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The Clinical Coordinator

Clinical Research News You Can Use

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Changes to Human Subjects Regulations

Last year, the Office of Human Subjects Protections (OHRP) issued revisions to the IRB regulations known as Common Rule. These rules were scheduled to be effective on January 19, 2018, but the effective date was delayed to July 19, 2018. OHRP has issued a notice of proposed rulemaking (NPRM) to further delay implementation of the new regulations to January 21, 2019 while allowing institutions to use the following three burden-reducing provisions of the new rule during the delay period.

Continuing Review – Currently, CPHS requires that all human subjects research that was reviewed by expedited or full board review must be reviewed and approved at least every year. Under the new rules, minimal risk research reviewed by the expedited review procedure will no longer require annual continuing review. Most new research projects approved by the expedited procedure on or after July 19, 2018 will fall under this new rule, and continuing review will not be required unless the CPHS approval letter states otherwise. Any amendments, reportable events, or study closure reports must continue to be submitted to CPHS in a timely manner.

HHS Grant Application – Under the current rules, IRBs are required to review the relevant HHS grant to ensure congruency. The new rules eliminate the requirement for IRBs to review the HHS grant application related to the research.

Definition of Research – The new rule clarifies that the following activities are deemed not to be research and so do not have to be submitted to the IRB for review and approval:

- Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information that focus directly on the specific individuals about whom the information is collected.
- Public health surveillance activities (including the collection and testing of information or biospecimens) conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

The comment period for this NPRM has ended, and we are awaiting further instructions from OHRP on the status of these new rules. The IRB office will keep you informed of any changes to the human subjects regulations.

Sheila Ryan, JD, MPH, CCRP Joins Memorial Hermann's CIRI as New Director

We'd like to welcome Sheila Ryan, JD, MPH, CCRP, who has recently joined Memorial Hermann as the Director of the Clinical Innovation and Research Institute (CIRI). As Director, Sheila will be responsible for oversight of clinical research across the Memorial Hermann Healthcare System, providing leadership for all aspects of research operations, including regulatory compliance, institutional and affiliate partnerships, research operational review, the investigational pharmacy, growth through grants and contracts, research finance, compliance audits, study subject safety, procedural effectiveness, and risk management.

Sheila comes well-prepared for this position, as she has held various roles in clinical research, research administration, and compliance for over a decade. Most recently, Sheila was a member of the research faculty at Baylor College of Medicine and Texas Children's Hospital where she served as the Director of Clinical Research in the departments of Pediatric Neurosurgery and Pediatric Urology—in this role, she oversaw and managed clinical research, managed grants and contracts, and wrote and developed grant proposals and publications. Sheila also has research administration experience from her time as the Executive Director and CEO of the Houston Veterans Affairs (VA) Research and Education Foundation, which administers all industry-funded grants at the Michael E. DeBakey VA Medical Center. Further, Sheila has been a member of Baylor College of Medicine's IRB since 2009.

Sheila obtained her JD from South Texas College of Law, her MPH in Epidemiology and Environmental Health from Saint Louis University, and her BA in Biology and Sociology from Augustana College. She is currently pursuing her PhD in Health Management and Policy and Health Economics at UTHealth.

Welcome, Sheila, and we look forward to working with you!

IRB One-on-One Consultation Services

The Committee for the Protection of Human Subjects (CPHS) is now offering IRB one-on-one consultation services on a weekly basis. Audrey Williams, PhD will be available on Thursday afternoons from 1-4pm in MSB B.640. While Audrey can help with iRIS submissions, the purpose of this time is to help investigators with human subjects' issues in addition to protocol revisions based on CPHS expectations, whether prior to iRIS submission or during the review process itself. Audrey is an extremely knowledgeable CPHS board member with six years of CPHS experience in addition to research experience in human and molecular genetics.

Congratulations to Misty Ottman, RN, BSN, CCRP!

The University of Texas System Board of Regents has selected Misty Ottman, RN, BSN, CCRP, Program Manager in the McGovern Medical School's Department of Emergency Medicine, as one of two inaugural recipients of the Regents' Outstanding Employee Awards. This award honors employees who have shown superior performance, innovation, enthusiasm, teamwork, and dedication in their jobs. Read more here.

Research at Harris Health

The Harris Health System values the search for knowledge to improve patient care. The **research-approval process** at Harris Health includes a rigorous review of each research protocol to protect the rights of patients and staff and to ensure compensation to Harris Health for resource utilization.

At the April 2018 coordinator forum meeting, Sara Ruppelt, PharmD, Monique Okeke, and Celia Fenceroy, PharmD, RPh spoke about research at Harris Health, research staff authorization, and investigational drug services (IDS), respectively, and shared relevant resources.

The main page for the research office is at: https://www.harrishealth.org/about-us/research

The Harris Health research fee schedule, IT research report request, and research patient registration form can all be downloaded here.

Contact Information:

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eProtocol, financial agreements, general research questions, and preliminary budgets

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UTHealth's Performance in Submitting Results to ClinicalTrials.gov

ClinicalTrials.gov staff recently analyzed how successful organizations were over the past year in correctly submitting results, and UTHealth ranked within the top 15th percentile of all academic institutions. We want to thank study teams across campus for cooperating in the process of submitting results to ClinicalTrials.gov!

As far as tracking UTHealth's success in submitting results on time to ClinicalTrials.gov, a high-profile public shaming effort (found at https://fdaaa.trialstracker.net/) will fill this role. This website lists studies with results due dates on or after January 18, 2018 that are past due for results. Let's all work together to avoid having UTHealth appear on this list.

It's important to take care of results duties to avoid fines from FDA, public shaming, and consequences from NIH (see the piece on page 3 of February's newsletter at this link), and we're here to help you. We'll be in touch with study teams in advance of future results due dates, and we're working on a backlog of past due results.

Don't hesitate to contact Elizabeth Gendel, PhD (Elizabeth.M.Gendel@uth.tmc.edu or 713-500-3587) for assistance.

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: May 31, June 27, July 17, August 9, and August 29, 2018
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, and network with administrators and staff from various research groups within UTHealth. More information here.
Date: June 27, 2018
Topic: TBD
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Registration is not required.

IRB One-on-One Consultation Services

Objective: Audrey Williams, PhD will be available to assist with human subjects' issues, protocol revisions based on CPHS expectations, iRIS submissions, etc.
Date: Thursday afternoons
Time: 1:00 pm – 4:00 pm
Location: MSB B.640

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

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