2018 APPLICATION SUBMISSION CHANGES

FREQUENTLY ASKED QUESTIONS

You’ve been hearing about a number of upcoming changes in proposal submission in 2018. Some changes are driven by our federal sponsors, some are the result of SkyVU “Go Live” and others are the result of Sponsored Programs Administration process updates. We hope to address your questions below:

What changes are driven by new sponsor requirements?

- New Forms E NIH Application
- New Human Subjects Form and requirements in the Forms E set
- New NIH definition of Clinical Trial
- Adobe package being retired

What changes are being driven by SkyVU as of December 15, 2017?

- VUMC employed faculty will no longer be in the people table in COEUS, if they do not have a VU role. VUMC faculty will be pulled from the Rolodex. Communication from December 1, 2017 is attached.

What changes are driven by Sponsored Program Administration processes?

- [https://www.vanderbilt.edu/sponsoredprograms/forms_library.php](https://www.vanderbilt.edu/sponsoredprograms/forms_library.php)
- Beginning January 1, 2018 the NEW Subrecipient Statement of Collaborative Intent Form will need to be used for all projects involving a subrecipient.

1. What do I need to know about the new FORMS-E applications package?

- FORMS-E applications are used under reissued FOAs for due dates on or after January 25, 2018.
- FORMS-E application packages are available in Coeus now. Be sure to select the correct FOA and application package.
  - For a transition period, both FORMS-D and FORMS-E applications and instructions will be active.
  - Applications submitted with the wrong package may not be considered for funding.
  - Applications submitted under the wrong FOA may not be considered for funding.
- Coeus will submit FORMS-E applications System-to-System submissions, unless the proposal includes human subjects/clinical trials
  - ALL applications will report whether human subjects, clinical trials, human specimens or data will be used or collected.
  - The HSCT Form (Human Subjects Clinical Trial) will be completed even if no human subjects are involved in the project. The form will populate in all applications.
Applications that propose humans subjects research will be submitted via ASSIST

ALL applications will report whether human subjects, clinical trials, human specimens or data will be used or collected.

If human specimens will be used or data collected, a narrative explaining why the proposal is non-human subject research will be required as an uploaded attachment. If you are using specimens and/or data and neither you nor your collaborators can identify the subjects from whom the specimens and/or data were obtained, either directly or indirectly through coding systems, this is not considered human subjects research and the HHS human subjects regulations (45 CFR Pat 46) do not apply at all. If your research involves only coded private information/data or coded specimens. OHRP does not consider this research to involve human subjects as defined under the HHS Protection of Human Subjects Regulation (45 CFR Part 46. 102(F) if the following conditions are both met: The private information/data or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
(a) the key to decipher the code is destroyed before the research begins;
(b) the investigators and the holder of the key enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased;
(c) there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; or
(d) there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased.

For more information and resources links, including effective dates, go to https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-062.html

2. When will FORMS-E application packages be available in Coeus?
   - FORMS-E application package is available now in Coeus for applications due on or after January 25.

3. When do I start using the FORMS-E application package?
   - All application submitted on or after January 25, 2018 must use FORMS-E applications packages
   - Even if submitting early applicants, use FORMS-E if the receipt date is on or after January 25, 2018
   - EXCEPTION - applicants eligible to submit under continuous submission must use FORMS-D until February 7, 2018
4. I know I will be submitting proposals to NIH that include human subjects using ASSIST. What information does NIH require?
   - Basic study information
   - Study population characteristics
   - Protection and Monitoring plans
   - Protocol synopsis
   - Other clinical trial related attachments
   - HSCT Form in ASSIST

5. My proposals to NIH include human subjects. Do I still use Coeus?
   - No matter what the submission portal is used, all proposals must be entered into Coeus for routing and approval.
     - FORMS-E applications with human subjects/clinical trials are submitted via ASSIST and are also entered into Coeus.
     - There are modified requirements for proposals entered into Coeus but submitted via a separate application portal (such as RPPR, PAMS, AHA, ProposalCentral).

6. What has to be routed in Coeus for a proposal submitted through ASSIST?
   - Complete all tabs of the Proposal Details
   - Do Not Bring in the Grants.gov Funding Opportunity
   - Project Summary/Abstract narrative
   - Subrecipient Statement of Collaborative Intent (SSCI) form
   - Project budget and justification (it is recommend that Coeus be used to calculate budgets.)

7. You indicated that NIH has a new definition of clinical trials. Where do I find it?
   - Refer to: https://grants.nih.gov/policy/clinical-trials/definition.htm

8. Does it matter if I know whether it’s a clinical trial or not? How can I be sure?
   - Yes, clinical trials proposals must be responsive to specific FOAs. Some FOAs specify that clinical trials are required, some make clinical trials optional, and some do not allow clinical trials.
   - Refer to Funding Opportunity
   - Refer to the NIH-provided resources to determine whether the study is a clinical trial.
   - Refer to: https://grants.nih.gov/policy/clinical-trials/specific-funding-opportunities.htm