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The Clinical Coordinator

Clinical Research News You Can Use

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Changes to Human Subjects Regulations

The new common rule has been officially delayed an additional 6 months, and will now go into effect on January 21, 2019. However, three burden reducing measures can go into effect starting on July 19, 2018, including a revised definition of research, elimination of the requirement for IRBs to review grant applications or funding proposals, and elimination of continuing review for certain categories of research.

CPHS has decided to implement these three burden reducing measures. Effective July 19, 2018, most expedited studies will no longer require continuing review. This will be phased in for studies that already have approval and an expiration date. IRIS will send notifications of continuing review 90, 60, and 30 days prior to the expiration date, and study teams will need to submit a final continuing review form. CPHS will issue a new continuing review approval letter with no study expiration date. Study teams will still be responsible for submitting all relevant information to the IRB such as updated CITI training, change requests, adverse events, protocol deviations, and study closure. Initial studies submitted after the effective date that qualify for expedited review will not receive expiration dates.

Additionally, full board studies in which there remain no research procedures (in data analysis only or all follow-up procedures are clinical) may also no longer require continuing review. The continuing review submission form will be revised shortly to capture studies in which all follow-up procedures remaining are performed for clinical purposes.

The definition of research has been revised to clarify that the following activities do not constitute human subjects research: scholarly and Journalistic activities, public health surveillance, criminal Justice activities (such as data collected through police surveillance), and operational activities in support of national security missions.

Finally, CPHS will no longer require submission of the grant application or funding request. However, the title on the approval letter issued by CPHS must match the title of grant for funding to be released. Therefore, study teams are encouraged to still submit the face page of the grant with the official study title for verification purposes.

If you have any questions about the new rule or the burden-reducing measures, please contact the CPHS office at 713-500-7943.

NIH Dissemination Plan

Applications to NIH for clinical trials must now include a "Dissemination Plan," which describes how the applicant will meet NIH's ClinicalTrials.gov requirements (see NOT-OD-16-149). Contact Elizabeth Gendel at Elizabeth.M.Gendel@uth.tmc.edu to obtain a recommended Dissemination Plan. Note that NIH's definition of "clinical trial" is very broad (definition and case studies at this link), and it is highly recommended that you contact your NIH Program Manager to confirm whether or not NIH considers your study to be a clinical trial.

Two New Process Changes for Coverage Analysis

The previous process for Coverage Analysis required extensive time and effort for the study team and presented information in a complex manner. Two new changes, described below, address these issues. The benefits of these changes are that significant time and effort burden will be removed from the study team and that research billing compliance efforts will be improved to ensure that all services and procedures being performed in the study are properly assessed.

1. **A new Coverage Analysis tool, which will be implemented on 9/1/18, presents information in a clear, concise manner that is easy to understand.**

The new tool will go live on 9/1/18, and all previous versions of the tool will be retired. Please note that new Coverage Analyses completed within previous versions of the tool, or new Coverage Analyses completed within RE-Tool, will not be accepted after 9/1/18. (Though, it will still be possible to access Coverage Analyses entered into the RE-Tool system prior to 9/1/18 in order to view and amend, if necessary.) CRF will speak on the new tool at the September Study Coordinator Forum.

2. **The Clinical Research Finance (CRF) team is now performing the initial data entry into the Cover Analysis/budget tool.**

After the CRF team completes initial data entry, the CRF team will email the initial draft of the Coverage Analysis to the department contact to complete the remaining data fields.

What data will the CRF team enter? The CRF team will enter basic study information such as Sponsor, Title, IRB number, and PI name to the Summary Tab The CRF team will also enter ALL study visits and ALL procedures and services defined within the protocol to the CA tab

What data will Study team enter? The study team will continue to be responsible for providing information regarding the study team, billing, pricing, effort, and locations where the services will be performed.

