Cornell University
Office of
Research Integrity and Assurance

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March 20, 2018

Dear Cornell Researchers,

We are writing to remind you of some important NIH policy changes for research involving human participants. Whether your research is currently funded by the NIH or whether you are seeking to apply for NIH funding, please review these policy changes and contact the IRB office if you have questions. Some of these changes **require you to take action at the proposal stage**. To clarify, these changes are separate from changes to the Common Rule (the federal regulations governing research with human participants) that have been delayed through at least July 19:

- **Single IRB (sIRB) for multi-site studies**: NIH-funded studies involving non-exempt research now must use a Single IRB (sIRB) if the same study will be conducted at multiple domestic sites. A sIRB is the IRB of record that provides the ethical review and related administrative coordination for all sites in a multi-site study. Funding proposals to the NIH for multi-site studies must include a plan identifying the Single IRB that will be used, and confirming that all sites have agreed to this arrangement. **At this time, Cornell is unable to serve as the Single IRB**. If you believe your proposal triggers the sIRB requirements, please work with IRB staff to facilitate options for meeting the requirement well in advance of the funding deadline. Please contact Guilaine Senecal at 255-8994 or gds64@cornell.edu for more information.
- **Your social/behavioral project may now be considered a "clinical trial"**: The term "clinical trial" now includes some biomedical, and social and behavioral research that meet certain criteria. If you plan to apply for NIH funding, we advise you to seek advice from the IRB office to determine whether your study could be considered a clinical trial. This is critically important, because certain NIH Funding Opportunity Announcements (FOAs) are applicable only to clinical trials or non-clinical trials; applying for the wrong FOA will make your submission ineligible for funding. A new NIH webpage includes case studies, FAQs and a decision tool to help researchers understand the new definition.
- For new studies that are now considered clinical trials:
    - The IRB approval will include a summary of requirements or recommendations.
    - **You may need to register the clinical trial on ClinicalTrials.gov**: NIH-funded PIs must register, submit updates, and post results information on ClinicalTrials.gov. Compliance will require significant time and effort throughout the study.
    - **Training in Good Clinical Practice (GCP)**: Researchers on a "clinical trial" must be trained in GCP. All study personnel listed on the protocol must have completed GCP training within the last 3 years. GCP training can be completed online through CITI and is in addition to the basic IRB training.

The Cornell IRB is here to assist you in navigating these new requirements. Should you have any questions about these policies, contact us at irbhp@cornell.edu, or 607-255-8994.