



Council of Principal Investigators

CPI Newsletter – May 2017

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Update from Dr. Penny Riggs, CPI Chair

Update from the May 3 CPI Executive Committee (CPI EC) meeting

The Workday Team met with CPI-EC to discuss plans for May's General CPI Meeting. Implementation of Workday will take place in December 2017. Training sessions will be available for researchers to attend in October, prior to the implementation period.

Dr. Glen Laine noted the progress at SRS and that improvements are ongoing. The new SRS website is live at <https://srs.tamu.edu>. Dr. Laine will be providing an update on the TTC changes moving forward at the May 10 general meeting. As always, PIs are encouraged to provide feedback regarding any items that should be addressed. Members of the CPI EC and guests praised Dr. Laine's success as VPR in fostering a collaborative research environment that promotes cooperation among PIs and administrators at all the CPI sponsor entities. In particular, CPI appreciates Dr. Laine's commitment to addressing PI concerns and suggested improvements to research infrastructure.

The CPI EC discussed the SRS-hosted demonstrations of the Electronic Research Administration Systems (ERA). The three ERA system demos that are underway have been identified as potential replacements for MAESTRO.

Interviews of Provost candidates were completed last week. The Provost Search Committee will meet with President Young soon, and information will be distributed to CPI as updates become available.

CPI News

The Spring Principal Investigator Representatives election and run-off elections have been completed. The vice chair nomination and election process will begin this week. New council membership details will be provided in the June newsletter.

Contact Rebecca Luckey, rluckey@tamu.edu or 979.862.9166 for more information.

The next general CPI meeting will be held June 14, 2017. I encourage CPI members to communicate with their constituents, and bring forward items of concern or interest for the research community. Thanks for your input over the past month. The CPI will continue to communicate with administrators regarding topics and issues of importance for the research community. Please continue to bring research-related issues (and solutions) to my attention at CPI@tamu.edu, or contact me directly at riggs@tamu.edu or 979.862.7015.

VPR Task Force on ERA Systems Demos Update – Dr. Ulisses Braga-Neto

The VPR Task Force met on March 27, 2017 to discuss:

How to ensure that the PI/admin/staff community can actively provide input on the process of selecting the new Electronic Research Administration (ERA) system. Vendor presentations are open to participation by the entire university community. PIs are strongly encouraged to participate in the selection process.

Since the last general CPI meeting, the schedule for the ERA system vendor visits was set:

Wednesday, May 3, 2017 – Huron (held this past week)

Tuesday, May 16, 2017 - Kuali

Tuesday, May 30, 2017 - Streamlyne

All the PI community is invited to attend and participate. As CPI's Representative for the VPR Task Force, I attended the May 3, 2017 meeting for the Huron demo and will attend the two future demos, so if you have questions or concerns, please contact me directly at ulisses@ece.tamu.edu.

You are invited to attend a demonstration of Kuali on Tuesday, May 16 beginning at **10:15 a.m.** for the demonstration being held at the National Center for Therapeutics Manufacturing (NCTM). You may park with a campus "C" or business "B" permit anywhere in lots 101 or 123.

If you have not already done so, please RSVP through the Survey Monkey link below by COB Friday, May 12th. A head count is needed so that lunch can be provided.

<https://www.surveymonkey.com/r/V3Z3KKQ>

NSF CAREER Mock Review Panel

NSF Workshop, Mock Review Panel and Workshop

When: May 22, 2017 8:00am – 4:00pm

Where: Rudder Tower 401

Contact: Jim Izat, Sr. Research Development Officer, jizat@tamu.edu

Deadline for registration is May 12!

This all day session co-sponsored by TEES and the Division of Research will feature a mock review panel participation experience for Jr. faculty. The program will include a keynote speaker, who will provide an overview of the NSF CAREER solicitation. There will also be a presentation by CAREER awardees, and several concurrent mock review panels in breakout rooms for participants, with a debriefing on the process to conclude the day. The keynote speaker is an NSF rotator now on faculty at Texas A&M. See <http://teesresearch.tamu.edu/events/> for more information and registration.

Write Winning Grant Proposals – NIH and NSF

Seminar, Writing Program

When: Seminar on September 21-22, 2017 (tentative)
Proposal Writing Program to run Fall 2017 through Spring 2018.