Time points. The CRF team will create a coverage analysis soon after the study has been submitted to the IRB. If you prefer to create a coverage analysis before the study is submitted to the IRB, then please let the CRF team know so that both teams are not working on the same item—please notify the CRF team by sending an email to CRF@uth.tmc.edu or by reaching out directly to the CRF administrator assigned to your department. If you need any type of assistance with the coverage analysis and internal budget prior to IRB submission, please email request to CRF@uth.tmc.edu.

FDA Conducts Audit of UTHealth Study for ClinicalTrials.gov Compliance

This past June, the FDA conducted a clinical investigation of a clinical trial at UTHealth with a focus on compliance with ClinicalTrials.gov regulations. This is the first instance we know of where compliance with ClinicalTrials.gov regulations was the focus. We are pleased to report that no deficiencies were found with the ClinicalTrials.gov record for the study. FDA's items for inspection of ClinicalTrials.gov records are listed on pages 18-19 of the BIMO manual at this link. Please review your ClinicalTrials.gov records to ensure that they would pass inspection should FDA drop in.

Contact Elizabeth Gendel at Elizabeth.M.Gendel@uth.tmc.edu with questions related to ClinicalTrials.gov.

University of Texas System Clinical Trials Xpress (CTX) Expands its Strategic Collaborations to Increase Clinical Trial Opportunities for the UT System Healthcare Enterprise

In 2018, the University of Texas System Clinical Trials Xpress (CTX) was selected by Parexel, the second largest clinical research organization in the world, as a site Alliance Network partner. With over 150+ Parexel trials opened in the US alone each year, this new alliance is expected to enhance the CTX platform of clinical trial opportunities across a broad range of therapeutic areas and bring greater exposure to all UT health institutions, as well as improve overall patient care.

Additionally, in May of 2018, CTX engaged in a strategic collaboration with Pharmaceutical Product Development (PPD), the fourth largest clinical research organization in the world. With over 2000+ trials activated in the past 5 years, CTX is poised to receive numerous trial opportunities for multisite consideration, hence further expanding the UT health institutions' portfolio of clinical studies and, most importantly, promoting the rapid advancement and development of new cutting-edge medicine to the benefit of patients.

Recognized as "game-changing" by industry sponsors and clinical research organizations, the CTX operating model offers industry sponsors and physician investigators a single point of access and dedicated, experienced team who accelerate the launch of multi-site clinical trials for the benefit of all participating UT institutions. Using established master clinical trial agreements, IRB reciprocity or other accredited commercial IRB platforms, and centrally-negotiated study budgets common to all participating sites and their affiliates, the CTX model consolidates study start-up processes to open multi-site clinical trials in 100 calendar days or less.

For more information, please visit www.clinicaltrialsxpress.org or contact CTX at ctxconcepts@clinicaltrialsxpress.com or 713-500-7927.

Spanish-Language Version of ResearchMatch

ResearchMatch is a free recruitment tool available to UTHealth clinical researchers. Recently, a Spanish translation of ResearchMatch has launched, and UTHealth researchers will now be able to use ResearchMatch to connect with and recruit Spanish-speaking volunteers. If you would like to recruit in Spanish via ResearchMatch, you will need to submit a Spanish ResearchMatch contact message to the IRB for approval. To obtain an English language template for the ResearchMatch contact message, or to ask any questions about ResearchMatch, please contact CTRC at clinicaltrials@uth.tmc.edu.

Adeyinka Aladejare Joins CTRC

Join us in welcoming Adeyinka Aladejare, MBChB, who has joined the Clinical Trials Resource Center (CTRC) as a graduate assistant. Yinka is currently a graduate student at UTHealth's School of Public Health in the department of Epidemiology. Her background is in clinical medicine, and she trained as a physician at Obafemi Awolowo University in Ile-Ife, Nigeria. Yinka worked for about four years before moving to the United States to start her graduate education at UTHealth. Welcome, Yinka!

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: August 29, 2018
Time: 9:30 am – 12:00 pm
Location: UCT 1155 (parking will be validated)
Registration is required. Register here.

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

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: September 26, 2018
Topic: New Tool for Coverage Analysis and Internal Budget presented by Kristin Parks, Director of Clinical Research Finance and Administration
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Registration is not required.

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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