Office of Research Compliance and Assurance

Research Compliance NEWS

Common Rule 2018 Updates: Human Subjects Research

LATEST NEWS – Published in the Federal Register on January 17th, *the Delay of the Revisions to the Federal Policy for the Protection of Human Subjects* delays the effective date and general compliance of the revised Common Rule to **July 19, 2018.**

The Common Rule, the federal regulations for the Protection of Human Subjects [45 CFR 46], has delayed implementation of revisions until July 19, 2018. A significant number of Common Rule changes relate to IRB management and function, but researchers will see some change to their work as well. The key changes include:

Continuing IRB Review requirements:

Continuing IRB Review will no longer be required for many studies that are approved through the Expedited IRB review process. This also includes studies where the only remaining activity is the analysis of identifiable data or activity to obtain follow-up clinical data.

Exempt Category List:

The exempt research categories have been expanded, while some categories have been clarified. Specifically, with appropriate safeguards implemented, studies utilizing benign behavioral interventions may qualify for Exempt Review. Additionally, more studies will qualify for exempt review through new processes called the "Limited IRB Review" of a protocol designed to ensure adequate safeguards of participant's privacy and confidentiality.

Consent form informational elements:

A new "Key Information" section must begin with a concise summary of essential study information that potential participants would want to know to make an informed decision about study participation. Additionally, consent must disclose any plans to conduct future research using information and/or biospecimens collected during the research. This statement is already required by the USA IRB and incorporated within the biological specimen template. However, if applicable, consent form must disclose whether: (a) subjects will share in commercial profit; (b) clinically relevant research results will be returned; and (c) research will or might include whole genome sequencing.

Use of a Single IRB (sIRB) for Cooperative Research:

Effective January 25, 2018, NIH-funded multi-site research must rely on a single IRB-of-Record (sIRB) for review. The Common Rule has delayed implementation for the use of a sIRB. Effective ***January 19, 2020*** all multi-site research that is federally funded—not just NIH-funded must rely on a single IRB-of Record for review.

The Office of Research Compliance and Assurance will post new web resources, updated consent templates, checklists, and IRB application forms prior to the implementation date. Informational sessions have been offered to the research community and additional sessions will be scheduled, as needed.

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Inside This Issue

Contact us at:
Office of Research Compliance
Ad 240
251-460-6625
dlayton@southalabama.edu

Recap: NIH Policy Changes

NIH has added a number of policy changes. Of these changes, there has been a change involving NIH's definition of a clinical trial. The NIH definition is broad, as the definition includes basic biomedical research and behavioral research, and not just studies treating a medical condition. The NIH has available an 15 minute video entitled Overview of New NIH Policies on Human Subjects Research and is an excellent source of information.

OFFICE RELOCATION

The Office of Research Compliance and Assurance has relocated to the Administration Building, Suite 240.

Good Clinical Practice (GCP) training is required by the NIH for all NIH-funded investigators and their personnel involved in the conduct, oversight, or management of clinical trials. GCP training went into effect January 1, 2017 and applies to all new and existing NIH clinical trials. The USA Human Subject's training webpage provides all relevant details and access to GCP training modules.

Also, the NIH requires all NIH-funded studies that meet their definition of a clinical trial to be registered in clinicaltrials.gov, including reporting of results. Additional information about clinicaltrials.gov registration is available on the USA Human Subjects website.

Lastly, effective January 25, 2018, all NIH-funded multi-site studies that involve non-exempt human subject's research must utilize a single IRB of Record (sIRB). The NIH policy applies to (i) NIH-sponsored multi-site studies, where the same protocol is used at multiple sites and (ii) domestic research only. (See article below entitled "*NIH Policy: Single IRB Review for Multi-Research Studies*" for more information)

NIH Changes to Certificates of Confidentiality

Effective October 1, 2017, NIH will automatically issue Certificates of Confidentiality to all research funded by NIH that is collecting or using identifiable sensitive information. Additional information can be found on the NIH Certificates of Confidentiality Kiosk at https://humansubjects.nih.gov/coc/NIH-funded. In part, the new policy reads:

"For the purposes of this Policy, consistent with subsection 301(d) of the Public Health Service Act (42 U.S.C 241), the term "identifiable, sensitive information" means information about an individual that is gathered or used during the course of biomedical, behavioral, clinical, or other research, where the following may occur:

An individual is identified; or

For which there is at least a very small risk, that some combination of the information, a request for the

information, and other available data sources could be used to deduce the identity of an individual."

