

NEWS AND NOTES

NIH UPDATES APPLICATION INSTRUCTIONS

NIH announced that as of January 25, 2019 there would be a language update as to how certain things are referred in grant applications and in review criteria - detailed in [NOT-OD-18-228](#). From this date forward, "Scientific Premise" should be referred to as "the Rigor of Prior Research" in proposal headings and text. See the January 2019 Newsflash or the linked NIH Notice for additional changes.

Another change that took effect regards proposals that involve human subjects - references to, "Inclusion of Children" was replaced with, "Inclusion Across the

Lifespan". NIH is now looking to see if the inclusion and exclusion of children - (0-18 years of age), and older adults is warranted by the research.

Since all of the inclusion documentation [i.e. "Women and Minorities", and "Across Lifespan"] are a single upload, you may include a sub heading for children - as long as you explain why you chose the age range targeted by the study.

Uploading to Clinicaltrials.gov just got easier

When conducting clinical trials, NIH-funded recipients are **REQUIRED** to register their study at ClinicalTrials.gov. To make this process easier, a new feature in the eRA Human Subject System was deployed as part of the 2/27/2019 system update. It allows applicants and recipients to export study records entries as an XML file which can be uploaded directly to the ClinicalTrials.gov's Protocol Registration and Results System. This improvement will allow users to get a jump start on the registration process with just a few clicks.

When using this optional feature please note that it: is only available for studies that have been classified as clinical trials and; means that one would have answered yes to the four questions at the top of the human subject form when submitting the proposal and completed sections four and five on the form itself. If one does not indicate that the study is a clinical trial, access to the

Export XML feature is not available. To process the download, include the following additional information:

- ✓ The **organization name** (this is a one-word name that is assigned when the study on the Protocol Registration and Results System (PRS) on ClinicalTrail.gov is created)
- ✓ A **unique identification protocol number** (normally be assigned by the sponsor)

When taking advantage of this new feature, you must take into account that only XML records can be uploaded to the system - it will not accept PDFs, word, excel or text files. While this does reduce the administrative burden, applicants will still need to review and edit the study record, and provide any missing information.

For step-by-step instructions and more information, see: [How to Upload Studies to ClinicalTrials.gov](#) and the [HSS: How to Export Study Record Data](#) video.

Update on NIH Post-Submission Materials Policy ([NOT-OD-19-083](#))

Any application submitted on or after May 25, 2019 will have to adhere to a new post-submission policy.

Post-submission materials (other than citations and videos) must adhere to all sponsor policies listed in the application instructions or general proposal submission guidelines regarding font size, margins, and paper size. Any specific formats and page limits referenced in the applicable application instructions will still apply. If no specific formatting or page limits are referenced, there is a one-page limit except in the case of Training Grants, as discussed below.

Acceptable materials are due to the Scientific Review Officer (SRO), no later than 30 calendar days prior to the peer review meeting and must be sent with the concurrence of the AOR (Sponsored Program Representative / Grants Administrator). The SRO will only accept post-submission material when sent by the AOR.

Preprints, other interim research products, and missing or corrected materials from the original submission will not be accepted as post-submission materials.

The following are considered acceptable post-submission items for most types of submissions:

- ✓ Revised budgets due to new funding or institutional acquisition of equipment;
- ✓ Biographical Sketches due to the hiring, replacement or loss of an investigator;
- ✓ Letters of support or collaboration due to the hiring, replacement or loss of an investigator;
- ✓ Adjustments resulting from a natural disaster such as loss of an animal colony;

- ✓ News of professional promotion or positive tenure decision for any PI or Senior / Key Personnel;
- ✓ News of an article accepted for publication since the submission of the application, which must only include a list of authors and institutional affiliations, title of the article, and journal or citation (if available); and
- ✓ Anything that was specified in the Funding Opportunity Announcement.

For Training Grants (T-Series) a list of publications up to three pages will be accepted. Previously, only a single page was permitted.

Training grants are also allowed to include:

- ✓ Notice of a trainee's or former trainee's graduation, employment, promotion, funding, or publications;
- ✓ A faculty member's promotion, funding, or publications (since submission of application); and
- ✓ Addition or removal of any faculty member involved in the training program (mentor or senior key persons).

Individual Fellowships (F applications) and Career Development (K Series applications) are also allowed to include the following:

- ✓ New funding for the Sponsor/Mentor limited to the project title, funding source, (such as the sponsored grant number) and, a brief description of the specific aims, and relevance to the fellowship or career development application under review; and
- ✓ Changes in Mentor(s) or other Senior / Key Person specified on the original application.

ESI Corner

These blog posts from the Edge for Scholars web site should be “must reads” for Early Stage Investigators:

<https://edgeforscholars.org/not-that-kind-of-grant-takes-of-early-career-investigator-grants/>

<https://edgeforscholars.org/not-that-kind-of-selection-takes-of-picking-which-grants-to-write/>

<https://edgeforscholars.org/couch-k23-r01-k99-r21-k08/>

THINGS TO KEEP IN MIND:

- Less is more when it comes to file names - NIH is now enforcing the fifty character file name limit. This limit is being validated by ASSIST and will issue an error if you exceed the fifty character limit. The limit includes spaces and the allowed special characters.
- The Signing Official, GAs and other OSP personnel, can now unlock ASSIST forms if a team member forgot to “save and release locks” on a form and is not reachable to remove it themselves. Forcing a form to unlock means that any data your colleague didn’t save will be lost. Despite this it is nice to know that with the assistance of OSP you will be able to get into the form.
- The OVPR/OSP’s new [5/2proposal submission deadline policy](#) is now in effect. They would like you to provide them access to your entire proposal, minus the science, at least **five** business days before the sponsor’s deadline. Your myResearch proposal should also be completely routed by that time, although the SOM review will now be done concurrently with the OSP review. Under this policy, OSP also requires that the complete proposal be released to them by 9 am two business days before the sponsor’s deadline. This translates to Thursday at 9 am for a proposal that has a sponsor deadline of Monday. [Waivers](#) to this policy need to be requested and will be approved on a case by case basis. For more information on this policy visit the OSP web site.
- myResearch IRB is now live and being used for all new and renewal projects. Visit the [Office for Research Compliance](#) for training materials.
- [Tell us about yourself](#). The more that The Office of Clinical Award Administration knows about you and your research the more they can assist you. Whether you are an Early Stage Investigator or an Established Investigator, there are always new rules popping up and opportunities being released that may be of interest to you. If we know what type of research you are interested in once we are notified of new funding announcements they will be sent directly to you. The more we know, the more we can help you.

SUMMER DEADLINES ARE CLOSER THAN YOU THINK

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; now is the time to start thinking about your fall grant submission 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 six weeks before the deadline - CAA will assist you with

setting up the project budget (based on sponsor requirements) and internal routing. About four weeks before the deadline, CAA will also assist you with creating the sponsor package for submission.

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 new 5/2 deadline policy. These deadlines are now concurrent.

Please contact at, somcaa@stonybrookmedicine.edu or ext. 8-4490, if you have any questions or would like a sample timeline for grant submissions

If there is a topic that you would like to see addressed in a future issue of News and Notes, please contact us at SOMCAA@stonybrook.edu.

Our web site is <http://osa.stonybrookmedicine.edu/caa> old newsletters can be found there.