



Clinical Research News You Can Use

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CPHS 2018 Report

We are happy to share with you the annual report describing CPHS activities in 2018, including workload and time to approval data. We are delighted that time to approval has 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 **55.5 days** in 2018. Expedited reviews were reduced from 46 days in 2009 to **20 days** in 2018. The time to approval for exempt applications reduced from 26 days in 2009 to **7 days** 2018.

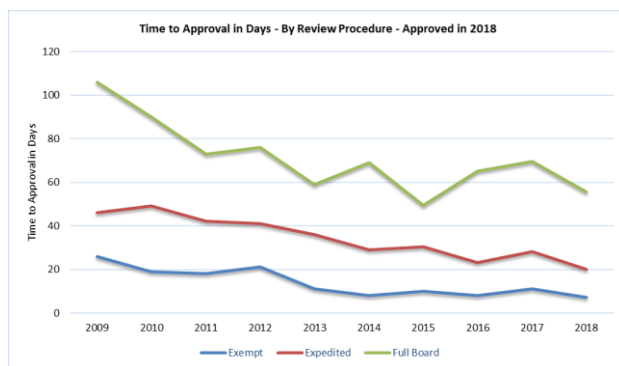


Fig. 1: Median time to approval by year

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 2018 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.

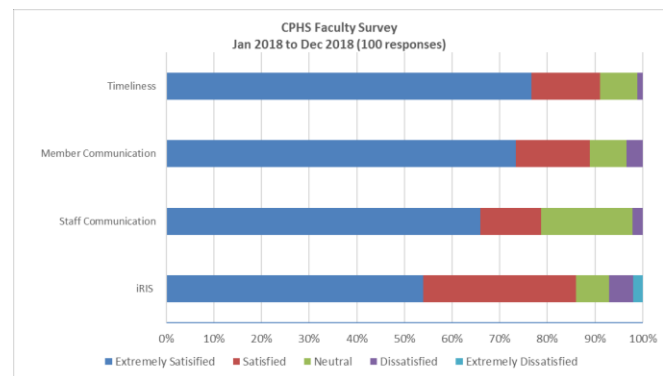


Fig. 2: CPHS faculty survey

The CPHS Executive Committee continues to monitor the review process to improve the quality and efficiency of UHealth’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 2018, we received 100 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. With the goal of simplifying consent documents, 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.

Let's Welcome Shwetha Pazhoor to CTRC!



We are pleased to announce that Shwetha Pazhoor MS, CCRP has joined UTHealth's Clinical Trials Resource Center (CTRC) as a Research Compliance Specialist. Shwetha earned her Master's degree in Bioscience from Mangalore University in Karnataka India and earned her CCRP certification in

2016. Shwetha comes to us from MD Anderson Cancer Center, where she worked as a Senior Clinical Studies Coordinator. Shwetha has managed national and international multicenter studies and has extensive clinical research experience in the areas regulatory management, audits, and training of new employees. In her role at UTHealth, Shwetha will be responsible for routine and for-cause GCP audits, training including Informed Consent Training, and Clinicaltrials.gov and FDA IND/IDE assistance.

We're so happy you're a part of the team, Shwetha!

Advarra Acquires Quorum IRB and Kinetiq

On March 5, 2019, Advarra announced that it has acquired both Quorum Review IRB and Kinetiq, the research and technology consulting division of Quorum.



The integration process is likely to take 6 months. If you have a research study that is under the oversight of Quorum IRB, there is no change in the process at this time, and you will continue to work with Quorum IRB through the OnQ platform; however, studies will migrate from OnQ to the Advarra Center for IRB Intelligence (CIRBI) platform in the coming months—changes will be communicated and coordinated with you well in advance, and any training needs will be provided on a routine and ongoing basis.

Any new studies should be submitted via Advarra's CIRBI platform (www.cirbi.net).

For more information on the transition process, you may visit the page [What You Need to Know](#).

As always, before submitting a new study to an external IRB, submit a request for permission to rely

on an external IRB via iRIS. Start a new application, and select the option "Request for permission to rely" in the "Determining Review Type" panel. The iRIS forms will be modified to include Advarra as an option, but until then, you may choose the option "Other" and enter Advarra in the free text field.

As a reminder, you do not have to modify the consent form provided by the sponsor. Staff at Advarra IRB will ensure that the UTHealth-required language is added to the sponsor consent template. If the sponsor does not accept UTHealth-required language, then contact the UTHealth IRB office at cphs@uth.tmc.edu, and they will review and send you an email confirmation if the sponsor-proposed language is acceptable to UTHealth.

