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The Clinical Coordinator

Clinical Research News You Can Use…

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Changes to Regulations for Human Subjects Protections

On 1/19/17, the U.S. Department of Health and Human Services (HHS) and 15 other federal departments and agencies published revisions to the regulations for protection of human subjects (also known as the Common Rule).

Purpose

The purpose of these revisions is to modernize, simplify, and enhance the current system of oversight. The current regulations, in place since 1991, were developed at a time when research was conducted predominantly at universities and medical institutions, and each study generally took place at a single site. Since then, research with human participants has grown in scale and become more diverse and data have become digital.

HHS lists the following important elements in the new rule:

- The requirement for consent forms to provide potential research subjects with a better understanding of a project's scope, including its risks and benefits, so they can make a more fully informed decision about whether to participate.
- Requirements, in many cases, to use a single institutional review board (IRB) for multi-institutional research studies.
- For studies on stored identifiable data or identifiable biospecimens, researchers will have the option of relying on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement. As under the current rule, researchers will still not have to obtain consent for studies on non-identified stored data or biospecimens.
- The establishment of new exempt categories of research based on the level of risk they pose to participants. For example, to reduce unnecessary regulatory burden and allow IRBs to focus their attention on higher risk studies, there is a new exemption for secondary research involving identifiable private information if the research is regulated by and participants protected under the HIPAA rules.
- Removal of the requirement to conduct continuing review of ongoing research studies in certain instances where such review does little to protect subjects.
- Requirement that consent forms for certain federally funded clinical trials be posted on a public website.

Effective date of new rule

The new rule will go into effect a year from now on January 19, 2018, and any resulting changes to UTHealth CPHS's policies and procedures will be announced.

Resources

The Final Rule and additional information can be accessed at this link. An HHS press release at this link provides an overview of the new rule.

Let's Welcome Carolyn McKinney to CTRC!

We are pleased to announce that **Carolyn McKinney, RN, BSN, CCRP** has joined UTHealth's Clinical Trials Resource Center (CTRC) as a Senior Research Compliance Specialist. Carolyn earned a Bachelor of Science in Nursing with a minor in Psychology from McNeese State University. Carolyn comes to us from M.D. Anderson and Baylor College of Medicine where she worked as a research nurse and a research nurse manager. Carolyn has extensive clinical research experience in the areas of clinical trial management, regulatory management, audits, personnel orientation and training, budgets and contracts, mentoring and supervision, and in the development of research programs. In her role at UTHealth, Carolyn will be responsible for the clinical research training programs coordinated by CTRC. Carolyn will also be responsible for conducting routine and for-cause GCP audits of clinical research studies. Carolyn enjoys yoga, photography, hula dancing, traveling, and spending time with her two daughters.

Please join us in welcoming Carolyn to UTHealth!

New ClinicalTrials.gov Requirements Effective as of 1/18/17 – Penalties for Noncompliance

New regulations and a new NIH policy for registration and results submission at ClinicalTrials.gov went into effect on 1/18/2017. See the CTRC website at this link for further information and links to resources.

It is important to note that FDA and NIH have stated that they will now begin to enforce compliance with registration and results reporting requirements. This will include **fines from the FDA** and **effects to NIH funding**.

Upcoming Certification Testing Dates

SOCRA SOCIETY OF CLINICAL RESEARCH ASSOCIATES

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

ACRP ASSOCIATION OF CLINICAL RESEARCH PROFESSIONALS

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in February and March of 2017. Applications are due by February 1, 2017, and you can find more information here.

New NIH Policy on GCP Training

NIH recently issued notice NOT-OD-16-148 that requires investigators and clinical trial staff who are responsible for the conduct, management, and oversight of NIH-funded clinical trials to complete Good Clinical Practice (GCP) Training. GCP training should be refreshed at least every 3 years.

The NIH definition of clinical trial is "A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes" (NOT-OD-15-015). As a general rule, if a study meets the requirements for registration at ClinicalTrials.gov, then it most likely also meets the NIH definition of clinical trial. NIH resources for determining whether your study is a clinical trial are found here, here, and here.

Per the NIH notice, NIH-funded clinical trial investigators and clinical trial staff who are involved in participant recruitment, enrollment, data collection, the consent process, data management, etc. should take the training. This includes research coordinators, research assistants, research nurses, etc. As a general rule, if someone on the clinical trial team was required by the IRB to complete the CITI human subjects modules, then it would be a good idea for that individual to also complete the GCP modules.

UTHealth faculty and staff can take the GCP course offered through the CITI Program (https://www.citiprogram.org/). Under the Main Menu, choose "Add a Course" and then answer "Yes" to Question 2 - "Do you need to take the Good Clinical Practice Course." The GCP course should appear on your list of courses. If you have completed GCP training with a different provider within the last 3 years, check to see if the training is listed on TransCelerate's GCP Training Mutual Recognition Program. If the training is recognized by TransCelerate, then you do not have to repeat GCP training. Please upload the training certificate to your profile within iRIS.

The NIH notice on GCP training is very brief and doesn't address the question of whether this policy is applicable for existing trials or only for awards initiated on or after January 1, 2017 (the Council on Governmental Relations is seeking clarification from NIH). PIs of existing NIH clinical trial grants may also contact their program official at the funding NIH IC for more guidance on whether they are required to take the training. Our recommendation for clinical trial investigators and clinical trial staff with ongoing NIH-funded clinical trials is to complete the GCP modules before January 1, 2017.

Please contact clinicaltrials@uth.tmc.edu if you have any questions or need help accessing the GCP modules within the CITI program.

Research Nurse Training Program at the Texas Heart Institute

For the last 2 years, the Texas Heart Institute (THI) has offered a research training program for nurses (the Clinical Research Nurse Coordinator Training Skills program in THI's Stem Cell Center, supported by a grant from NIH's National Heart Lung Blood Institute). The goal of the program is to train nurses as clinical research nurse coordinators. Candidates should have limited to no research experience.

For further details, see this link.

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: February 2, 2017
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: February 8, 2017
Topic: Research Conflicts of Interest, Vyju Ram, MD
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: February 21, 2017
Time: 9:00 am – 3:00 pm
Location: UCT 1505C (parking will be validated)
Registration is required. Register here.

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: February 28, 2017
Time: 1:30 pm – 4:00 pm
Location: UCT 1155 (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.

Sujatha Sridhar, MBBS, MCE
Director
713-500-3622

Carolyn McKinney, RN, BSN, CCRP
Senior Research Compliance Specialist
713-500-3578

Elizabeth Massey Gendel, PhD
Senior Research Compliance Specialist
713-500-3587

Chaitra Mahesh Muthalgiri, MBBS
Graduate Assistant
713-500-3551

Noopur Singh, BSE
Graduate Assistant
713-500-3551