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The Clinical Coordinator

Clinical Research News You Can Use

INSIDE THIS ISSUE

Tips for Successful IRB Submissions

When an initial application is submitted the to the IRB for review and approval, the IRB staff conduct a pre-review to ensure completeness of the submission. A review of studies approved by the full board revealed that over two-thirds of submissions are returned for correction at least once, and few were returned 5 times for corrections. The most common reason for a submission to be returned for corrections is missing documents.

CITI Training and CVs – Missing CVs and CITI Training is a very common reason for a protocol being returned for corrections. An effective way of managing this problem is to upload CVs and CITI training certificates into the user profile for everyone in the study team.

Department Reviews – All studies reviewed at a full board meeting must have undergone a department review. Include a department review form with the submission. This is also applicable for studies that will be reviewed by an external IRB.

Routing issues – Initial submissions must be routed to be signed by the PI and all co-investigators. You can check the status of the routing under "Track Location" in "Submission History." If you know that some of the co-investigators are away and unable to sign the submission, then you may wish to add them later through a personnel change request.

Inconsistent information – Ensure that the information in the IRB application, protocol, and consent form are consistent. A common example of inconsistency is when the recruitment target does not match across these three documents.

Inadequate information about study – Under human subjects regulations, the IRB is required to ensure that each study meets the criteria for approval. A detailed and well-written protocol provides the IRB reviewers adequate information to make approval decisions. NIH has published protocol templates for clinical trials and social behavioral trials. The CPHS website has simple protocol templates that could be used for chart review studies and survey studies.

Consent forms – The most common problem with consent forms is that they are too technical and information is not presented in a manner that helps potential participants make a decision about whether to join the study or not. Using the most current CPHS template consent forms would be helpful. Choose the template that best matches your study.

Ancillary Forms – Submissions for research that involve MHH should include the MHH form within iRIS. Studies involving samples from pathology must include the Pathology Review form. Studies involving diagnostic imaging must include the DI Review Form.

Once a study has been submitted, check "Track Location" regularly, as well as respond to emails from IRB coordinators in a timely fashion. Studies are assigned on a first come first serve basis, and when slots for the agenda get filled up, the next submission might have to wait a full week to be assigned to an agenda.

Work closely with the IRB coordinator assigned to the study—everyone in the research enterprise is working towards the same goal—to conduct excellent and ethical research! Contact the IRB office at:

Email: cphs@uth.tmc.edu
Phone: 713-500-7943
Website: https://uth.edu/cphs

SMART IRB

The UTHealth IRB is most definitely very smart, but when we use the term "SMART IRB," we are referring to a national, integrated, comprehensive platform that includes an IRB reliance agreement and an online system. The SMART IRB agreement has been signed by over 575 institutions, including UTHealth and Memorial Hermann System.

The SMART IRB initiative was launched with support from the CTSA to enable institutions to comply with the common rule mandate to use a single Institutional Review Board (sIRB) for multi-site studies, which will go into effect in Jan 2020. The rule that multi-site studies funded by NIH must use a sIRB has been in effect for more than a year. See NIH Notice NOT-OD-16-094.

In addition to academic medical centers and hospitals, several commercial IRBs are also participating members in the SMART IRB platform.

UTHealth IRB as Reviewing IRB: When you have a new multi-site study and would like to use the SMART IRB reliance platform, check to see if all the sites in your study are participants in the SMART IRB platform by visiting the Participating Institutions page of SMART IRB. Please do not commit UTHealth IRB as the reviewing IRB without first speaking with the UTHealth IRB office. UTHealth has limited capacity at this time, both in staffing and infrastructure, to serve as a sIRB. The UTHealth IRB will make determinations on a case-by-case basis whether to accept the role of the reviewing IRB for a research proposal, and this will be based on type of research study, risks to human subjects in the proposed research, number of sites involved, experience of the UTHealth PI and study team with coordinating multi-site research, etc.

If UTHealth IRB agrees to be the reviewing IRB, you may initiate the process both within iRIS and within the SMART IRB platform. Our SMART IRB expert, Laura Lincoln, BS, IRB Coordinator for Panel 4, will be happy to help you navigate this process. Setting up a new study within the SMART IRB platform is not difficult but includes several steps, such as entering the names of the site PIs for each site, uploading the protocol and consent forms, etc.