Consent documents should be updated with wording related to the Certificate of Confidentiality. Please refer to the NIH Certificates of Confidentiality Kiosk for sample language.

NIH Policy: Single IRB Review for Multi-Research Studies

Beginning January 25, 2018, the NIH policy on the Use of Single IRB (sIRB) for Multi-Site Research requires multi-sites studies conducting the same protocol use a sIRB to conduct review and approval of the proposed research. The goal of this new policy aims to eliminate duplicative review for qualifying research studies. For example, the policy for sIRB review does not apply to career development, research training or fellowship awards. The policy requires grant applicants to include a sIRB plan in the grant application or contract proposals. The NIH provides guidance documents for the sIRB information to be included in the grant application. These references include the NIH FAQs, Section D "NIH Grant Application/Contract Proposal Preparation" and Section 3.2 of the PHS Human Subjects and Clinical Trials Information Form Application Guide. The USA IRB provides a template to assist researchers in preparation of the sIRB plan available on the Human Subject's website under the section called Single IRB.

The NIH does not require a letter of support from the sIRB indicating its willingness to serve as the sIRB. However, the USA IRB believes this is best practice. Therefore, USA IRB will require that your grant application include a Letter of Support from the USA IRB documenting its support for the use of a sIRB. A letter of support to acknowledge sites' agreement to rely on an external IRB review is the standard mechanism for accomplishing this. A sample letter format will be provided for the study site to utilize and request the letter from the USA IRB.

The University of South Alabama's policy and procedures for use of a sIRB is located on the Single IRB website.

Reminder! IRB 101 for Students Educational Outreach

The Office of Research Compliance and Assurance and the IRB Office are available to provide class room presentations to students on information involving human subject's research and the IRB submission process.

Please email dlayton@southalabama.edu if you'd like to schedule an educational session.

RESPONSIBLE CONDUCT OF RESEARCH TRAINING SERIES

*Brown Bag Lunches Are Welcomed!

What is RCR?

Education in the responsible conduct of research provides a shared understanding of the rules and ethical norms to perform research. Researchers have both professional and regulatory related responsibilities to conducting research responsibly, such as practicing scholarly activities and research with integrity. RCR training aims to develop commonality in building shared values in order to promote a culture of compliance, and empowerment to continue conversations within the work environment.

Who Should Attend?

Faculty, Postdoctoral Students, and Senior Graduate Students

Where?

The University of South Alabama

Student Center Room #211

Register

Registration is required for each session

CLICK HERE to Register!

Email Questions to aswilliams@southalabama.edu

The Office of Research Compliance and Assurance

UNIVERSITY OF SOUTH ALABAMA

DATES (2017-2018)

The first Thursday of every month
12:00p.m. to 1:00p.m.

OCTOBER 5TH
Responsible Authorship, Publication and Citations

NOVEMBER 2ND
Research Misconduct and Questionable Research Practices

DECEMBER 7TH
Data Acquisition, Management and Statistical Analysis

JANUARY 4TH
Peer Review of Grants and Papers

FEBRUARY 1ST
Retractions in Academic Literature

MARCH 1ST
Mentor/Mentee Responsibilities and Relationships

APRIL 5TH
Collaborative Research including Collaborations with Industry

MAY 3RD
Conflict of Interest (personal, professional, financial)

Research Compliance Website Updates

Website resources and updates include:

- A section for posting Compliance Updates and Information
- Research Compliance current and archived e-newsletters
- NIH Single IRB Policy and Procedures
- Research Education and Learning Portal

  This portal provides a matrix outlining the minimum education requirements for personnel, including undergraduate/graduate student's involved in research activities or working in a laboratory setting. The matrix should be reviewed to determine which educational requirements apply to your designated research activities.

  Resources are provided for easy access to information regarding required training affiliated with research activities.

Have a Question or a Comment?

Dusty Layton
Executive Director
460-6625
dlayton@southalabama.edu

Angela Williams
Assistant Director
460-6509
aswilliams@southalabama.edu

Stefanie White
Associate Director, Research Quality Assurance & Improvement
460-7573
swhite@southalabama.edu

Human Subjects Research

SuzAnne Robbins
IRB Compliance Specialist
460-6308
irb@southalabama.edu

Animal Care & Use and Biosafety

Jennifer Chaplin
Research Compliance Coordinator
460-6863
jchaplin@southalabama.edu