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The Clinical Coordinator

Clinical Research News You Can Use…

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Major Changes to Human Subjects Regulations

The Department of Health and Human Services has issued revisions to the IRB regulations known as Common Rule, which becomes effective on January 19, 2018. The new rules strengthen protection for participants while reducing administrative burdens and increasing flexibility. While there are additional requirements for informed consent, additional exemption categories and the rescinding of the requirement for continuing review for minimal risk research will reduce regulatory burdens for researchers and research staff. Here is a summary of some of the major changes:

Continuing Review

Changes: 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. CPHS may require continuing review for certain research studies reviewed by the expedited procedure.

No continuing review for most minimal risk research.

Implementation: Most new research projects approved on or after January 19, 2018 by the expedited review procedure will fall under this new rule and continuing review will not be required unless the CPHS approval letter states that continuing review is required. Any amendments, reportable events, and study closure reports must continue to be submitted to CPHS in a timely manner. For existing research projects, CPHS staff will evaluate the study when it comes up for continuing review and decide whether to move the study under the new regulations and not require further continuing review or to keep the study under the old regulations and require continuing review.

Exemptions

Changes: The revised regulations include new categories for exemption; however, some exemptions may require "limited IRB review" which means that they must be reviewed by an IRB member. Limited IRB review is the review of the research by an IRB chair or experienced IRB member to ensure that there are adequate provisions to protect privacy of the participant and confidentiality of the data.

Exemption category #1 allows for research in established or commonly accepted educational settings. The new rule adds a condition that the research is not likely to have adverse impacts on students learning, required educational content, or assessment of educators who provide instructions.

Exemption category #2 has been clarified to include collection of identifiable information with the potential to cause harm if disclosed, provided a limited IRB review is conducted.

Exemption category #3 includes research involving benign behavioral interventions. To qualify for exemption, the intervention must be brief in duration, harmless, not physically invasive, painless, and unlikely to have significant adverse lasting impact. The investigator must have no reason to believe that the subjects will find the interventions offensive or embarrassing.

The existing exemption category #4 covers secondary research use of identifiable private information. The new rule has been expanded to include prospective data review.

New exemption categories #7 and #8 address secondary research involving identifiable protected health information (PHI) for which broad consent was obtained.

Implementation: The current iRIS application can handle the changes to exemptions. The forms will be slightly tweaked to include benign behavioral interventions. All exemption requests reviewed and approved after January 19, 2018 will be reviewed under the new rules. Existing studies that were determined to be exempt will not be affected.

Informed Consent

Changes: The new rules require that consent forms must begin with a concise and focused presentation of key study information that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. The concise and focused presentation must include five factors:

Consent forms must begin with a concise and focused presentation of key information.

- the fact that consent is being sought for research and that participation is voluntary;
- purpose of research, duration of participation, and procedures to be followed in the research;
- reasonably foreseeable risks or discomforts to the participant;
- benefits to the participants or others; and
- alternative procedures or courses of treatment, if any, that might be advantageous to the prospective participant.

Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather, facilitates the prospective participant's understanding of the reasons why one might or might not want to participate. Consent forms must also include additional new consent elements when identifiable private information or identifiable biospecimens will be collected as part of the research study. Informed consent documents for federally funded clinical trials must be posted in a federal public website.

Implementation: All new research projects that are approved on or after January 19, 2018 must use the revised consent template. The revised template will be published on the CPHS website in early January 2018. CPHS staff will assist researchers and research staff with the concise and focused presentation. It is most likely that clinical trial consent forms will need to be posted on ClinicalTrials.gov—we will keep you informed on the process for posting when we have more guidance from OHRP.

Single IRB-of-Record (sIRB)

Changes: Most federally-funded collaborative research studies that involve more than one institution in the US will be required to use a single IRB (sIRB). The NIH sIRB policy for multicenter non-exempt clinical research will be effective January 25, 2018.

Implementation: Please contact the CPHS office if you are the lead investigator on a multicenter NIH grant for assistance with budgeting for single IRB review.

There are several other changes that affect CPHS operations. CPHS office staff is in the process of revising CPHS policies and procedures and the iRIS application forms to comply with the new rules.

