (e.g., COVID-19 research, ARDS studies, etc.)?
- Is this a request for expanded access use (a.k.a., compassionate use)?
- Is this comparative effectiveness research involving no additional research procedures?
- Will participants have to come to clinics for research-specific visits?
- Will the participant have to come onto hospital premises for any study-specific procedures?
- Will compliance to the study protocol be affected by research staff issues, such as remote working, absences, etc.?
- What proportion of study procedures are usual care vs research-specific procedures?

Currently Enrolled Participants: For UTHealth investigator-initiated clinical trials that have active participants, consider if it is possible to change in-person study visits to remote visits (such as telephone calls, using telemedicine technology, etc.). Consider if it is possible to reduce the number of in-person study visits without jeopardizing the subjects' safety or well-being.

For sponsor-initiated clinical trials or multicenter clinical trials where the UTHealth PI is not the lead PI – contact the study sponsor/lead PI to develop a plan. Remember to submit a change request to the IRB via iRIS before implementing any such changes. FDA Guidance on Conduct of Clinical Trials During COVID-19 Pandemic.

We strongly recommend developing an action plan for ongoing research studies to mitigate disruption caused by COVID-19 containment and response efforts. An example of a comprehensive plan developed by Dr. Mary Kay Koenig, Department of Pediatrics, is provided here.

The FDA guidance linked above recommends maintaining a log of any changes to protocol or alternate procedures for each clinical research study. COVID-19 Alternate Procedure Log Template.

Please continue to check the UTHealth COVID-19 website and COVID-19 Clinical Research Preparedness page for up to date information.

Routine Monitoring Visits by Non-UTHealth Individuals

UTHealth has suspended routine monitoring visits for clinical trials conducted at UTHealth/Memorial Hermann Health System/Harris Health until April 30, 2020, effective immediately. This restriction will be continually reassessed and updated based on the COVID-19 situation.

Is remote access to regulatory data available for monitoring? Depends on the study. Some research teams are able to provide remote access for sections of the regulatory files.

Is remote access to MHH clinical data available for monitoring? It is possible, but limited. Reach out to Sheila Ryan at CIRI, MHH, or Shibu John, Manager, Centralized Scanning, at 713-802-3908. MHH TMC IDS can grant remote access to the Drug Accountability System and temperature monitoring system. Please email requests with CRA name and email address to ids.pharmacy@memorialhermann.org. The remote access will charged as one monitor visit. There will be a 5 business day lead time for remote access requests.

Is remote access to Harris Health clinical data available for monitoring? No, Harris Health policies require that the monitor may review data in the electronic medical record only under the direct supervision of Harris Health authorized research staff. Monitors or any other sponsor representatives shall not be granted direct access to the electronic health records. However, the Investigational Drug Service (IDS) can scan and email requested subject DARFs and temp logs when needed. The contact person for Harris Health IDS is Celia Fenceroy, and she can be contacted at 713-873-4457.

If there are reasons for a monitoring visit to occur urgently, please reach out to clinicaltrials@uth.tmc.edu with the request.

Memorial Hermann TMC - Investigational Drug Service

MHH IDS services are impacted by the hospital's emergency plan in response to COVID-19. To confirm dispensing feasibility, the IDS pharmacy requests that study teams contact IDS prior to obtaining consent. Also, to minimize treatment disruptions, the IDS pharmacy requests that study teams coordinate emergency plans for existing subjects with scheduled study drug treatment and share these plans with IDS. Effective immediately, IDS will temporarily stop accepting patient's return of study medication to the IDS pharmacy. Contact: ids.pharmacy@memorialhermann.org or pager (713) 704-7243 x 22701

QUIZ – FDA Amendments Act – Clinical Trial Registration and Results Entry

1. Section 801 of the Food and Drug Administration Amendments Act of 2007 (which is the regulation known as FDAAA 801) requires that _____ be registered at ClinicalTrials.gov.
2. The _____ number is a unique identifier that ClinicalTrials.gov assigns a study when it is registered.
3. According to FDAAA 801, studies that meet the definition of "Applicable Clinical Trial" must be registered at ClincialTrials.gov no later than ____ days after enrolling the first participant.
4. The "Responsible Party" is responsible for registering and reporting results for "Applicable Clinical Trials." At UTHealth, the "Responsible Party" of investigator-initiated clinical trials is _____.
5. Results for "Applicable Clinical Trials" must be submitted no later than _____ after the "Primary Completion Date," which is defined by FDAAA 801 as the date that the final participant was examined or received an intervention for the purposes of final collection of data for the primary outcome, whether the clinical study concluded according to the pre-specified protocol or was terminated.

