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The Clinical Coordinator

Clinical Research News You Can Use

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CPHS 2019 Metrics

We are happy to share with you the annual report describing CPHS activities in 2019, including workload and time to approval data. We are delighted that time to approval has been reduced for all categories—exempt, expedited, and full board reviews.

The time to approval includes the time taken by the IRB staff to process applications and CPHS members to review the submissions, as well as the time taken by investigators to respond to stipulations. As shown in Fig. 1, the median time to approval for initial submissions reviewed at a full board meeting was reduced from a median of 106 days in 2009 to **63 days** in 2019. Expedited reviews were reduced from 46 days in 2009 to **19 days** in 2019. The time to approval for exempt applications reduced from 26 days in 2009 to **10 days** 2019.

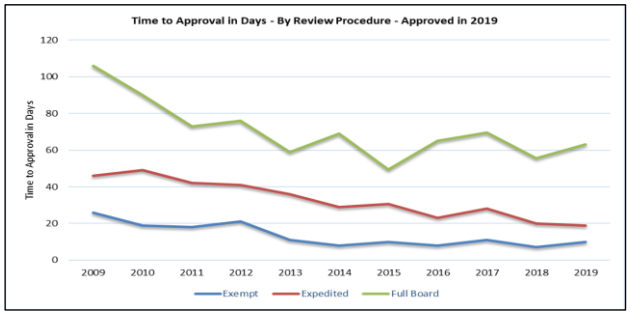


Fig. 1: *Median time to approval by year*

IRB staff make a concerted effort to assign the most suitable level of review based on the research risks. As a result, the proportion of studies that go to the full board has been reduced—only 10% of the protocols approved in 2019 were reviewed at a full board meeting compared with a third reviewed by full board in 2009. Over 10% of submissions were reviewed by an external IRB, and 8% were determined to be not human subjects research. This does not include the quality improvement projects, the over 250 projects that registered in the REDCap QI Registration system.

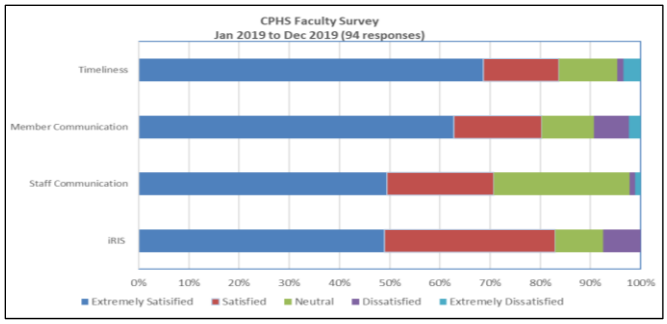


Fig. 2: *CPHS faculty survey*

The CPHS Executive Committee continues to monitor the review process to improve the quality and efficiency of UTHealth's human research protection program. Researchers and research staff are invited to provide feedback regarding the IRB review and approval process when they receive outcome letters. In 2019, we received 94 responses to the CPHS Faculty Survey. As shown in Fig. 2, a majority of the respondents were either satisfied or extremely satisfied with timeliness and IRB communications. One recent goal for improvement was to simplify consent documents, and CPHS has issued a new template for interventional studies and a new simple consent template for clinical research studies involving no greater than minimal risk based on SACHRP guidelines.

To read the entire report, visit CPHS Faculty Report. Please send your comments, concerns, and feedback to clinicaltrials@uth.tmc.edu.

Clinical Research Staff Orientation

This educational program is designed to be a general overview of clinical trial research at UTHealth. These sessions are open to research staff, research nurses, research coordinators, and research assistants who are new to clinical research at UTHealth.

The one-day session begins with an overview of review and approval process by the IRB and MHH and regulatory services. There is also an introductory session on budgeting and coverage analysis. Further, experienced research staff address topics on clinical trial management, including informed consent, study document management, and the life cycle of a clinical trial from feasibility assessment and recruitment to study closure. The orientation session is intended complement the two day Clinical Research Education Course held once a year in the fall.

The orientation session is offered three times a year, with the next session in May 2020.

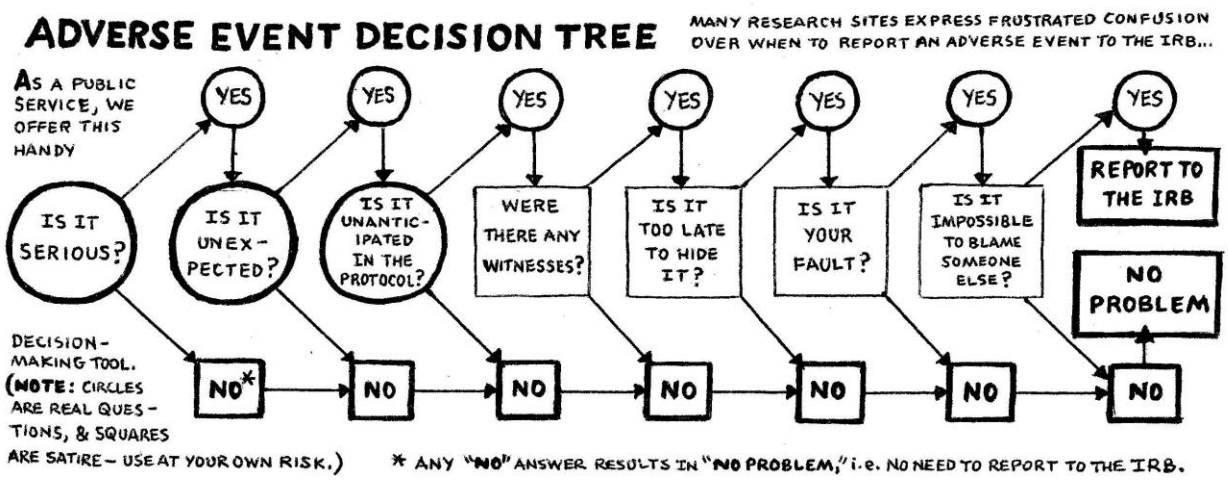
Date:	**Tuesday, May 19, 2020**
Time:	9 am to 3 pm
Location:	University Center Tower 1505c 7000 Fannin Street
Register here:	Clinical Research Staff Orientation

