

Office of Sponsored Programs

RESEARCH ADMINISTRATORS FORUM

January 2018



NEW YORK UNIVERSITY





Agenda

- Single IRB (sIRB)
- NIH's definition of Clinical Research



Budget Implications of the NIH Single IRB (sIRB) Policy

- Effective for grant applications received for due dates on or after January 25, 2018. For contracts, the policy applies to all solicitations issued on or after January 25, 2018
- Applies to the domestic sites of NIH-funded multi-site studies where each site will conduct the same protocol involving non-exempt human subjects research
 - Does not apply to career development, research training or fellowship awards
- For collaborative projects with foreign sites:
 - If an award involves both domestic and foreign sites, the domestic sites are expected to use a single IRB and the foreign sites could use their own IRBs or Ethics Boards
 - An award that involves *only* foreign sites would not be expected to use a single IRB under the NIH single IRB policy. Similarly, an award that involves one domestic site and multiple foreign sites would not be expected to use a single IRB



Budget Implications of the NIH Single IRB (sIRB) Policy (cont.)

- **When NYU is the Lead Site**
 - Utilizing BRANY IRB as the single IRB for the multi-site research project
 - Faculty should include the cost of BRANY single IRB services as a direct cost line item in the proposal budget



Budget Implications of the NIH Single IRB (sIRB) Policy (cont.)

- **Estimated Rates to be used:**
 - Direct cost items
 - **"sIRB Initial Review"**: includes a review of NYU's protocol, informed consent document(s), drug/device brochure (if applicable), and review of NYU's IRB application: \$1,500
 - **Participating site review**: multiple, participating site specific applications: \$1,000 per site
 - **Continuing review**: Review of each site's application for continuing approval (once a year): \$1,000 per site
 - **Modifications to research**: \$0
 - **Foreign Language Consent**: translations coordinated by BRANY including sIRB acknowledgement: the cost of translation is billed on a per word basis and invoiced as a pass through cost so this needs to be estimated.
 - **Note**: *In the event that sponsor policy dictates a cap on sIRB costs that can be charged directly, use the cap and notify Nancy Daneau*



Budget Implications of the NIH Single IRB (sIRB) Policy (cont.)

- **Budget Justification Requirements**

- When NYU is the lead site/coordinating center, the following language should be included in the budget justification:

- "In accordance with NIH Policy on the use of single IRBs for multi-site research, Principal Investigator/NYU will be utilizing the BRANY IRB as the single IRB for this multi-site research project. BRANY IRB has full AAHRPP accreditation and 18 years of experience serving as both a central IRB for multi-site research, and a local IRB to academic medical centers, research institutions, and research sites. BRANY IRB will be responsible for conducting the ethical review of this multi-site study for NYU and all participating sites, and will carry out the regulatory requirements as specified under the HHS regulations at 45 CFR Part 46. BRANY will review the study protocol, investigator brochure (when applicable), and informed consent template that will be common to and used by all participating sites. The research sites participating in this study have agreed to abide by NIH's single IRB policy, will sign an IRB Authorization Agreement (aka "reliance agreement") with BRANY for the study, will complete a separate, site specific application, and rely on the IRB review performed by the BRANY IRB on behalf of NYU. Participating sites for this multi-site study are expected to rely on the BRANY IRB to carry out the functions that are required for institutional compliance with IRB review set forth in the HHS regulations at 45 CFR 46. Participating sites are responsible for meeting other regulatory obligations, such as obtaining informed consent, overseeing the implementation of the approved protocol, and reporting unanticipated problems, any serious and/or continuing non-compliance, and study progress to the BRANY sIRB and NYU Lead Investigator."



Budget Implications of the NIH Single IRB (sIRB) Policy (cont.)

- When NYU is a participating site (collaborator), and another entity will serve as the Lead Site
 - NYU will rely upon another entity's IRB for sIRB management
 - For budgeting purposes, the PI will have to obtain from the entity's sIRB a cost for review of NYU's application as a participating site and use that cost estimate in the development of the collaborative proposal
 - NYU's IRB will review and approve of NYU's use of the external entity's sIRB



Budget Implications of the NIH Single IRB (sIRB) Policy (cont.)