Answers: 1. Applicable Clinical Trials (ACTs), 2. National Clinical Trial (NCT), 3. 21 calendar, 4. The UTHealth PI, 5. 1 year

Online Training

As many of us are working remotely, we have paused our monthly coordinator forum and all other in-person training events. Here are some online webinars and other resources for your consideration.

CITI Clinical Research Coordinator (CRC): CRC courses focus on key topics essential to the conduct of clinical research. They are specifically tailored to the needs of clinical research coordinators. CRC courses provide foundational and advanced role-based training for clinical research professionals. The courses cover information that expands beyond but is directly connected to the Human Subjects Research (HSR) and Good Clinical Practice (GCP) courses. The Foundations course delivers basic CRC training that organizations may use for onboarding new CRCs. Included are the operational and regulatory essentials that CRCs need. It also provides a basis for learners who will later move on to the advanced course. In the Advanced course, learners gain a deeper understanding of the CRC's role by exploring key operational, leadership, regulatory, and technical elements associated with daily work. This course is available for free under the UTHealth CITI subscription. Instructions on accessing CITI Program.

Informed Consent Training: Study coordinators involved in informed consent for interventional trials conducted at all Memorial Hermann facilities are required to take this training. This is a one-time training requirement involves review of one or more educational videos or websites listed on the Informed Consent Training webpage and completing the quiz. A certificate will be issued for those who score above 80%.

Advarra: Advarra continues to have 15 IRB meetings a week, and the IRB has been prioritizing the review of the numerous COVID-19 protocols received, as well as amendments relating to changes in research conduct because of unforeseen circumstances (guidance on Advarra operations during the COVID-19 outbreak). Advarra offers guidance and answers questions about the research impact of the COVID-19 pandemic (Coronavirus Guidance). Advarra also offers complimentary, direct support for sponsors and study teams seeking guidance regarding the research impact of the current public health situation (Ask Advarra).

WCG: WCG offers weekly online panels, designed to support healthcare researchers via the industry's leading voices and perspectives. The panelists share expertise in real-time to inform our collective efforts to discover effective therapies and minimize the disruption to ongoing and upcoming clinical trials. The next webinar is on 4/1/2020. COVID-19 Webinar Series

ACRP: ACRP has developed a resource center to monitor COVID-19 developments and their impact on clinical research and keeps their website updated to share new resources as they become available. ACRP COVID-19 Resource Center

Other Educational Opportunities: List compiled and maintained by Aryn Knight BS, CCRP, SoCRA Chapter Chair – Houston/Galveston - Monthly Educational Opportunities.

FDA Guidance: FDA has issued guidance on conducting clinical trials during the COVID-19 pandemic: Conducting Clinical Trials during COVID-19 Pandemic.

NIH Guidance: NIH recognizes the significant effects that this emergency is having on NIH-funded clinical trials and other human subjects studies. For details on expanded flexibilities, such as mid-project period extensions and administrative supplements for unanticipated costs, see NOT-OD-20-087.

Study Coordinator Forum - Informed Consent Skit

The study coordinator forum meets every month on the fourth Wednesday from 11:30 am to 1 pm. Last month, study coordinators who attended the forum were in for a pleasant surprise. We had world class talent in the form of Elizabeth Gendel, who acted as a study participant being approached to take part in a research

study, and the ever funny Josephine Turner, an experienced study coordinator who earned her informed consent chops at the Clinical Research Unit and who currently conducts perfect informed consent discussions with soon-to-be moms for maternal fetal medicine research. Josephine modeled how not to do an informed consent to much laughter—for example, she took a break during the informed consent discussion to answer a personal phone call loudly in the presence of the potential participant and disclosed personal details of another study subject. After a costume change, Josephine played it a second time to expertly model a professional consent process.

The study coordinator forum welcomes research coordinators, research nurses, and research administrators to participate. The forum provides both an opportunity for education and information sharing among research personnel. Presentations highlight best practices and ethical considerations in clinical research management to engage dialogue and problem solving among research practitioners. Updates to research practice are provided from the IRB, the Clinical Trials Resource Center, Sponsored Projects Administration, and the MHH Clinical Innovation and Research Institute (CIRI). Many of these sessions are recorded, and you can **watch videos of past events** by visiting the UTHealth Video On Demand Portal. Login with your UTHealth username and password. Select the talk you would like to view. Please do write to us with your feedback and comments.

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 suite 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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We would love to hear from you. Please send your comments and suggestions to clinicaltrials@uth.tmc.edu.