Costs for IRB review of federally funded research are usually considered an indirect cost (IDC) that is covered under an institution's Facilities and Administration (F&A) rate and may not be included in the budget; however, the IDC funds do not include the cost of reviewing other sites. Review of other sites is a new task for the IRB, and the cost of reviewing other sites must be included as a direct cost in the grant budget. When the UTHealth IRB will be the reviewing IRB for federally funded studies, do include the review fee in the study budget.

UTHealth as Relying Institution: For studies in which an external IRB will be the reviewing IRB, the UTHealth IRB office will receive a request via the SMART IRB platform. Please follow our usual process for requesting for permission to rely on an external IRB via iRIS.

We recommend that you contact the IRB office early in the process. IRB staff will be happy to help you navigate all of the available options to help you make an informed decision. More information is found on the CPHS website here.

Requirement to Upload ICF per Revised Common Rule

Section 45 CFR 46.116(h) of the revised Common Rule states that for clinical trials conducted or supported by a Federal department or agency, one IRB-approved informed consent form (ICF) that was used to enroll subjects must be posted by the awardee on a publicly available Federal Web site. For UTHealth PI-initiated clinical trials, investigators will post ICFs to ClinicalTrials.gov. See page 5 of the March newsletter at this link for UTHealth-specific details, as well as the OHRP website at this link. Also, on May 17, 2019 NIH released the guidance at this link.

Test your knowledge of Good Clinical Practice (GCP)! Answers are found below.

1. What does IRB stand for?
2. _____ means any board, committee, or other group formally designated by an institution to review, approve the initiation of, and conduct periodic review of biomedical research involving human subjects.
3. What is the minimum number of Institutional Review Board (IRB) members?
4. Studies involving only retrospective chart reviews or anonymous surveys *might* be exempt from IRB review, as they are considered minimum risk studies.
5. The 2 kinds of initial IRB review are _____ & _____ .

Answers:
1. Institutional Review Board [at UTHealth, the IRB is also called CPHS (Committee for the Protection of Human Subjects)], **2.** Institutional Review Board (IRB), **3.** Five, **4.** True, **5.** Expedited review and full board review

New FDA Website Launched April 29, 2019

After three years in the works, the US Food and Drug Administration (FDA) launch of a redesigned, more customer-centric website at FDA.gov on Monday, April 29, 2019. An FDA spokesperson said, "Most URLs will change. Automatic redirects will be established, but users should update their bookmarks." Read more about it here and here.

OHRP Final Rule Guidance Webpage

OHRP has set up a webpage for easy access to all you need to know about the revised Common Rule at this link. Find draft guidance documents, helpful Q&As, information about posting clinical trial informed consent documents, and more.

Clinical Research Professional Certification Exam Prep Courses

The Society of Clinical Research Associates (SOCRA) is offering a **Clinical Research Professional Certification Preparedness and GCP Review Course** in conjunction with the SOCRA Annual Conference on September 25th, 2019 in San Antonio Texas. To learn more click here.

The Association of Clinical Research professionals (ACRP) also provides several **CCRC Exam Preparation** resources and courses. You can learn more about the courses offered here.

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: 5/30/19, 6/18/19, 7/10/19, 8/1/19, 8/27/19
Time: 1:30am – 4:00pm (except 5/30/19 is 9:30am – Noon)
Location: UCT 1155 (parking will be validated)
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: June 26, 2019
Topic: TBD
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Registration is not required.

TMC – SoCRA METS

Objective: The TMC Clinical Research Professional Training and Education Committee and SoCRA Houston Galveston are pleased to announce the Monthly Education Training Series (METS), which is designed to serve as a monthly training and educational event for clinical research professionals from TMC member institutions.
Date: June 5, 2019
Topic: "FDA is Here, Now What?" by Sylvia Johnson, President/CEO, JI-Solutions, LLC. The talk will cover steps on how to prepare for an FDA audit, what happens during an FDA audit, who should meet with the FDA, mechanisms to ensure a favorable outcome and inspection do's and don'ts.
Time: 3:30 pm – 4:30 pm
Location: Third Coast Restaurant, 6th Floor Room II, 6550 Bertner Avenue
Registration is required. Register here.

IRB Office Hours

If you would like help submitting an iRIS application or writing a protocol or consent form, or if you want to learn more about IRB reciprocity agreements, then consider taking advantage of IRB office hours.
MSB hours: 2nd and 4th Thursdays from 1:00 pm – 4:00 pm at MSB B.640
SOD hours: 1st Thursdays from 1:00 pm – 4:00 pm at SOD 4416 (Research Office conference room)
An appointment is not necessary

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, suggestions and feedback to clinicaltrials@uth.tmc.edu