The U.S. Department of Health and Human Services (HHS) has announced proposed revisions to the Common Rule, which is the set of regulations that govern research on individuals who participate in research.

The proposed revisions are detailed in the Notice of Proposed Rulemaking (NPRM), which was published in the Federal Register on September 8, 2015. The NPRM has been a long time coming, as it follows the Advanced Notice of Proposed Rulemaking (ANPRM), which was issued in July 2011. HHS will take public comments on the NPRM for 90 days beginning September 8, 2015.

Some of the major changes being proposed are the rules relating to informed consent. With regard to informed consent in general (such as consent to participating in clinical trials), the rules would be significantly tightened to make sure that the process becomes more meaningful. Consent forms would no longer be able to be unduly long documents, with the most important information often buried and hard to find. They would need to give appropriate details about the research that is most relevant to a person’s decision to participate in the study, such as information a reasonable person would want to know, and present that information in a way that highlights the key information. In addition, to assure that these rules do indeed change current practices, there will be a one-time posting requirement for the consent forms for clinical trials, so that anyone drafting a consent form will do so knowing that it will eventually be subject to public scrutiny.

In addition, informed consent would generally be required for secondary research with a biospecimen (for example, part of a blood sample that is left over after being drawn for clinical purposes), even if the investigator is not being given information that would enable him or her to identify whose biospecimen it is. Such consent would not need to be obtained for each specific research use of the biospecimen, but rather could be obtained using a “broad” consent form in which a person would give consent to future unspecified research uses.

The NPRM also attempts to strengthen the effectiveness and efficiency of the oversight system by making the level of review more proportional to the seriousness of the harm or danger to be avoided. Research that poses greater risk to subjects should receive more oversight and deliberation than less risky research. The NPRM seeks to avoid requirements that do not enhance protection and impose burden. Cumbersome and outdated regulatory standards overwhelm and distract institutions, IRBs, and investigators in ways that stymie efforts to appropriately address the real risks and benefits of research.

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The result of these types of changes, as the NPRM proposes to implement them, is that some studies that currently require IRB review would now become exempt. Some that are currently exempt would specifically be declared as outside the scope of the regulations (“excluded”), and thus would not require any administrative or IRB review. Further, in terms of determining when a study is exempt, a web-based “decision tool” will be created. That decision tool will provide a determination of whether or not a study is exempt. That result, so long as the tool was provided with accurate information, will be presumed by the Common Rule agencies to be an appropriate determination of exempt status. It is expected that in many instances the tool would be used by the investigators themselves, thus obviating both the need for further review and the concern that the institution might be subjecting itself to future liability by allowing investigators to use the tool.

In sum, the proposed modifications described above are designed to continue to uphold the ethical principles upon which the Common Rule is based, as applied to the current social, cultural, and technological environment.

More information on the NPRM can be found on the HHS website at this link.

Let’s Welcome Vanessa Fuller to CPHS!

Vanessa Fuller is the newest member of the CPHS team, serving as IRB Coordinator for Panel 3. Vanessa has worked for UTHHealth for 13 years. She started out as a research assistant and spent the last three years as a research coordinator in the Department of Emergency Medicine. She grew up in Missouri, and in 1993 she moved to Texas, where she attended the University of Houston on an athletic scholarship and graduated with a Bachelor of Science degree. Vanessa is married and stays quite busy with her two children ages 6 and 2.
National Research Administrator Day
Adapted from a National Day Calendar announcement at this link

National Research Administrator Day is on Friday, September 25! Research administrators are crucial to the research enterprise—they serve faculty and researchers, protect the institution, and assure sound stewardship of sponsored research dollars. Friday the 25th is a day to celebrate all that they do.

National Research Administrator Day was submitted by the National Council of University Research Administrators (NCURA) in August of 2015. The Registrar at National Calendar Day proclaimed that National Research Administrator Day be observed annually on September 25.

Upcoming Certification Testing Dates

CCRP certification: For those of you interested in becoming a Certified Clinical Research Professional, the next test date in Houston, TX is at The Methodist Hospital on November 7, 2015 with a registration deadline of September 26, 2015. You can find more information here.

CCRC certification: The next exam dates for certification as a Clinical Research Coordinator (CRC) are in February and March of 2016. Applications are due by February 1, 2016, and you can find more information here.
Upcoming Training

Study Coordinator Monthly Forum
Objective: Discuss best practices in clinical research management and network with administrators and staff from various research groups within UTHealth.
Date: October 27, 2015
Time: 11:30 am – 1:00 pm
Location: MSB 2.135
Lunch provided for the first 40 participants.
Registration is not required. Information here.

Clinical Research Education Program
Objective: Promote excellence in clinical trial management for research nurses, study coordinators, and other research staff. This three day program focuses on clinical trial management, good clinical practice, and efficient trial conduct.
Date: October 20 – 22, 2015
Time: 8:30 am – 4:30 pm
Location: Cooley University Life Center
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: September 29, 2015
Time: 1:30 pm – 4:00 pm
Location: UCT 1155
Parking will be validated.
Registration is required. Register here.

Center for Clinical Investigation (CCI) Meeting
Objective: Aid clinical research and reduce the burden on individual teams by identifying best practices, streamlining clinical research management processes, and providing education, training, and support to clinical research staff.
Date: October 12, 2015
Time: 2:00 pm – 3:00 pm
Location: UTPB 1100.55
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 790. Please visit https://www.uth.edu/ctrcenter/ for more information.

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