

NEWS AND NOTES

HELPFUL HACKS FOR MYRESEARCH

- FIRST IN A SERIES -

myResearch is the new Electric Research Administration (ERA) product being utilized by Stony Brook University, effective July 1, 2018. As with all changes, there is an adjustment period while users become acclimated to doing things a new way. To help bridge the transition from COEUS to myResearch, the Office of Clinical Award Administration (CAA) will provide you with updates on tips and tricks as they are discovered. In this issue of News and Notes we are going to focus on navigation issues, which have yielded the biggest number of complaints we have heard about thus far.

There are three separate modules that make up the myResearch Grants process - Funding Proposal, Budget, and Credit Distribution. Each has its own separate navigation pathways but there are tricks to getting from

one place to another in an easier, “beyond the standard”, method. Both the Funding Proposal and Budget functions have a “Jump To” feature which allows you to

navigate directly to any page within that module. Note: you are not currently able to jump directly between the Funding Proposal and Budget modules.

The easiest way to get from the Funding Proposal to the Budget features is through the edit functions. If you entered either of these modules through their edit tabs you will be taken to the main dashboard of that proposal upon hitting the “exit” button. From the dashboard you have easy access to all three of the modules as well as to the sub-menus including the proposal history, attachments and the credit distribution routing. Credit Distribution functions can only be accessed through the sub-menu on the left side of the proposal dashboard.

Please let us know if this tip helps you to transition to becoming an expert user on myResearch. And if you find any helpful hacks, please let us know so we can share them.

Pilot Studies - Uses and Misuses

On its website, The National Center for Complementary and Integrative Health (NCCIH) discusses the uses and misuses of pilot studies https://nccih.nih.gov/grants/whatnccihfunds/pilot_studies. As defined by Porta, Dictionary of Epidemiology, “a pilot study is a small scale test of the methods and procedures to be used on a larger scale”. The goal of pilot

work is not to test hypotheses about the effects of an intervention, but rather to assess the feasibility/acceptability of an approach to be used in a larger scale study. So in a pilot study you are not answering the question “does this intervention work” but gathering information to first figure out if you are able to answer the question at all.

When designing a pilot study, it is important to set clear quantitative benchmarks for feasibility. Since no two studies are the same, these benchmarks should be different for each study.

To determine if you can complete the pilot study, ask these questions:

- * Can I recruit my target population and keep participants in the study?
- * Can I randomize my target population?
- * Will participants do what they are asked to do?
- * Can the treatment(s) be delivered per the approved protocol?
- * Are the treatment conditions acceptable to participants?

Common misuses of pilot studies include:

- * Attempting to assess the safety/tolerability of a treatment;
- * Seeking to provide a preliminary test of the research hypothesis; and
- * Estimating effect sizes and power calculations of the larger scale study.

This concept is gone over in greater details in the link listed above. But the overall conclusion of the posting is that pilot studies should not be used to test hypotheses about the effect of an intervention. The “does this work” questions are best left to the full-scale efficacy trial and the power calculations.

GRANT FORCAST?

All federal funding opportunities are now listed on Grants.gov regardless of the portal through which the proposal will eventually be submitted. Grants.gov encourages agencies to publish their “forecasted opportunities” allowing researchers a little extra time to prepare for a submission. Opportunities are published as forecasted when funds are not yet formally available, are pending budgetary/discretionary spending approvals, or

pending federal agency program decisions. Next time you are [searching](#) for a proposal opportunity and you do not see anything that meets your criteria, check the forecasted opportunities option and you may find both the perfect fit and a little extra time.

NIH Effort - it is all in the numbers

Effort is defined as the amount of time you commit to your grant related activities on a particular project. Reviewers use this figure to assess whether you can complete your research given the amount of effort you pledge to spend on the proposed project. Proposed effort determines how much of your salary will be paid/recovered by the project. But how do you determine this figure?

It is often best to start with the FOA. Does the call state minimum or maximum effort requirements? Certain types of funding opportunities such as

mentored career development, fellowships and Merit awards have specific effort requirements that the PI must meet. Next, you should check with your department/ school to see if it has grant funded effort requirements. The policy of the School of Medicine (SOM) on cost share effort is that you can not exceed 5%, both actual and projected, at any given time without prior authorization from the Dean’s Office.

When thinking about effort, keep in mind that the effort level should fit the project’s needs. If your effort is deemed to be on the high side for the proposed

project, reviewers may recommend cutting your effort/budget. If the proposed effort is considered too low, they may question your commitment to the project. Finally, if the effort you request is totally out of line for the proposed project, reviewers will question your competence and may factor that into your overall impact/priority score.

As a rule of thumb, new investigators should allocate at least 25% effort on each application that they submit as a PI. Established investigators can target at least 10 – 15% if they are the PI.

