NEWS AND NOTES

GRANT SUBMISSION OPTIONS
ASSIST and Workspace Go Mainstream

In a recent correspondence with NIH we learned the following statistics regarding proposal submissions:

- 14% still use Adobe Forms [aka 424 forms]
- 31% use the ASSIST portal [a requirement at SBU as of the next submission cycle]
- 54% use System to System solutions (which we will be able to once my RESEARCH for grants is active); and
- < 1% are using Workspace the Grants.gov form replacement.

In addition, "Adobe Forms" are being phased out by the end of 2017, the new NIH "E" forms will not be issued in that format. They will only be issued through ASSIST and Workspace. I recommend that you get used the new submission methods before you need to and either ASSIST or Workspace for your next proposal.

Note that ASSIST is only an option for NIH. For all other Federal submissions, except NSF for which you can still use Fastlane, you will need to use Workspace until "myRESEARCH" is online sometime in 2018.

To get access to Workspace you will need to contact your OSP Grants Administrator directly. Visit Whom To Contact for more details.

CLINICAL TRIALS SUBMITTED AS PARENT R01?
NHLBI and HCCIH Weigh In

Many of the institutes at NIH are releasing policies on the types of clinical trials that can be submitted to the R01 Parent Announcement, currently PA-16-160. The last two ICs to release guidance on this issue are The National Heart, Lung and Blood Institute (NHLBI) and The National Center for Complementary and Integrative Health (NCCIH).

In notice NOT-HL-17-519, NHLBI announced that it will no longer be accepting Phase II and beyond clinical trial applications submitted in response to the NIH Parent R01 Announcement. They will continue to accept early phase clinical trials applications, phase one, with a primary intent of exploring hypotheses related to biologic and pathobiologic mechanisms of health and/or disease submitted to the Parent R01. To submit a Phase II and above clinical trial to NHLBI it will need to be in response to either their FOA's or FAO's that they participant in that allow such clinical trials, an example of this is PAR-16-405. For additional information on NHLBI research support mechanisms for clinical trials click here.

Notice NOT-AT-17-006 issued by HCCIH, defined the types of clinical studies that may be submitted in response to the Parent R01, both current and reissuances. NCCIH recognizes a difference between clinical trials that are designed to answer specific questions about the clinical effect of interventions and mechanistic studies that have the primary goal of understanding how an intervention works. As of May 8, 2017 NCCIH will no longer accept any applications that propose clinical trials, that have an objective of determining the clinical safety, tolerability, feasibility, efficacy and / or effectiveness of pharmacologic, non-pharmacologic, behavioral, biologic, surgical, or device interventions in response to the Parent

Announcement. Although they will accept applications to the Parent that is defined as a mechanistic study, which is one that is designed to understand the mechanism of action of intervention, a biological process or pathophysiology of a disease. They will also continue to accept applications for observational studies such as secondary data analysis, survey studies, cohort studies or case-control studies through the Parent. A list of the FA's that you can apply to as a clinical trial can be found here.

If you are unsure where your proposed study falls, it is strongly recommended you consult with your program officer prior to submitting an application.

As more institutes release guidance on this subject, notices will be forwarded to specific department that are effected as well as included in future newsletters.

THE THREE TYPES OF RESEARCH PERFORMANCE PROGRESS REPORTS
Going Beyond Your Annual Report

Earlier this year, 2017, NIH released two additional classifications of Research Performance Progress Reports (RPPR), Final and Interim. The Final RPPR is similar to the annual report but standardizes the information that is required for close out reporting. The Interim RPPR is a new report that is now needed when a PI is submitting a renewal application. If the renewal proposal is not funded the interim report will serve as a final report; however, if the renewal proposal is funded it will serve as the annual report of the final year of the previous competitive segment. Previously, the submitted renewal application served as an interim report.

All three types of the RPPRs need to include the following: accomplishments, products, participants and other collaborating organizations, and the impact. Annual reports

also need to include any changes/problems experienced during the past project period as well as budgetary information. While the Final and Interim reports need to only include project outcomes.

All RPPR reports need to be completed via ERA Commons and submitted by the signing official assigned to your department in The Office of Sponsored Programs. It was recently brought to our attention that a PI cannot delegate authority for final reports, only the PI has access to them.

For additional information on the three varieties of RPPRs you can visit this link, or review NOT-OD-17-022 (Final) and NOT-OD-17-037 (Interim). As always if you have questions feel free to contact the Office of Clinical Award Administration at 84490 or andria.adler@stonybrook.edu.

ANNUAL STIPEND INCREASE FOR GRAD STUDENTS

NIH has released the Graduate Student stipend rate for FY 2017 in NOT-OD-17-04, which revised NOT-OD-17-072, at $23,844. Tuition and Institutional Allowance rates for fellowships remain unchanged. Students with Individual Fellowships that have already been issues should receive a revised NGA to reflect this change

NIH LAUNCHES NEXT GENERATION RESEARCHERS INITIATIVE

NIH has launched the Next Generation Researchers Initiative to bolster support for early-stage and mid-career investigators to address longstanding challenges faced by researchers trying to embark upon and sustain independent research careers. Details can be found on the new and constantly updated web site or on this blog post. In the comment section of the blog post the exclusion of New Investigators was brought up time and again. To show the differences between New and Early Stage Investigators we have included the NIH definitions:

New Investigator: A Program Director or Principle Investigator (PD/PI) is considered a New Investigator if he/she has not previously competed successfully as PD/PI for a substantial NIH research award. An investigator will retain their New Investigator status if he/she receives any of the smaller research grants, training, infrastructure, and career awards that appear on this list.

Early Stage Investigator: A PD/PI who qualifies as a New Investigator is considered an Early Stage Investigator (ESI) if he/she is within 10 years of completing his/her terminal research degree or is within 10 years of completing medical residency (or the equivalent).

The Office of Clinical Award Administration would like to get to know you better, so that we can serve you better. To accomplish this we created a short 12 question survey. If you have not already completed this survey, released this spring, we invite you to do so at: https://www.surveymonkey.com/r/SBMCLINICALRESEARCHERS32017.

The goal of this survey is to understand what clinical departments are currently working on and where they may need assistance. Hopefully we also learn about people's research 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 received and analyzed, training materials and workshops will be offered based on the findings.

As a means to share information within the SOM and with all Clinical Researchers a Yammer page, named Office of Scientific Affairs–Clinical Award Administration has been established, https://www.yammer.com/stonybrook.edu/#/threads/inGroup?type=in_group&feedId=10779779&view=all . To log on 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.