Where: Seminar Venue TBD

Contacts: Shannon Prescott, Senior Administrative Coordinator, sprescott@tamu.edu
Jorja Kimball, Executive Director, jkimball@tamu.edu

Expanded to include NSF proposals, the Division of Research will host a 1-1/2 day seminar for researchers interested in submitting grant proposals to the NIH and NSF on September 21-22, 2017. As in the past years, Dr. John Robertson of Grant Writers' Seminars and Workshops (GWSW), will again speak on NIH proposal development and add information related to NSF to the seminar in an additional half day.

The seminar will be comprised of three units: (1) Sep 21 morning: CORE – Principles, Funding Priorities, and Preparation of the Overview/Executive Summary; (2) Sep 21 afternoon: NIH; (3) Sep 22 morning: NSF.

The Division will also expand the semester-long 2018 Grant Proposal Writing Program (with GWSW) to include both NIH and NSF. A maximum of 30 candidates will be accepted to the program.

NIH Implementing Limits on Grant Support

Over the past several years, NIH has been addressing an imbalance in research funding across the career spectrum. They have made progress in reversing the decline in grants to early-career investigators, but that has been offset by a decline in the percentage of awards to mid-career investigators, and currently 10% of NIH-funded investigators receive over 40% of NIH funding. Additionally, analysis indicates that research output gradually diminishes as individual grant support increases.

To address this, the [NIH Director has announced](#) that NIH will implement a limit to the number of grants on which an individual may be PI. Guided by the Grant Support Index (GSI, previously identified as the [Research Commitment Index](#)), applications from investigators with a GSI over 21 (equivalent to 3 single-PI R01 grants) will require a plan on how to adjust the investigators existing grant load. This new initiative also is discussed in an [Open Mike Blog](#) from the Deputy Director for Extramural Research. Implementation of this cap has not been formalized. NIH will be seeking feedback from the scientific community on how best to implement the GSI limit over the next few months.

Scientific Rigor and Transparency in NIH Grant Applications: Rigor and Relevant Biological Variables in the Approach Section

NIH introduced new instructions and review requirements in January 2016 regarding scientific rigor and transparency for research grant proposals ([NOT-OD-16-011](#)) and mentored career development award applications ([NOT-OD-16-012](#)). With these changes, applicants of research grant proposals are to address Scientific Premise in the application's Significance section, Scientific Rigor and Relevant Biological Variables in the Approach section, and Authentication of Key Biological and/or Chemical Resources in a new application attachment. Applicants, presumably, have incorporated rigor and transparency in their research in the past. Now, however, it is necessary that applicants specifically address these topics in their applications and it is to their benefit to make it easy for the reviewers to identify these sections. The last bulletin addressed Scientific Premise. This month, we visit Rigor and Relevant Biological Variables.

“Scientific Rigor is the strict application of the scientific method to ensure robust and unbiased experimental design, methodology, analysis, interpretation, and reporting of results and applies to the proposed research.” Per the guidance to reviewers, “[t]he applicant should describe experimental controls, plans to reduce bias (blinding, randomization, subject inclusions and exclusion criteria, etc.), power analyses, and statistical methods, as appropriate.” If vertebrate animals are to be used, the number of animals to be used no longer needs to be justified in the Vertebrate Animals Section (but still include the total numbers of animals proposed). Instead, justification of the number of animals is a consideration of rigor and should be addressed in the Research Strategy, Approach.

Complete guidance on how reviewers are to assess scientific premise, scientific rigor, consideration of biological variables, and the plan for resource authentication can be found in [“Reviewer Guidance on Rigor and Transparency: Research Project Grant and Mentored Career Development Applications”](#). This should provide excellent guidance to applicants on what reviewers are looking for and, therefore, what to provide in the application.

For additional guidance to applicants on this topic, as well as examples of Rigor in successful applications, see NIH's web page on [Rigor and Reproducibility](#).

NSF Requiring Template for Identifying Collaborators, Other Affiliations

On April 24, 2017, the National Science Foundation (NSF) initiated a new pilot requiring the use of a spreadsheet template for identifying Collaborators and Other Affiliations information for Principal Investigators (PIs), co-PIs, and other senior project personnel identified on proposals. *This new pilot will only be for FastLane proposal submissions*. Grants.gov proposal submissions will continue to follow the instructions in NSF Grants.gov Application Guide Chapter VI.2.4.