Test Your Good Clinical Practice Knowledge

1. A life-threatening adverse drug experience is considered to be a _____ adverse event.
2. Good Clinical Practice regulations have a provision for IRBs to approve clinical trials with exception from informed consent in planned emergency research, i.e. participants in life-threatening situations may be enrolled in a clinical trial without obtaining their consent. TRUE or FALSE?
3. The FDA regulation 21 CFR 50 addresses _____.
4. CFR in the previous question stands for _____.

Answers:
1. serious, 2. true, 3. protection of human subjects, 4. code of federal regulations

JUST FOR LAUGHS



Data and Safety Monitoring Plans

An appropriate Data and Safety Monitoring Plan is one of the regulatory criteria for approval. Research proposals should include adequate provisions for monitoring of data collected for scientific validity and safety of research subjects. The monitoring plan for a particular research study depends on the complexity of the research study and the possibility of potential harm to subjects.

The Data Safety Monitoring Plan should state who will assume monitoring responsibility. This will depend on the type and risk of the research study and may include the investigator, experts within the department or institution, independent consultants, the sponsor, or a combination of the above. Some examples include, but are not limited to:

Principal Investigator – For a research study involving moderate increase over minimal risk, it may be appropriate for the Principal Investigator to manage the data and safety monitoring. Continuous close monitoring by the Principal investigator may be an adequate and appropriate format for monitoring with prompt reporting of unanticipated problems involving subjects and others, including serious adverse events, to CPHS. For studies involving multiple sites, this function could be managed by the team of Principal Investigators of each site or, on the other hand, the lead or overall Principal Investigator for the entire research study.

Independent Expert(s) – Data and safety monitoring may be performed by an expert or group of experts in the disease who are familiar with the agent being studied. Using an independent expert or team of experts is particularly helpful in monitoring of unblinded data for a double-blind research study, as this will help ensure a meaningful review by independent experts while maintaining the blind amongst the research staff.

Data Safety Monitoring Board (DSMB) – The DSMB is a committee that is established specifically to monitor data throughout the life of a research study to determine if it is appropriate, from both scientific and ethical standpoints, to continue the research study as planned. For high-risk studies and for sponsor-initiated large, blinded studies involving multiple sites, it is recommended that a formal DSMB be appointed.

- *Sponsor organized DSMB* – Sponsors may appoint an independent DSMB.
- *Investigator established DSMB* – Principal investigators (PIs) may establish an independent DSMB.

Frequency and Extent of Monitoring – The plan should state how often monitoring will be performed and who will perform monitoring. There are several possible options for frequency of monitoring. Monitoring may be planned at specific points in time, after a specific number of subjects have been enrolled, or upon recognition of harm. The plan should state what data will be reviewed for safety monitoring.

The CTRC staff are happy to assist with writing DMSB charters and reports, as well as coordinating DSMB meetings. DSMB Charter templates and more information are available on the webpage Data and Safety Monitoring.

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 and Time: Thursday, 3/12/20; Tuesday, 4/7/20; Wednesday, 4/29/20
Time: 1:30 pm - 4:00 pm
Location: UCT 1155 (parking will be validated)
Registration is required. Register here.

Study Coordinator Monthly Forum

Objective: Discuss best practices in clinical research management. More information here.
Date: March 25, 2020
Time: 11:30 am – 1:00 pm
Topic: IRB Reciprocity (SMART IRB) presented by Laura Lincoln and Sylvia Romo
Location: MSB B.100
Lunch will be provided for the first 40 participants. Registration is not required.

TMC – SoCRA METS

Objective: Monthly training and educational event for clinical research professionals.
Date: Wednesday, March 4, 2020
Time: 3:30 pm – 4:30 pm
Topic: Predicting Success in Investigator Initiated Trials: Practical Considerations by Bambi Grilley, RPh, Baylor College of Medicine
Location: Third Coast Restaurant, 6th floor room I, 6550 Bertner Avenue
Registration is required. Register here.

Clinical Research Staff Orientation

Date: Tuesday, May 19, 2020
Time: 9:00 am – 3:00 pm
Topic: General overview of clinical research processes at UTHealth
Location: UCT 1505C. Parking validation available.
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).

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.