April 12, 2017 CPI General Meeting

Research Compliance and Biosafety Questions Submitted

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.

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.

<u>iRIS</u>

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

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