

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

Three things to you need to know right now:

1. Three New NIH Parent Funding Announcements

With submissions due on or after January 25, 2019 NIH will now have **three** new **Parent Funding Announcements** for both R01 and R21 submissions. For R01 submissions they are [PA-19-055](#) Clinical Trials Required, [PA-19-056](#) Clinical Trial Not Allowed and the **New** [PA-19-091](#) Basic Experimental Studies with Humans Required. For R21 submissions they are [PA-19-054](#) Clinical Trial Required, [PA-19-053](#) Clinical Trial Not Allowed and the **New** [PA-19-092](#) Basic Experimental Studies with Humans Required.

The Basic Experimental Studies with Humans Required is defined as studies that meet the NIH definition of a clinical trial and the federal definition of basic science. Going forward NIH will refer to them as “prospective basic science studies involving human participants.” Types of studies that should submit under the new parent include studies that prospectively assign human participants to conditions (i.e., experimentally manipulate independent variables) and assess biomedical or behavioral outcomes in humans for the purpose of understanding the fundamental aspects of phenomena.

According to the notice of record on this topic [NOT-OD-18-212](#), there will be leniency if an investigator uses the incorrect FOA to submit an application until September 24, 2019. But the application will be reviewed based on the review criteria of the FOA that they are submitted to.

Keep in mind, all applications for *prospective basic science* studies involving human participants will require the Human Subjects and Clinical Trial Information form to be completed.

Note: it is also important to **verify** if the IC you are targeting is participating in the Parent Announcement you are applying for. If you are unsure please reach out to The Office of Clinical Award Administration (CAA) 8-4490 for verification.

2. NIH's new Inclusion Across the Lifespan Policy

The upcoming deadlines are also the first ones that require you to follow the Inclusion Across the Lifespan policy which is replacing the Inclusion of Children. Details and guidance can be found in

[NOT-OD-18-116](#) as well as the Open Mike blog dated 1/21/2018 titled: NIH Announces Inclusion Across the Lifespan Policy.

It has been NIH's policy that children (individuals under the age of 18) and older adults, must be included in all human subjects' research, conducted or supported by NIH, unless there are scientific or ethical reasons not to include them. Proposals submitted on or after **January 25, 2019** must address the age appropriate inclusion or exclusion of individuals in the proposed research project. Applications/proposals must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, you must provide an acceptable justification for the exclusion. Examples can be found in notice NOT-OD-18-116. Reviewers will consider whether the proposed age range is appropriate in the context of the specific scientific aims.

Keep in mind if your study is funded, your progress report will now have to include de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment (in units ranging from hours to years).

This policy only applies to new awards going forward. If you submit a competitive renewal it will apply to the next segment of the project.

Other changes that take effect at the same time are included in [NOT-OD-18-228](#) and the [Summary of Significant changes to NIH GPS for October 2018](#).

Please feel free to contact the Office of Clinical Award Administration if you have any questions. We can figure it out together.

3. Deadlines are Closer than You Think

Most of this Newsflash focuses on NIH policy changes but there are other funding options that we all work with that have upcoming deadlines.

In today's hyper competitive funding environment it is important that you put the best product together every time. A fundable proposal takes time and planning, which means now is the time to start thinking about your winter/spring grant submission(s) schedule. Starting at least two months before the deadline allows you time to work with your collaborators, partners, and reviewers without a closely looming deadline. Once you let CAA know your submission schedule, they will make sure you are kept up-to-date on all sponsor updates and policy changes.

When you are ready, we suggest no later than 5/6 weeks before the deadline, CAA will assist you with setting up the project budget based on sponsor requirements, and internal routing. As the

deadline gets closer, about 4 weeks before the deadline, CAA will also assist you in creating the sponsor package for submission upon your request.

It is always important to keep in mind internal deadlines when planning a proposal submission; School of Medicine requires five days for all approvals and The Office of Sponsored Programs has a five day before the sponsor deadline for all submission material. These deadlines are not concurrent.

Please contact us if you have any questions or would like a sample timeline for grant submissions

Keep in mind:

As the New Year begins The Office of Clinical Awards Administration wants to know how you interact with us. We invite to take this short survey, <https://goo.gl/forms/udi0KfgsRQBsaOg03>, to let us know how we are doing and ways in which we can serve the clinical departments at Stony Brook University Medical Center better. Thank you in advance to taking the time to complete this.

If you have questions about the information included in this NewFlash, or relating to the submission of sponsored projects, feel free to contact us at 631-638-4490/ext 8-4490 or via email at SOMCAA@stonybrookmedicine.edu.