

## Report on Research Compliance Volume 15, Number 7. July 31, 2018 UT Southwestern Shares Strategies To Reduce Animal Research 'Burdens'

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By Theresa Defino

Whether they are termed regulatory, administrative, or self-imposed, institutions struggle with the “burdens” or tasks required of them as part of the strings that come attached to federally supported research. Arguably, nowhere is this greater than when the research involves animals.

NIH, the U.S. Department of Agriculture (USDA) and the Food and Drug Administration are currently “conducting a review of applicable regulations and policies for the care and use of laboratory animals and will make revisions, as appropriate, to reduce administrative burden on investigators while maintaining the integrity and credibility of research findings and protection of research animal.” The review is required under the 21st Century Cures Act (RRC 2/18, p. 3).

But there’s no need to wait. Regardless of their source, close scrutiny of burdens with an eye to “risk mitigation strategies and process improvement” can serve to decrease or eliminate them. That’s the word from Stacy Pritt, director of the animal care and use committee (IACUC) at the University of Texas Southwestern Medical Center (UTSW). Pritts is also a faculty associate in psychiatry and UTSW’s interim chair of its Conflict of Interest Committee.

### Inefficient Systems May Add Burdens

Pritts addressed the topic at the recent research compliance conference in Austin, Texas, sponsored by the Health Care Compliance Association, which owns and publishes RRC.

Institutions, she said, can “make a difference” especially when it comes to “self-imposed regulatory burden.” Two factors may lead to unnecessary burdens: institutions may purposefully “go beyond the regulations,” but they also may fall victim to “inefficient administrative systems” at institutions.

“People don’t understand that inefficient administrative systems are one of the leading causes of administrative or self-imposed regulatory burden,” she said. Regulatory requirements stem primarily from the USDA, which has oversight of species that fall under the Animal Welfare Act. Institutions with funding from NIH and other Public Health Services (PHS) agencies for animal research also must comply with regulations enforced by the Office of Laboratory Animal Welfare (OLAW).

OLAW’s policies are based on the PHS Policy on Humane Care and Use of Laboratory Animals and the *Guide to the Care and Use of Laboratory Animals*, which was updated in 2011. While OLAW doesn’t often issue formal guidance, officials publish columns in journal called *Lab Animal* that Pritt said “become de facto policy.” She also noted that OLAW publishes FAQs.

Animal research funded by the National Science Foundation also falls under OLAW’s purview. USDA issues regulations, guidance documents, “and now they have tech notes,” Pritt said. She added that other agencies, including the Department of Veterans Affairs, the Department of Defense and NASA also have separate regulations for animal research.

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The regulations and policies differ and may conflict, leading to another “source of regulatory burden,” Pritt said.

At the heart of UTSW’s oversight of animal research are risk mitigation strategies that may be new to many IACUCs, but the concept is an approach already in use by institutional review boards (IRBs), Pritt explained. “Unlike IRBs, IACUCs don’t have to do a risk determination on individual protocols, so that’s not how the regulations are set up. Our [animal research] policies or guidances--they’re not risk based.”

In the five years since Pritt joined UTSW, the academic medical center has taken the following steps to reduce administrative burdens in the oversight of animal research:

- ◆ Eliminated a formal, written letter notifying principal investigators (PIs) of approval by the IACUC. Previously this letter was signed and sent through the campus mail system. At UTSW, PIs were receiving the letter and an email; now, just the email suffices.
  - ◆ Eliminated annual protocol reports except if the research is funded by the DoD or related to USDA covered species. Previously, the IACUC annually reviewed each animal research protocol. However, this is not required for animal research supported by PHS funding. At the time of implementation, 600 UTSW protocols “did not need annual reports, so none of these were actually subject to this type of annual review or report.” UTSW had “overstepped.” It now completes 60 or fewer of such reports each year.
  - ◆ Introduced a new post-approval monitoring (PAM) program based on a risk assessment of each study. The “complexity” of a study will determine the type/frequency of PAM that is necessary. Additional factors are whether a study involves a “USDA-covered species” or has experienced “ongoing compliance concerns.” For example, research that involves satellite housing—“where the PI is taking care of animals outside of their own facility”—is subject to one or two yearly PAMs and the usual semi-annual inspections. Animal use locations are inspected once a year, while “facilities” where the animals live have to be inspected twice a year.
- When Pritt came to UTSW, all of the approximately 300 PIs conducting animal research were undergoing PAM “twice a year in addition to the semi-annual inspections.” UTSW also selects a different individual to conduct a PAM versus an inspection to alleviate “confusion” about the purpose of the oversight activity.
- ◆ Began an “observational” PAM program “where research procedures are directly observed by trained IACUC staff and veterinarians. “To help gather appropriate risk-based information about all protocols regardless of funding or species, we created a voluntary, unanticipated outcome reporting process,” which allows veterinarians, veterinary technicians, etc., to alert the PI to “voluntarily report” an unanticipated outcome using a type of form generated by the research electronic data capture (REDCap) system. “Researchers also take advantage of this system on their own and report unanticipated events without any prompting.” Currently, UTSW is receiving one or two such reports per month. An unanticipated outcome might be if genetically modified mice “developed a physical attribute that was not anticipated at the time of the genetic manipulation and therefore not described on the protocol.”
  - ◆ Switched its computer “protocol” system to enable easier submission of protocol amendments or changes.
  - ◆ Created functionality for the reporting of personnel changes and for funding changes on an amendment process that is separate from the process of submitting protocol amendments involving procedures.
  - ◆ Eliminated mandatory referral to the full IACUC of studies that fall into the USDA Category E—research that causes “unalleviated pain or distress [as] pain categories do not represent true risk to animal welfare.” Protocols that go to the full committee include those that are “complex” and that “need evaluation for impact to animal welfare and regulatory risk.”

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