The [NSF Proposal and Award Policies & Procedures Guide \(PAPPG\) \(NSF 17-1\)](#) requires PIs, co-PIs, and other senior project personnel identified on NSF proposals to individually upload Collaborators and Other Affiliations information as a Single Copy Document (see PAPPG Chapter II.C.1.e).

NSF uses this information during the merit review process to help manage reviewer selection. To expedite identification of potential reviewers, having a standard, searchable format for this information is essential. The new pilot will standardize Collaborators and Other Affiliations information across the Foundation and will ensure

that the information is submitted in a searchable format. Results from the pilot will be assessed and will determine how to proceed with this section of the proposal in the future.

The NSF will require the submission of a spreadsheet template to identify collaborators and other affiliations. Please note that the spreadsheet template:

- Has been developed to be fillable. However, the content and format requirements must not be altered by submitters.
- Must be saved in .xlsx or .xls formats and directly uploaded into FastLane as a Collaborators and Other Affiliations Single Copy Document.
- Will be converted by FastLane from an .xlsx or .xls file to a PDF file.
- Has been tested in Microsoft Excel, Google Sheets, and LibreOffice.
- Will enable preservation of searchable text that otherwise would be lost. Must be uploaded in .xlsx or .xls formats only. Uploading a Collaborators and Other Affiliations Single Copy Document in any other format may delay the timely processing and review of your proposal.
- Will be directly linked in FastLane.

The template and associated instructions may also be accessed directly at:
<https://www.nsf.gov/bfa/dias/policy/coa.jsp>. FastLane User Support at 1-800-673-6188.

Sign Up for Notifications about Limited Submission Proposal Opportunities

The list of current Limited Submission Proposal (LSP) opportunities, maintained by the Division of Research, is available at <https://u.tamu.edu/LSP>.

To receive notifications about new LSP opportunities as soon as they are announced, email Ms. Shelly Martin at shelly.martin@tamu.edu.

Bulletin for Principal Investigators

The Division of Research at Texas A&M University issues a brief weekly bulletin for Principal Investigators that highlights research accomplishments and projects, funding opportunities, honors and promotions, workshops, and other items that may be of interest to the PI community. [Click here](#) to subscribe or unsubscribe to the bulletin.

April 12, 2017 CPI General Meeting

Research Compliance and Biosafety Questions Response

AWO/IACUC

- Q. At the beginning of the year, the Animal Welfare Office started sending AUP information to project sponsors. In our most recent case, an AUP update was sent to a DOD, resulting in the DOD (different entity within DOD) deciding they needed to have their own AUP.**

This needs to stop. Every agency has its own IACUC, and they all want to do their job. But as a PI, it is redundant, and a waste of my time, to create an AUP for each separate entity along the funding chain. Particularly when everyone was okay with having a single AUP when the work was initiated. We need to get an AUP reciprocity agreement in place between all the involve parties before TAMU Animal Welfare or SRS sends this information. It is the same material, seen by similar groups, doing similar AUP reviews in 2 different geographic locations, for the exact same reason. While I am certain that each IACUC feels this is a great expenditure of their time, it doubles the time and effort required on the part of researchers.

- A.** The DOD ACURO office performed a site visit in July 2016 and audited all DOD-funded Animal Use Protocols (AUPs). Prior to the audit, it was the responsibility of the PI to send all documents to the ACURO office. During the audit, the site visitors found incidences of noncompliance where changes to TAMU IACUC AUPs were made but the ACURO office was not informed and did not approve the changes. DOD-funded projects are required to secure ACURO approval before animal work can begin or changes to animal projects can occur. This ACURO approval is not the same thing as TAMU IACUC approval. It is intended to ensure compliance with ACURO policies and procedures Following the audit, ACURO required that the Animal Welfare Office take a more proactive role and change their processes to ensure that ACURO was informed of all protocol submission approvals (including personnel changes and other amendments), and issued their approval before animal activities began. The current process for DOD-funded protocols involves a two-step review/approval process. The TAMU IACUC approves the AUP or amendment and then sends it to ACURO for their review and approval in accordance with their policies and procedures. The PI does not need to submit any documentation to ACURO as that is now all handled via the Animal Welfare Office. ACURO does not require a separate AUP. Once ACURO sends the approval letter to the Animal Welfare Office, the Animal Welfare Office will issue the final approval letter to the PI and animal activities can begin.

