

SF 424 Forms Version E

Effective January 25, 2018 all proposals submitted to the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the Agency for Healthcare Research and Quality (AHRQ) must use federal Standard Form (SF) 424 Application Package Form Version E (FORMS-E). As of this date, these four PHS agencies will no longer accept proposals submitted in the previous Standard Form (SF) iteration, FORMS-D.

The most significant change to the Standard Forms package is the addition of a new form “PHS Human Subjects and Clinical Trials Information” (<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm>). This new required form consolidates human subjects information previously collected across multiple forms and attachments, expands the information captured to now include study-level data, and incorporates two major changes to NIH human subjects policy - the expanded definition of clinical trial to include behavioral studies and the new single Institutional Review Board (sIRB) policy.

The updated definition of clinical trials has an impact on NIH Funding Opportunity Announcements (FOAs) which now clearly indicate whether a proposal classified as a clinical trial will be accepted in response to that call. Additional information regarding this change, including a chart specifying which FOAs will accept clinical trials research, can be found within NIH Policy Notice NOT-OD-18-106 (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-106.html>).

Resources

We encourage the Cornell research community to view the video recording of the December 2017 Cornell Office of Sponsored Programs (OSP) Roundtable “New NIH Human Subjects Requirements” (https://vod.video.cornell.edu/media/December+2017+OSP+Round+Table+Recording/1_skrzmckp). This joint presentation by OSP and the Office of Research Integrity and Assurance (ORIA) addresses each of the new NIH human subjects policies, the revisions to NIH Funding Opportunity Announcements (FOAs), and the new “PHS Human Subjects and Clinical Trials Information” form from a Cornell perspective.

Additional resources can be found in the following links;

- SF424 FORMS-E Summary of Significant Changes
<https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.120-significant-changes.htm>
- NIH Video Tutorial “A Walk Through the PHS Human Subject and Clinical Trial Information Form” (9 minutes)
<https://grants.nih.gov/policy/clinical-trials/new-form/video>
- NIH Video Tutorial “Overview of New NIH Policies on Human Subjects Research” (15 minutes)
<https://grants.nih.gov/policy/clinical-trials/tutorial/story.html>

Questions?

For questions regarding FORMS-E or NIH Funding Opportunity Announcements (FOAs), please contact your OSP Federal Team Grant & Contract Officer (<https://www.osp.cornell.edu/Contacts/whoismygc.html>) or Jamie Sprague, Sr. Grant & Contract Officer & Federal Team Lead, at jas2233@cornell.edu.

For questions regarding human subjects, including NIH’s new policies, please contact the ORIA Institutional Review Board (IRB) staff at irbhp@cornell.edu.