HRPP Newsletter

December 2017
Volume 3, Issue 9

Announcements

Winter Break Closure

The University will be closed from Monday, December 25, 2017 through Tuesday, January 2, 2018. Our office will be working diligently until Winter Break to ensure IRB reviews are completed in a timely manner. We want to take this opportunity to alert you to changes in our office, update you on the upcoming changes to federal requirements and wish everyone a safe an enjoyable break.

Meet our Assistant IRB Compliance Officers

Please join us in welcoming our two new Assistant IRB Compliance Officers.

Sara Mulville, MA, was promoted to the position of Assistant IRB Compliance Officer in August. Many of you already know Sara who joined the HRPP as an IRB Compliance Specialist in July 2015. Prior to that she was a public health educator with the Knoxville County Health Department. Sara has done an outstanding job during her time with our office and we are confident in her continued success in this new role.

Jennifer Engle, Ph.D., joined the HRPP as an Assistant IRB Compliance Officer in September and has prior experience in both social behavioral research and clinical research. Jennifer comes to UT from Thompson Cancer Survival Center where she worked as a Clinical Trials Regulatory Compliance Specialist. Prior to that she was a Research Project Manager at Vanderbilt University Medical Center. Before that Jennifer conducted social behavioral research for seven years providing her a with a wide range of research experience. Jennifer holds a doctorate in Human Development and Family Studies.

“Who is my IRB Liaison?”

Due to the recent reorganization of our office, colleges are now assigned to one of three in-office staff members instead of two. Additionally, the contact information below lists your first point of contact based on topic.

Topic	Who to Contact
General Questions Examples include submission status, completing IRB/iMedRIS Forms, CITI training, application requirements, meeting deadlines, iMedRIS user support, etc.	Contact: HRPP/IRB Office 865-974-7697 utkirb@utk.edu
Study or Research-Specific Questions Examples include IRB review required?, responding to IRB-requested changes, research topics such as study procedures, recruitment, informed consent, HIPAA, FERPA, confidentiality, etc. **IRB Liaison by College or Unit:**	Contact: Your IRB Liaison
Agricultural Sciences & Natural Resources Arts & Sciences Communications & Information Social Work Veterinary Medicine	Contact: Sara Mulville 865-974-2314 smulvill@utk.edu
Architecture & Design Business Education, Health & Human Sciences University-wide Units (Student Life, Libraries, NIMBioS, Athletics, etc.)	Contact: Jennifer Engle 865-974-7494 jengle@utk.edu
Audiology & Speech Pathology Engineering Law Nursing	Contact: Kristine Hershberger 865-974-7687 kh@utk.edu
Reportable New Information Examples include unanticipated problems/adverse events, complaints, concerns about participant welfare or safety, etc.	Contact: Colleen Gilrane 865-974-7697 irbchair@utk.edu OR Kristine Hershberger 865-974-7687 kh@utk.edu
Education/Training Examples include departmental training, classroom visits, etc.	Contact: Colleen Gilrane 865-974-7697 irbchair@utk.edu
Reliance Agreements/Single IRB & Collaborative Research	Contact: Kristine Hershberger 865-974-7687 kh@utk.edu
Clinicaltrials.gov	Contact: Kristine Hershberger 865-974-7687 kh@utk.edu

Regulatory Changes – Revised Common Rule

Most of the changes to the *Federal Policy for the Protection of Human Subjects*, also known as the Common Rule, are scheduled to go into effect on January 19, 2018. In early October the HHS Office for Human Research Protections submitted a request for a one-year delay in the implementation of these changes to the U.S. Office of Management and Budget (OMB). OMB has yet to respond to this request making the actual implementation date of these changes uncertain.

Overview of Major Changes

Below is an overview of the major changes scheduled to go into effect next month. Other changes related to collaborative research will go into effect in 2020.

New and Revised Definitions – The definition of who is a human subject has been expanded to encompass "obtaining, using, studying or analyzing" as well as include both identifiable data and identifiable biospecimens.

Clarification of activities that do not meet the definition of "research".