- The NYU IRB will draft a letter, to be included in the proposal, that documents its support for the use of the other entity's sIRB. Contact NYUIRB at ad105@nyu.edu, cc ask.humansubjects@nyu.edu to request the letter, at least **one week** before you need it

- Required in the letter:

- The name of the NYU PI
- The name of the lead PI and the lead site
- The name of the proposed sIRB, if already identified
- The title of the study/grant
- The grant deadline
- A copy of or link to the NIH Request for Applications (RFA) or Funding Opportunity Announcement (FOA)
- What role(s) NYU will play in the research
- Whether this grant is for a single study, multiple studies and/or a network that will design and conduct studies
- Any additional relevant information (cost of the review of NYU's IRB application as a participating site)
- What form the reliance agreement will take (sample agreement from the sIRB institution)

Note: As of March 2018, this IRB procedure has changed, please refer to: <https://wikis.nyu.edu/pages/viewpage.action?pageId=92308321>



NIH's Definition of Clinical Trials

- NIH has clarified its definition of clinical trials to enhance the accountability and transparency of clinical research. Also reflected by extensive [changes in Forms-E](#), NIH is enforcing its definition of a clinical trial with the end goal of better capturing studies that fall within the definition.
- Why these changes?
 - NIH describes the main reasons for this change as its need to:
 - support trials investigating **high priority questions**
 - avoid **needlessly duplicating** previously conducted trials
 - exercise **proper stewardship** over public resources, in part by **developing and maintaining robust data**
 - **respect ethical obligations** to participants who give their time and sometimes put themselves at risk for the sake of advancing science
 - **promote broad, transparent, timely, and responsible dissemination of information** from NIH-funded clinical trials



Changes to NIH Definition of Clinical Trials (cont.)

- **NIH Definition of a Clinical Trial**
 - A research study in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes
- **Four questions to determine whether or not a study is a clinical trial:**
 - Does the study involve human participants?
 - Are the participants prospectively assigned to an intervention?
 - Is the study designed to evaluate the effect of the intervention on the participants?
 - Is the effect that will be evaluated a health-related biomedical or behavioral outcome?



Changes to NIH Definition of Clinical Trials (cont.)

- What is the impact for proposal applications?
 - NIH requires institutional applications to indicate when clinical research is being proposed
 - Some proposal announcements from the NIH will continue to identify particular solicitations and submissions that will result in clinical research and are eligible for funding as such; other opportunities will not dictate the type of research and therefore require the Investigator and Institution to make the determination
 - If a research proposal is submitted without being properly identified as a clinical trial per NIH's definition, it can be rejected without review
 - For assistance with making the determination, please contact NYU's IRB at ad105@nyu.edu, cc ask.humansubjects@nyu.edu



Changes to NIH Definition of Clinical Trials (cont.)

- **Example Case Study**

A study involves the recruitment of school children to evaluate two different tools for monitoring food intake. Food consumption behavior will be measured by asking children to activate a pocket camera during meals and to use a diary to record consumed food. Changes to eating behavior will be assessed.

- **Does the study involve human participants?** Yes, children are human participants.

- **Are the participants prospectively assigned to an intervention?** Yes, the participants are prospectively assigned to two food monitoring methods.

- **Is the study designed to evaluate the effect of the intervention on the participants?** Yes, the study is designed to determine whether using the monitoring methods changes eating behavior.

- **Is the effect being evaluated a health-related biomedical or behavioral outcome?** Yes, eating behavior is a health-related outcome.

✓ **This study is a clinical trial.**



Changes to NIH Definition of Clinical Trials (cont.)

- Example Case Study

A study involves the recruitment of children at two schools to monitor eating behavior. Children's food choices will be monitored using a remote food photography method. Food consumption and the accuracy of food monitoring methods will be assessed.

•**Does the study involve human participants?** Yes, the children participating in this study are human participants.

•**Are the participants prospectively assigned to an intervention?** No, not in this context. The study involves observing and measuring eating behavior, but not modifying it. This is an observational study.

X This study is not a clinical trial.



Changes to NIH Definition of Clinical Trials (cont.)

- For more information, please see:
 - [NIH FAQs on the Clinical Trial Definition](#)
 - [NIH Case Studies](#), for examples on how the definition is applied
 - [Further Clarification on Case Studies](#)



Resources

- [Single IRB WIKI Page](#)

- [Clinical Trials WIKI Page](#)