- Q. What can be done to create an AUP reciprocity agreement between TAMU and sponsor agencies? Seems logical to me, and should be applicable to institutions meeting/requiring the same standards.**

- A.** The institution where the animals are held or used has the responsibility for approving and maintaining oversight of the AUP. Reciprocity agreements are in place between institutions when animal work is conducted at one institution and grants are awarded to another institution.

Some sponsor agencies, such as the DOD, do have oversight bodies that provide a secondary level of review of an AUP prior to the release of funds or the approval of animal activities. An agency-specific review is a review intended to assess compliance with the agency's policies and procedures.

Biosafety

- Q. For Biosafety, it would be preferable to have consistency regarding training and regulations. For example, BSL2 and BBP renewal training is annual. Or it's every 3 years. We are asked to do Training in CITI. Or in TrainTraQ. Personnel who use equipment in another PI's lab are required to be named on that PI's IBC permit. Or not. Seems like something changes every year making it difficult to know what is required for compliance and what are just randomly imposed requirements.**

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- A. Biosafety training requirements are set by the Institutional Biosafety Committee (IBC). Current IBC training requirements are as follows:

BSL-2 training: All personnel working in BSL-2 labs, including Principal Investigators, must complete BSL-2 training. Initial BSL-2 training should be completed in a classroom, instructor led setting. BSL-2 training sessions are provided by Office of Biosafety staff members weekly, often more than once a week, on different days of the week, and at different times of day to accommodate schedules. Once completed, BSL-2 training is valid for five (5) years. Refresher training is completed on-line (via TrainTraq for employees) and via CITI (for visitors or volunteers).

Bloodborne Pathogen Awareness (BBP) training: Initial BBP training should be completed in a classroom, instructor led setting. BBP training sessions are provided by Office of Biosafety staff members weekly, often more than once a week, on different days of the week, and at different times of day to accommodate schedules. Once completed, BBP training is valid for one year. (Please note: Annual BBP training for personnel at occupational risk of exposure to Bloodborne pathogens is a State of Texas requirement, not an IBC requirement.) Refresher BBP training is completed on-line (via TrainTraq for employees) and via CITI (for visitors or volunteers).

NIH Guidelines/University Rule/DURC training: required of all IBC permitted Principal Investigators. This training is on-line, available in TrainTraq. This training must be completed once and refreshed only if significant updates or revisions to the training become necessary.

- Q. Undergraduate research is a priority but it is difficult for undergrads to get all necessary training done quickly enough to be working in the lab. Would it be possible to have single day(s) early in each semester when students could get BSL, Bloodborne pathogens, and other in-person training all at the same time so they can get started in their chosen laboratories more quickly?**
- A. Yes. Actually, such training sessions are already being conducted each semester around campus, in addition to the weekly training schedule. Please contact the Office of Biosafety at biosafety@tamu.edu or 979.458.3525 to request a date and time for trainings to be provided to your group of students.

IRB/HRPP

- Q. The library would like an update on expedited review of minimal risk research involving humans. I had a number of library colleagues who are interested in learning more about any changes planned on the review process.**
- A. Currently, investigators are not required to categorize the level of IRB review. All that is needed is for investigators to clearly describe the research procedures and the HRPP will apply the least restrictive category permissible for the level of review.
- Anticipated updates to the Common Rule are expected to impact the expedited review process. As soon as guidance is released from OHRP on the revised Common Rule, this information will be shared with the investigators.
- Q. Studies in authentic classroom situations that run as the business-as-usual must be exempt and shouldn't require to collect consent. Asking students and parents to sign on a consent severely hurts the ecological validity of the study due to a large number of students not turning in the consent hence not qualified for data analysis. This is actually an extremely serious issue in particular in running a large-scale dissemination study. I was indeed running an exempt study in a previous institution that no longer is available here at A&M—as a consequence I needed to disqualify more than 70% of students in some school hence didn't meet the necessary number of samples.**
- A. Any time an investigator is requesting access to student records (for students under 18 years of age), written parental consent is required. The need for parental consent when students are under the age of 18 is determined by the Common Rule, FERPA and the Protection of Pupil Rights Amendment (PPRA).