An explicit definition of **clinical trial** has been added. "*Clinical trial* means 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 the interventions on biomedical or behavioral health-related outcomes." This is the same definition used by NIH.

New and Revised Exemption Categories – The revised regulations modify the existing categories, adds new categories and also adds limited IRB review to some categories. For example:

- Secondary research involving identifiable private information that is protected by HIPAA can be reviewed at the exempt-level, while currently it must be reviewed at least the expedited-level.
- Some research involving brief benign behavioral interventions with adults.

Changes to Informed Consent

- Re-organization of consent documents to begin with a concise and focused presentation of the key information that is most likely to assist in understanding the reasons why one might or might not want to participate in the research.
- New elements of informed consent related to future use of information/biospecimens, disclosure (if applicable) of profit from commercial use, return of research results and information related to genome sequencing.
- Posting consent forms on a designated public website in for some clinical trials

Continuing Review – Elimination of continuing review for **some** minimal risk research.

Single IRB Review – The revised Common Rule mandates single IRB review for most federally funded collaborative research projects conducted in the U.S. beginning January 20, 2020. However the NIH Single IRB Policy goes into effect on January 25, 2018 (all competing grant applications for due dates on or after January 25, 2018).

What to Expect

Though it is possible that the federal government could choose to take action to delay the implementation of these changes, we may not learn about that decision until January 18, 2018. Due to this uncertainty, the UT IRB plans to implement the necessary changes scheduled to go into effect on January 19th. Should changes occur, we will announce them as soon as they are known.

- IRB application changes on or before January 18th.
- New informed consent templates posted on the IRB website in early January.
- Guidance and instructions posted on the IRB website in early January.
- Throughout January and into the new year, a training video and education materials will be provided.

Interested in Learning More?

Science: *What do revised U.S. rules mean for human research?*

Council on Governmental Relations: Common Rule Summary Table

Association for Psychological Science: Revision to the Common Rule: Implications for Behavioral and Social Sciences Research

NIH Single IRB Policy

The NIH Single IRB policy goes into effect on **January 25, 2018**. This policy requires that certain types of NIH-funded research involving multiple institutions to use a single IRB (sIRB) for the research conducted at all of the study sites. Use of an sIRB avoids duplicative review by multiple institutional review boards. This policy applies to research studies that are:

- Funded by grants (new, renewal, revision, or resubmission), cooperative agreements or contracts submitted to NIH *on or after January 25, 2018*, ***and***
- Involve non-exempt human subjects research, ***and***
- Research conducted domestically, ***and***
- Involve multiple study sites, all of which are conducting the same protocol. This includes multi-site studies where most sites are conducting the same protocol but one or a few sites are responsible solely for overall study coordination, laboratory services, statistical services, or other study support functions.

This policy does not apply to research studies that are:

- Funded to institutions outside of the U.S., ***or***
- Conducted at foreign sites (though domestic sites of the same study must be reviewed by sIRB), ***or***
- Funded through career development, research training or fellowship awards, ***or***
- Where review by the proposed sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy, ***or***
- Collaborative projects involving multiple sites, but the different sites complete different parts of the study, ***or***
- Granted an exception to this policy by NIH due to a compelling justification. These exceptions are expected to be granted infrequently.

We anticipate that most research studies subject to these requirements will be clinical trials, but keep in mind that the definition of “clinical trial” has been expanded.

What to Expect

Look for additional information in early January. We plan to send additional notifications to you via email and post more detailed guidance on our website. Throughout January and into the new year, education materials and trainings will be rolled out.

For More Information

Implementation of the sIRB policy FAQ

Scenarios illustrating the use of direct and indirect costs for single IRB review

FAQ on Costs

News

NIH Announces Revisions to Policies and Guidelines

Recently the National Institutes of Health (NIH) announced it is amending NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research to require recipients conducting applicable clinical trials ensure results of valid analyses by sex/gender, race, and/or ethnicity are submitted to Clinicaltrials.gov. The agency also announced plans to revise the NIH Policy and Guidelines on the Inclusion of Children.