

Research Community,

There are some significant changes coming for NIH funding for proposals submitted on January 25, 2018 or later. ***Anyone applying for NIH funding needs to be aware of these changes in order to avoid negative consequences including the possibility of rejected proposals or other penalties.*** Please review the following information and contact your SRA Grants Officer with any questions.

Clinical Trial Definition Expanded to Include Behavioral Studies (effective 1/25/18)

NIH has expanded the interpretation of their clinical trial definition to include a much broader range of activities. The result will be that many new studies that would not have been considered a clinical trial in the past, will now be classified as a clinical trial effective January 25. Although NIH has provided a large number of case studies as examples to assist researchers with the expanded interpretation, nationally, there remains confusion and questions regarding these case studies and the proper classification of studies. Since the correct format to prepare and submit your proposal is dependent upon the proper classification, it is critical to evaluate this classification prior to preparing your proposal. **Investigators are strongly encouraged to contact the NIH program officer to verify whether their proposal meets the definition of a clinical trial and document that decision accordingly. The proper processing of the proposal is contingent upon this determination.** For more information, please

visit: <https://www.research.fsu.edu/research-offices/human-subjects/news-and-events/>

Additional Requirements if Study is Classified as a Clinical Trial

For funded studies that are classified as Clinical Trials, there are new requirements:

- For all human subjects and/or clinical trial research applications with due dates on or after January 25, 2018, the use of the new FORMS-E Application Packages are required. This includes a new clinical trials and human subjects information form which consolidates all human subjects & clinical trial related information into one place, and expands the information required for studies that meet the NIH definition of a clinical trial. *For more information, please see <https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm> or <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html>.*
- NIH requires all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials to be trained in Good Clinical Practice (GCP). To obtain information about accessing this training as an FSU Investigator, please visit <https://www.research.fsu.edu/research-compliance/training/citi-login-instructions/good-clinical-practice/>.
- If a study is classified as a clinical trial under the NIH definition, additional **reporting** is required. Effective January 18, 2017 for clinical trials that meet the FDA definition of an “applicable clinical trial” and/or NIH definition of a clinical trial and funded by the NIH, the following applies: For PI-initiated clinical trials, the PI is required to register the project in ClinicalTrials.gov within 21 days of enrollment of the first subject, complete periodic updates as required, and report summary results information within one year of the primary completion date. The NIH also issued a companion policy requiring that

language on the dissemination of clinical trial information be included in new or competing applications submitted on or after January 18, 2017. The FDA and NIH have established strict timelines for updating ClinicalTrials.gov and have incorporated heavy penalties for failure to meet these timelines.

Single IRB Policy

For applications/proposals with due dates on or after January 25, 2018, NIH expects all domestic sites of NIH-funded multi-site studies, where each site conducts the same protocol involving non-exempt human subjects research, to use a single IRB (sIRB). This can be either an independent IRB, or the institutional IRB of one of the participating sites.

- Applicants will be expected to include a plan for use of a sIRB in grant applications & contract proposals submitted to NIH.
- Scope includes all multi-site studies, and are **not** limited to clinical trials.

IMPORTANT NOTE: FSU Investigators preparing a proposal on a multi-site study should contact the IRB to discuss the details of the award and whether FSU can act as the single IRB.

For more information, see [_https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm](https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm) or <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html> or <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-076.html>

If you have questions, please contact Jane Mostoller at jmostoller@fsu.edu or me for further information.

Thank you,
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