PPRA states that any type of survey, analysis or evaluation that concerns one or more of the following areas requires notification to parents and students in accordance with the schools written procedures:

- political affiliations or beliefs of the student or the student’s parent;
- mental or psychological problems of the student or the student’s family;
- sex behavior or attitudes;
- illegal, anti-social, self-incriminating, or demeaning behavior;
- critical appraisals of other individuals with whom respondents have close family relationships;
- legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
- religious practices, affiliations, or beliefs of the student or student’s parent; or
- income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

Each school or school district may have different written procedures.

Q. Can you address any changes in human subjects research approval that are anticipated?

A. Changes to the Common Rule are expected to become effective soon. These changes will likely impact the manner in which human research is reviewed and approved at TAMU. The HRPP will keep investigators informed of changes as guidance is published by OHRP.

Currently, projects are carefully evaluated to determine whether or not they meet the FDA’s or OHRP’s definition of human subjects; if the project does not meet the applicable regulatory definition a “Not-Human Subjects Determination” is being made.

The manner in which human subjects applications funded or supported by a federal grant are processed via SRS and Maestro is being updated in coordination with SRS. As information becomes available, it will be shared with investigators.

iRIS

Q. First, I want to say that the staff on the IRB team have been consistently supportive, helpful and courteous. The process can get frustrating, so their style of interaction helps a great deal. The biggest hurdle for me and my doctoral students continues to be the iRIS website. If design improvements are not possible, perhaps a detailed manual can be developed to help us understand the language, sequences of steps, and expectations so we can navigate the site with less anxiety and frustration.

A. We are very close to moving to the next version of the software. There are a few changes in the layout and structure of the site, but the basic pieces are the same. We will provide updated assistance via help handouts and videos to assist in navigating the site. We are not able to put screenshots of the software on our website, per the vendor contract. However, we can send information via email or within iRIS.

Any iRIS-related technical questions can be submitted via email to outreachrcb@tamu.edu or via phone to 979-845-4969 during normal business hours.

General

Q. Are there common errors or suggestions for PIs to streamline the processes for IACUC, IRB, Biosafety approvals?

A. The compliance staff is available to help address any issues the research community may have with the submission process and is always open to suggestions on enhancing processes.

We recommend that investigators contact the staff directly before submitting an application. This reduces the likelihood of common submission errors and helps investigators have a better understanding of what to expect in the review and approval process.

The review of an AUP is conducted by several compliance units concurrently (EHS, BOHP, Biosafety, IRB, CRRC). The AUP can only be approved after all the other compliance units have signed off. If there are compliance issues to be addressed, it will slow down the approval of the AUP. The best way to streamline an AUP approval is to ensure that the IBC permit and EHS permits (if applicable) are up to date and congruent with the AUP, all training requirements of all AUP participants have been completed, and that all AUP participants are enrolled in the Biosafety Occupational Health Program (BOHP).

For Biosafety permits, ensuring appropriate training has been completed as well as any BOHP requirements will be helpful in processing and reviewing the permit.

For IRB applications, clearly describing the procedures that involve human subjects will assist in making the appropriate determination for review. In the near future, the IRB form in iRIS will allow an option to request a human subjects determination before filling out the entire application.

Q. What is best way for PIs to help communicate with compliance divisions, and help streamline or improve processes?

A. We are committed to providing high quality services to the research community and are always open to suggestions on enhancing processes and procedures to be more efficient and effective. We are also committed to maintaining compliance in a manner that does not unduly burden researchers.

The directors of the Biosafety Office, the Animal Welfare Office and the Human Research Protection Program would be happy to hear your ideas and suggestions. Feel free to reach out to them directly. Below is their contact information. In addition, the Associate Vice President for Research and Research Compliance Officer is also available to provide assistance.

Dr. Tennille Lamon: tennillek@tamu.edu

Dr. Christine McFarland: ctmcfarland@tamu.edu

Ms. Aliese Seawright: a.seawright@tamu.edu

Ms. Katherine Rojo del Busto: krdb@tamu.edu

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