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The Clinical Coordinator

Clinical Research News You Can Use…

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CPHS Faculty Report

The CPHS Executive Committee initiated a Human Research Protection Program (HRPP) quality improvement program in 2010 to identify strategies to reduce regulatory burdens for researchers, CPHS members, and CPHS staff, while also providing the highest quality of protection for human subjects participating in research. The seventh annual CPHS Faculty Report provides metrics describing CPHS activities in 2016, including workload and time to approval data.

Despite the increase in new applications (from 678 in 2009 to 1,149 in 2016), there has been a steady decrease over the years in the time to approval (Fig 1), which is the time from initial submission of the protocol to final approval. This includes the time taken by the CPHS staff to process applications and for 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 106 days in 2009 to 69 days in 2014 and further reduced to **65 days** in 2016. Expedited reviews were reduced from a median of 46 days in 2009 to **23 days** in 2016. The time to approval for exempt applications reduced from 26 days in 2009 to **8 days** 2016.

CPHS has implemented various strategies to reduce regulatory burdens. For instance, CPHS staff make a concerted effort to assign the most suitable level of review based on the research risks. Only 15% of the protocols approved in 2016 were reviewed at a full board meeting. About 10% (102) of the protocols approved by the IRB in 2016 were reviewed by an outside IRB under IRB reciprocity agreements, and 5% (57) were determined to be not human subjects research.

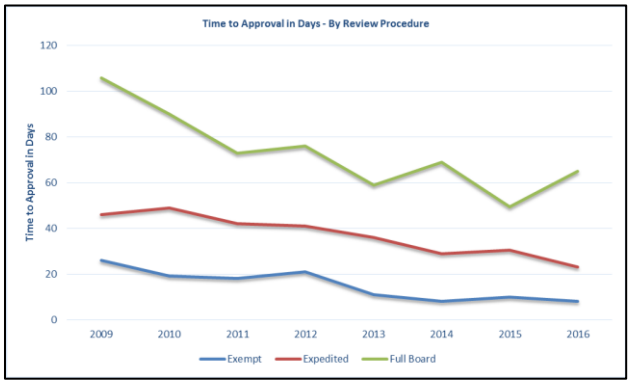

Fig 1: *Median time to approval by year.*

CPHS has also worked to reduce the number of times an application is returned to study teams for corrections, a factor that increases time to approval. Applications are returned most often due to missing documents, such as CVs and human subjects training. To address this issue, CPHS staff worked with study teams to attach CVs to the user profile so that the CV can be used for multiple protocols. Also, instead of requiring investigators and research staff to provide CITI training certificates, IRB staff began recording human subjects training directly from the CITI website. These actions have reduced the number of times a protocol is returned back for corrections. Indeed, the number of submissions of corrections was reduced from 2,706 in 2014 to 1,984 in 2016, despite there being more total submissions in 2016 (12,229) than in 2014 (8,415).

The CPHS Executive Committee continues to monitor the review process to improve the quality and efficiency of UTHealth's human research protection program. To read the entire report visit CPHS Faculty Report. Please send your comments, concerns, and feedback to clinicaltrials@uth.tmc.edu.

New Staff Members and a Promotion in IM-Gastroenterology

We are pleased to welcome **Cara Harry, BSN, CCRP** to the Department of Internal Medicine's Division of Gastroenterology, Hepatology, and Nutrition as a Clinical Research Coordinator II. Cara has earned a bachelor of science degree in nursing from Alverno College (Milwaukee, WI). Cara is a certified clinical research professional and has over 10 years of experience working in the clinical research field. Cara will be responsible for coordinating clinical trials in the Internal Medicine-GI department. Welcome, Cara!

L to R – Cara Harry, Urvashi Patel-Knox, Jordan Varing

We are happy to announce that **Urvashi Patel-Knox, CCRP** has recently been promoted to the position of Research Coordinator II in the Department of Internal Medicine's Division of Gastroenterology, Hepatology, and Nutrition. Urvashi has been in the clinical research field for over 10 years. Before she came to UTHealth in 2014, she was at Baylor College of Medicine, MD Anderson, and Novum Pharmaceutical Research Services. Urvashi was also previously a part of MD Anderson's Department of Donor Operations and Blood Bank. Congratulations on your promotion, Urvashi!

We are delighted that **Jordan Varing, MPH** has joined UTHealth. Jordan is a 2011 graduate of Texas A&M University with a bachelor of science in biomedical sciences, and he's a 2014 graduate of Texas A&M University Health Science Center with a master of public health in health policy and management. He began his career in clinical research in March of 2012 at a private site, coordinating sponsored trials in cardiology, dermatology, and rheumatology. In October of 2016, he moved to Houston to begin working as a research coordinator in the Department of Internal Medicine's Division of Gastroenterology, Hepatology, and Nutrition. Welcome, Jordan!

Upcoming Certification Testing Dates

CCRP certification: For those interested in becoming a Certified Clinical Research Professional, the next exam in Houston is at Methodist Hospital on May 6, 2017 with a registration deadline of March 24, 2017. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in September and October of 2017. Applications are due by August 14, 2017, and you can find more information here.

GCP CORNER

Test your knowledge about Good Clinical Practice (GCP) and answer "True" or "False" to the following statements. The answers are found below.

1. Data reported on the CRF, which are derived from source documents, should be consistent with the source documents or the discrepancies should be explained.

2. The investigator, or person designated by the investigator, should document and explain any deviation from the approved protocol.

3. If a subject refuses to accept a copy of the signed informed consent document after signing the original, then the subject cannot participate in the clinical trial

Answers:

1. True 2. True 3. False (If a copy of the signed informed consent document was offered to the subject, but the subject refused to take the copy, then documentation of the subject's refusal and the reason for the refusal should be made in the subject's study records, but the subject can remain on the study.)

The International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practice (GCP) are freely available on the web at http://ichgcp.net/.

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: March 15, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (parking will be validated)
Registration is required. Register here.

Clinical Trials Xpress (CTX) Patient Recruitment and Technology Symposium

Objective: CTX is hosting a two-day patient recruitment and technology symposium. Join other academic and industry experts to learn what's trending on the local and national landscape, as well as critical challenges and innovative technology-driven solutions for patient recruitment and enrollment planning. More information here.
Date: March 29-30, 2017
Time: 8:30 am – 3:30 pm
Location: Cooley Center
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: April 12, 2017
Topic: TBD
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Lunch provided for the first 40 participants.
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: April 18, 2017
Time: 9:00 am – 3:00 pm
Location: UCT 1505C (parking will be validated)
Registration is required. Register here.

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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