Our institutional representative for Advarra IRB is Rebecca Forney, Client Services Coordinator. She can be reached at Rebecca.Forney@advarra.com.

If you'd like more information on IRB Reciprocity in general or working with commercial IRBs in specific, visit the [CPHS website](#). If you have any questions about the external IRB reliance process, contact the CPHS office at 713-500-7943 or cphs@uth.tmc.edu.

Transitioning Away from ClinCard for Patient Stipend Payments
Clinical Research Finance

As most of you are aware, UTHealth was informed by our ClinCard (patient stipend) vendor, Greenphire, Inc., that they have increased our transaction fees and will now assess a monthly service fee. Due to these substantial cost increases, utilizing ClinCard has become cost prohibitive. UTHealth has opted to move away from ClinCard over the next three months. You can continue to use

the ClinCard system for active studies through June 30, 2019. UT System is in the process of issuing an RFP for a new system, and there is a UTHealth committee working to quickly identify alternative solutions. We apologize for this unfortunate inconvenience and short notice. We will work quickly to find the long term solution.

Patient stipend payment until an alternative solution is identified	
<p><u>Studies that have at least one single payment of \$250 or more:</u></p> <ul style="list-style-type: none"> • Issue a check to the participant • Non PO voucher • Participant must complete a W9 form (Name, Address, SSN, Signature) • Participants who likely will receive >\$600 in a calendar year must be set up as a vendor (taxable income) 	<p><u>Studies that pay less than \$250 at a single visit and less than \$600 per participant in a year:</u></p> <ul style="list-style-type: none"> • Purchase gift cards through Procurement from National Gift Card (supplier # 0000083809) • Specific Store, including Amazon, may be selected • Visa gift cards may be purchased for an additional fee <p><i>NOTE: only purchase a 6-8 week supply at a time because the cards may expire and cannot be returned.</i></p>

Checklist for Completing the R&A Form for Industry-Sponsored Clinical Trials
Clinical Research Finance

When R&A forms are submitted for industry-sponsored clinical research agreements, they must be accompanied by a completed coverage analysis and internal budget (also called the CAIB document). The Clinical Research Finance (CRF) team has created a handy checklist to help ensure that the R&A form for industry-sponsored clinical research

projects and accompanying CAIB document are completed accurately and are consistent. This checklist will be available on Sponsored Projects Administration’s website in the section “[Forms and Templates](#),” and may also be obtained by contacting the CRF team at CRF@uth.tmc.edu.

Michelle Mayon Joins the CRU



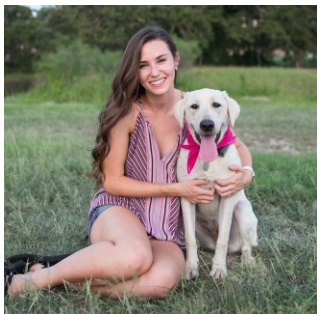
We are pleased to welcome Michelle Mayon, BS, CCRP to UTHealth. Michelle brings a wealth of knowledge and experience to her new role in the Clinical Research Unit

(CRU) as a Senior Regulatory and Compliance Specialist.

Michelle received a Bachelor of Science degree from Sam Houston State University and has over 18 years

of experience in clinical research operations, management, and regulatory processes. She worked for several years as the CRC Manager at Medicus Alliance Clinical Research Organization. Additionally, Michelle was the study start up specialist at Clinical Trials Xpress and was part of a team that helped accelerate study start-up timelines through the use of established master clinical trial agreements, IRB Reciprocity Agreements, and identifying and resolving issues proactively. We are delighted to have Michelle Mayon join the research community at UTHealth!

Kirsten Bevan Rydell Joins Internal Medicine Division of Infectious Diseases



We are pleased to welcome Kirsten Bevan Rydell, BS to UTHealth. Kirsten recently started as a study coordinator in the Division of Infectious Diseases in the Department of

Internal Medicine. Kirsten received a Bachelor of Science degree from Texas A&M University in 2017, and she worked at Texas A&M in the Department of Geosciences as a lab technician for a year after graduating before moving to Houston. Kirsten is currently working on her MS in epidemiology with a minor in biostatistics at the School of Public Health.