Do plan on attending the Study Coordinator Forum on January 24, 2018 for a presentation from CPHS staff on the new rules and changes to CPHS policies and procedures.

More information on the new rules are here.

Let's Welcome Laura Lincoln to CPHS!

Laura Lincoln is the newest member of the CPHS team, serving as the IRB Coordinator for Panel 4. Laura and her family moved to the Houston area two years ago. Her previous roles include Human Protections Administrator for the Oregon State University IRB, Research Protocol Analyst with the City of Hope Data and Safety Monitoring Committee, and most recently Quality Assurance Analyst with the Houston Methodist Research Institute. Laura earned her BS in Broadcasting and Film at Boston University.

New NIH Policy on Certificates of Confidentiality

Stephanie M. Francisco, CPHS

Beginning on October 1, 2017, the NIH enacted a new policy regarding Certificates of Confidentiality (CoC). A CoC protects the privacy of research subjects by limiting the disclosure of identifiable, sensitive information. With the new policy, the NIH will now automatically issue CoCs for all applicable NIH-funded research; previously, NIH awardees would need to apply for a CoC. All NIH research that was commenced or ongoing after December 13, 2016 will be issued a CoC. CoCs provide an additional layer of protection for subjects' privacy and confidentiality, for example, by allowing investigators to conduct research with subjects who use illicit drugs without the need to report them to any authorities. However, there are a few caveats where subjects' information may be disclosed, such as cases in which there has been child abuse. Researchers may still apply for CoCs even if their research is not funded by the NIH, and Certificates are valid for 5 years.

For more information about CoCs, see the website at this link. The new NIH CoC policy is at this link.

UTHealth Good Clinical Practice (GCP) Corner

Essential Documents

1. "Essential documents" are documents that permit evaluation of the conduct of a trial and the quality of the data produced and serve to demonstrate the compliance of the investigator, sponsor, and monitor with standards of Good Clinical Practice (GCP). TRUE OR FALSE?

2. Filing essential documents in a timely manner will not assist in the successful management of a trial by the investigator, sponsor, and monitor. TRUE OR FALSE?

3. The sponsor and PI should maintain a record of the location(s) of the essential documents, including source documents. TRUE OR FALSE?

4. When a copy is used to replace an original document [e.g., source documents, case report form (CRF)], the copy should fulfill the requirements for certified copies. TRUE OR FALSE?

5. Essential documents are usually not audited as part of the process to confirm the validity of the trial conduct and integrity of data collected. TRUE OR FALSE?

6. Check all that are examples of "essential documents" to be filed at the site:
   □Protocol & Amendments □PI Signed Protocol and Amendments agreements □Investigator Brochure & Updates □Advertisement □IRB approval memos □CVs & Medical Licenses (PI & Co-Investigators) □Normal Lab Value Range □Lab Facility certification and accreditation □Annual Continuing Review Approval memos □Drug Accountability Log □IP shipping records □Trial initiation monitoring report □Monitoring Visit reports □Signed, dated, & Completed Case Report Form □Documentation of CRF corrections □SAE reports □Safety Reports □Subject Screening Log □Subject Enrollment Log □Delegation of Authority Log □Training Log □Signed Informed Consent forms □Source Documents

Answers: 1. True. **2.** False. **3.** True. **4.** True. **5.** False. **6.** All.

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: January 11, 2018
Time: 9:30 am – 12:00 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: January 24, 2018
Topic: Updates to the Common Rule (presented by IRB Director Cynthia Edmonds, MLA)
Time: 11:30 am – 1:00 pm
Location: MSB B.645
Lunch provided for the first 40 participants.
Registration is not required.

Grants 101

Objective: Provide an overview of the process of preparing and submitting a grant application from UTHealth. These sessions are open to anyone who would like to attend but are designed primarily for junior investigators who have not previously submitted proposals as a PI, as well as for administrative support staff who assist faculty members with grant preparation and submission. Attendance is a pre-requisite for faculty members who wish to participate in Grants 102. More information here.
Date: January 8 and 9, 2018
Time: 8:30 am – 12:00 pm
Location: Cooley Conference Center
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 1840. Please visit https://www.uth.edu/ctrc/ for more information.

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