Funding Agency Updates

News from the NIH Office of Science Policy

June 21, 2016

Release of the Final *NIH Policy* on the Use of a Single Institutional *Review Board for Multi-Site Research*

Today, in the <u>Federal Register</u> and the <u>NIH Guide to Grants and Contracts</u>, the NIH published its final <u>NIH Policy on the Use of a Single Institutional Review Board for Multi-Site</u> <u>Research</u>. This policy establishes the expectation that all sites participating in multi-site studies involving nonexempt human subjects research funded by the NIH will use a single Institutional Review Board (sIRB) to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects. The intent of this policy is to enhance and streamline the process of IRB review and reduce inefficiencies so that research can proceed as expeditiously as possible without compromising ethical principles and protections for human research participants.

The NIH recognizes that the sIRB policy will be a paradigm shift in IRB review. As such, the final policy will not take effect until May 25, 2017. NIH has prepared a number of resources to assist the research community in preparing for the implementation of the policy. A set of <u>FAQs</u>, as well as <u>guidance</u> on scenarios illustrating the use of direct and indirect costs for single IRB review under the policy are now available on the <u>NIH Office of Science Policy</u> website. Another tool available for the research community is the NIH National Center for Advancing Translational Sciences (NCATS) single IRB reliance platform for multi-site clinical studies: the <u>NCATS</u> <u>SMART IRB Reliance Platform</u>.

For additional perspectives on this issue, we encourage you to read a <u>statement</u> on the importance of the sIRB policy from NIH Director, Dr. Francis Collins, as well as the latest "<u>Under</u> <u>the Poliscope</u>" blog co-authored by Dr. Carrie D. Wolinetz, and Dr. Mike Lauer.

The resources and guidance above are available now on the <u>NIH Office of Science Policy</u> website. Additional resources will be added to the website as they become available.

If you have any questions or require further information about the single IRB policy, please contact us at <u>SingleIRBpolicy@mail.nih.gov</u>



Dear Colleagues:

I wanted to make you aware that the Foundation's entire suite of Award Terms and Conditions (see full listing below) has been revised to implement the requirements stipulated in Appendix XII to Part 200 of 2 CFR § 200 (the Uniform Guidance) regarding the Federal Awardee Performance and Integrity Information System (FAPIIS), as well as other clarifications to the conditions. Each set of terms and conditions is accompanied by a comprehensive summary of changes made to that document.

The revised Terms and Conditions will apply to all new NSF awards and funding amendments to existing NSF awards issued on or after July 1, 2016.

Revisions have been made to the following documents:

- Grant General Conditions (GC-1);
- Cooperative Agreement Financial & Administrative Terms and Conditions (CA-FATC);
- Cooperative Agreement Supplemental Financial & Administrative Terms and Conditions for Managers of Large Facilities;
- Cooperative Agreement Supplemental Financial & Administrative Terms and Conditions for Managers of Federally Funded Research and Development Centers (FFRDCS);
- · International Research Terms and Conditions;
- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Phase I Grant General Conditions;
- Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Phase II Grant General Conditions; and
- Administration of NSF Conference or Group Travel Grant Special Conditions (FL 26).

These Award Terms and Conditions are available electronically at: http://www.nsf.gov/awards/managing/award_conditions.jsp?org=NSF.

If you have any questions regarding these changes, please contact the DIAS/Policy Office on (703) 292-8243 or by email to <u>policy@nsf.gov</u>.



Dear Colleagues:

NSF continues to focus on the automated compliance checks of proposals in order to decrease the burden on both the research community and NSF staff. Effective July 25, 2016, all proposals will be subject to a new series of automated compliance validation checks to ensure proposals comply with requirements outlined in Chapter II.C.2. of the *Proposal and Award Policies and Procedures Guide* (PAPPG).

The new set of automated compliance checks will trigger error messages for each of the following rules:

Biographical Sketch(es) and Current and Pending Support files are required for each Senior Personnel associated with a proposal; and

Biographical Sketch(es) can only be uploaded as a file, must not exceed two pages and can no longer be entered as text.

Note About Proposal File Update (PFU): Proposers should be aware should that if a proposal was received prior to July 25 and contained only one Biographical Sketch and/or Current & Pending Support file (rather than individual files for each senior personnel), a PFU addressing any section of the proposal will result in the proposal not being accepted if it does not comply with these new compliance checks. The checks will be run on all sections of the proposal regardless of which section was updated during the PFU.

Note About <u>Grants.gov</u>: Proposers should also be aware that <u>Grants.gov</u> will allow a proposal to be submitted, even if it does not comply with these proposal preparation requirements. Should NSF receive a proposal from <u>Grants.gov</u> that is not compliant, it will be returned without review.

Please note that the new set of compliance checks **are in addition to** the compliance checks that currently exist in FastLane. You can view a complete list of FastLane auto-compliance checks, including these checks, by clicking <u>here</u>. The list specifies which checks are run depending on funding opportunity type (GPG, Program Description, Program Announcement, or Program Solicitation) and type of proposal (Research, RAPID, EAGER, Ideas Lab, Conference, Equipment, International Travel, Facility/Center, or Fellowship). It also specifies whether the check triggers a "warning" or "error" message for non-compliant proposals.

We encourage you to share this information with your colleagues. For system-related questions, please contact the NSF Help Desk at 1-800-381-1532 or <u>Rgov@nsf.gov</u>. Policy-related questions should be directed to <u>policy@nsf.gov</u>.