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

1. Good clinical practice (GCP) is a set of broad FDA regulatory requirements, standards and recommendations that apply to thousands of highly specific tasks, processes and roles in the conduct of clinical research.
2. The objective of the ICH GCP Guideline is to provide a unified standard for the European Union (EU), Japan, and the United States to facilitate the mutual acceptance of clinical data by the regulatory authorities in these jurisdictions.
3. The World Medical Association (WMA) has developed the _____ as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
4. The Belmont report rests on the following 3 fundamental principles for human subject research: _____, _____ and _____ .
5. _____ is a set of research ethics principles for human experimentation created as a result of the Nuremberg trials at the end of the Second World War.

Answers:

1. True. 2. True. 3. The Declaration of Helsinki. 4. Respect for persons, Beneficence, and Justice. 5. The Nuremberg Code.

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.
- This requirement to post ICFs applies to clinical trials involving any intervention type, including behavioral, social, or educational interventions.
- The ICF must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject. Currently, there is no efficient way for UTHealth central administrators to track this date; therefore, it is very important for study teams to be aware of the ICF upload requirement and to ensure that the ICF is uploaded to ClinicalTrials.gov by the legal deadline.
- Redactions of, for instance, confidential commercial information are permitted. Before posting any ICFs to ClinicalTrials.gov, contact Elizabeth Gendel, who will coordinate a review of the ICF by the Office of Technology Management (OTM) and Sponsored Project Administration's (SPA's) Contracts team to identify any information that should be redacted.

OHRP describes three scenarios in which studies may be subject to the Revised Common Rule (and, for clinical trials, thus subject to the ICF upload requirement):

- 1) The requirement to upload the ICF applies to all clinical trials conducted or supported by a Federal department or agency that were initially approved by an IRB on or after January 21, 2019. For the purposes of determining whether a study approved with conditions is subject to the Revised Common Rule, the date that the IRB voted to conditionally approve the study is the date that should be used (rather than the date that all conditions were met).
- 2) Any study that used the 3 burden-reducing provisions during the delay period (July 19, 2018 through January 20, 2019) will be required to comply with the entirety of the Revised Common Rule (including, for clinical trials, the ICF upload requirement) starting on January 21, 2019, even if the study was initially approved by an IRB before January 21, 2019.
- 3) For a study that was approved by an IRB before January 21, 2019 and that did not use the 3 burden-reducing provisions during the delay period, an institution may still decide to transition this study to the Revised Common Rule after January 21, 2019, and if so and if the study is a clinical trial, then the ICF upload requirement applies.

New OHRP FAQs on Revised Common Rule

OHRP has recently added eight new FAQs on the Revised Common Rule, which are found [at this link](#). Some of the new FAQs clarify how to apply the general compliance date of January 21, 2019 in

order to determine whether a study is subject to the Revised Common Rule. In addition to the FAQs, OHRP has posted a guidance on various transition dates [at this link](#).

Upcoming Training

iRIS Training

Objective: Provide hands-on training in the iRIS system, which is used to submit research protocols to UTHHealth's CPHS and AWC.

Date: April 10, 2019

Time: 1:30 pm – 4:00 pm

Location: UCT 1155 (parking will be validated)

Registration is required. [Register here.](#)

Orientation for Clinical Research Staff

Objective: General overview of clinical research at UTHHealth, including study start up processes and clinical trial management.

Date: March 28, 2018

Time: 9:00 am – 2:30 pm

Location: UCT 1505C (UCT parking will be validated)

Lunch will be provided.

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 UTHHealth. More information [here.](#)

Date: April 24, 2019

Topic: Introduction to Clinical Research Statistics – Geraldine Wood, PhD, RN, FAAN

Time: 11:30 am – 1:00 pm

Location: MSB 3.001

Registration is not required.

TMC – SoCRA METS NEW!

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: inaugural event on April 3, 2019

Topic: "Insights Into the Clinical Trial Protocol" presented by Noelle Gaskill, MBA, ACRP-CP, Vice President, Research Operations, SignalPath LLC

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 CTCRC office is located at UCT 1840. Please visit <https://www.uth.edu/ctrc/> for more information.

[Sujatha Sridhar, MBBS, MCE](#)

Director
713-500-3622

[Shwetha Pazhoor, MS, CCRP](#)
Research Compliance Specialist
713-500-3578

[Elizabeth Massey Gendel, PhD](#)
Senior Research Compliance Specialist
713-500-3587

[Adeyinka Aladejare, MBChB](#)
Graduate Assistant
713-500-3551

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