For more details on this subject, refer <https://www.niaid.nih.gov/grants-contracts/putting-effort-your-application>.

NIH's Late and Continuing Submission Policies

Know the facts

There are two distinct NIH programs that allow a PI to submit their proposal beyond the published deadline - the Late Application Submission program and the Continuous Submission program.

The Late Application Submission program allows for an **additional two weeks** after the published deadline for PA, PAR and RFA announcements which do not state that no late applications will be accepted in the following conditions:

- Death of an immediate family member of the PI (or MPI);
- Sudden acute severe illness of the PI (MPI) or an immediate family member; and
- Temporary or ad hoc service by a PI on an NIH advisory group during the two months preceding or following the applications published due date. Additional details of this criteria can be found in [NOT-OD-15-039](#).

For PIs that also have Continuous Submission rights, the late application submission policy applies to activities that are not covered under the CS program such as R01, R21 and R34 funding opportunities that do not use standard due dates.

The Continuous Submission program allows for submission at any time for **R01, R21 and R34 applications/programs that use standard dues**

dates for members of review and advisory groups and reviewers with recent substantial service. While you can submit on a rolling basis if you are on the [list, there](#) are deadlines to make specific council reviews. These deadlines are:

- for the cycle I review council (standard deadlines Feb/March) April 16;
- for the cycle II review council (standard deadlines June/July) August 16; and
- for cycle III review council (standard deadlines Oct/Nov) December 16.

If you are submitting for an AIDs deadline you have an extra month past the R01 deadline for all submissions. Cycle one needs to be submitted by February 7, cycle II by June 7 and cycle III by October 7.

You should keep in mind that the Continuous Submission program applies only to **R01, R21 and R34** applications submitted by eligible PI and MPIs to FOAs **with standard due dates**. All other types of applications fall under the late submission policy.

If using either of these programs to delay your submission past the stated deadline, keep in mind that your cover letter must address the reason for the delay as well as state which program you are utilizing.

THINGS TO KEEP IN MIND:

- Delegate – as an NIH PI you have the ability to grant permission to other people, which would allow them to assist you with some administrative tasks. These tasks include, but are not limited to, tracking the status of your grant applications and awards, preparing all types of progress reports (including interim and final reports) and uploading human subject tables. If you would like to add Andria Adler from the Office of Clinical Awards Administration as a delegate on your Commons Account, please contact her for additional information.
- NIH has changed the RPPR format to allow effort reporting on grant progress reports to include decimals. You can now report actual effort worked instead of having to round to the nearest person month. This means that 10% can be reported as 1.2 months rather than 1, and you can list 5% effort as .6 months rather than not report effort under one person month.
- In volume 2.1 of the CAA News Flash we introduced you to NIH's ART tools that helps you find the best study section for your proposal. They have now added a similar tool called Matchmaker to the RePORTER site that helps you identify NIH-funded projects similar to yours. The Matchmaker tool has been enhanced to make it easier to identify the NIH program official whose portfolio includes the projects in your research area. As any seasoned investigator knows having a relationship with a program officer is always in your best interest.
- Upcoming Grants.gov updates – as of 10/20/2018:
 - Persons that have more than one email address will be required to merge their accounts to login to Grants.gov under a single email address. To merge your accounts, you need access to all the email addresses associated with the accounts. If you no longer have access to all the listed email accounts, contact the Grants.gov helpdesk
 - The process to reset lost/forgotten passwords will change. A temporary password will be sent to the email address associated with your account. Please make sure that your email address is up-to-date.
- If you know where to look, the NIH web site contains a lot of helpful information. Here are a few pages that you may find helpful:
 - Early Stage and Early Established Investigator Policies
 - Types of Grant Programs (most common ones – which one is right for you)
 - How to Apply – Application Guide
 - R01 Application Timeline (NIAID)
 - NIH Guide to Grants and Contracts (where to find funding announcements)
 - Clinical Research Toolbox (NCCIH)

FALL 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 has a five day before the sponsor deadline for all submission material; these deadlines are not concurrent.

Please contact us, 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.

In order to serve you better, The Office of Clinical Award Administration would like to get to know you better. To accomplish this, we've created a short Investigator Profile survey. If you have not already completed this survey, we invite you to do so [here](#).

With this information, we hope to learn about specific areas of interest so that we can be on the lookout for the perfect opportunity to kick start additional funded projects and collaborations. Once enough preliminary data is analyzed, training materials and workshops will be offered based on the findings.

To share information with all Clinical Researchers, a Yammer page titled, "[Office of Scientific Affairs–Clinical Award Administration](#)", has been established. To login to Yammer, you will need to use your @stonybrook.edu email address. Please let me know if you would like me to invite you to join the group.

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