News Flash – Breaking News from the Office of Clinical Awards Administration

Three things to you need to know right now:

1. NIH released two new **R01** Parent Announcements: '**Clinical Trial'** projects should apply through **PA-18-345**; all others, use **PA-18-484**. As of 12/5/2017, the following Institutes are participating in Parent announcement 18-345: NHLBI, NIDA, NIEHS, NIGMS, NIDA, NIA, NIAAA, NIAID, NHGRI, NIMH, NIAMS, NIMHD, NINDS, NNINR, and NCCIH. If the institute targeted for a Clinical Trial based R01 is not listed above, please contact The Office of Clinical Award Administration, 84490, to see what options are available.

   A similar **R21** Parent, **18-344**, was also released for **Clinical Trial Required** projects, all others should use **PA-18-489**. Not all the same institutes are participating in the R21 Clinical Trial Required call as the R01 announcement. For the R21 Clinical Trial Required announcement, 18-344 only NGRI, NIAAA, NIAMS, NIA, NID, NIDCD, NIEHS, NIDIA, NIMH, NIMHD and NINR are accepting proposals. NCI has its own R21 PA for clinical trials, PA-18-020, whereas NIMH has its own R21 call, 18-350, for proposals clinical trials not allowed.

   The new **R03** announcement is **PA-18-488** - Clinical Trial Not Allowed. You will need to see if the institute that you are targeting has an R03 Clinical Trial Required call. Some that do, include NICHDS, PA18-481, while others, like NCI, 18-021 have calls where Clinical trials are optional.

   NIH is issuing three different types of funding announcements, Clinical Trial Required, Not Allowed and Optional this change makes it important that you look at the designation before applying to a PA to make sure that you are applying to the correct one. If you are unsure if your project is a clinical trial or not you can refer to NOT-OD-17-118 for the updated criteria.

2. In NOT-OD-18-103 (dated 11/16/2017) NIH announced that it intends to publish the Project Outcomes section of all Final and Interim Research Performance Progress Reports (RPPRs), submitted on or after 10/1/2017, the start of their new fiscal year, on NIH RePORTER, making them available to the general public. This will allow recipients to provide the general public with a concise summary of the cumulative outcomes or findings of the project at the end of each competitive segment. A similar practice has been in effect at NSF for years.

   The NIH will only publish project outcomes that have been reviewed and approved by NIH staff.

   It is important that all PIs when writing the Outcomes portion ensure that it:

- Is written for the general public in clear and concise language
- Is suitable for dissemination to the general public
- Does not include proprietary, confidential information or trade secrets
- Is not more than half a page

If the description of the project outcomes are found to be unacceptable, recipients will be required - upon NIH request - to submit revised outcome statements using the FRAM portal on eRA Commons.

If you have questions about this new process, please contact the Office of Clinical Award Administration at 631-638-4490.

3. In notice NOT-OD-17-098, NIH once again updated their policy on what is acceptable appendix material, eliminating clinical trial-related material for all NIH/AHRQ/NIOSH applications due on or after January 25, 2018. Much of the clinical trial related materials will be specified and required in the new PHS Human Subject and Clinical Trials information form (part of the new E forms that will be required on the same date), and no longer allowed in the appendix unless specially stated as required in the funding opportunity announcement.

   As of 1/25/2018 the only allowable appendix materials are:

   - Blank data collections forms, blank survey forms and blank questionnaire forms or screen shots thereof.*
   - Simple list of interview questions *
   - Blank informed consent / assent forms
   - Other items ONLY if they are specified in the FOA as allowable appendix materials

   *These blank forms and lists are not and do not include items such as: data, data compilations, list of variables or acronyms, data analysis, publications, manuals, instructions, descriptions or drawings / figures / diagrams of data collection methods or machines devices.

The January – March federal deadlines usually have the most changes associated with them as they come at the start of New Year. To assure you have the most current sponsor related information, it is important you make the Office of Clinical Award Administration aware of your projected submission schedule. Once you, do we will make sure that you are notified of all sponsor / program-related changes as soon as they are announced.

If you would like to be notified of targeted funding opportunities when they are released, complete our survey using this link: CAA Research Survey