



**NCURATV 2008 Satellite Broadcast Workshop Series**  
**Complex Agreements**  
*Case Study*  
**June 10, 2008**  
**11:30 am – 3:30 pm EDT**

**Case Study Part 1**

Midsized State University (MSU) plans to submit a large center proposal to the Department of Homeland Security (DHS) for the establishment of a multidisciplinary Center for Serious Naturally Occurring Toxins. The Center will provide research and education for handling both accidental and deliberate exposures to naturally occurring and weaponized environmental toxins.

MSU will be the lead institution for the consortium that includes three other academic institutions, Enormous State University (ESU), Prestigious Private University (PPU) and Tiny State University (TSU), along with a private industry partner, Weapons-R-U's.

MSU's principal investigator (PI) has been talking to her colleagues and they have developed a good idea of which institutions will provide specific types of expertise.

The institutions and investigators are excited and think the proposal has an excellent chance of success, especially in view of groundbreaking research done by collaborators at MSU and PPU on naturally occurring freshwater algae toxins. TSU has been asked to participate in the consortium in view of its Department of Defense-funded Center for Animal Toxins at the TSU College of Veterinary Medicine. Similarly, ESU has been asked to join the consortium because of its nationally-recognized Department of Toxicology at the ESU Medical Center. Finally, Weapons-R-U's has been asked to join the consortium because of its experience in manufacturing detection kits for biologic and nuclear hazards for the Departments of Energy and Defense.

You are the director of the Office of Sponsored Programs at MSU and learn of the proposed collaboration 30 days before the proposal is due.

**Case Study Part 2**

While working with your research administrator peers at TSU, PPU and ESU, you receive a letter from the Legal Department at Weapons-R-U's, requesting that MSU and the other academic institutions execute the company's standard teaming agreement before the proposal is further developed and submitted. The agreement contains numerous provisos, including a broad confidential disclosure and proprietary information provision, requirements for full indemnification as well as damages and attorneys fees for Weapons-R-U's for breach of contract provisions, as well as an exclusivity provision that requires the academic institutions to solely partner with Weapons-R-U's for the current DHS proposal.

While pondering the request from Weapons-R-U's, you also learn that all of the collaborators have background technology and know-how that they plan to bring to the consortium. In addition, you discover PPU recently patented and licensed a technology developed by one of its faculty investigators on the proposal, which is integral to the consortium's research efforts. You further learn that PPU licensed the technology to the inventor's start-up company, IM Tenured, Inc.

### **Case Study Part 3**

You successfully manage the above-mentioned challenges, the proposal is submitted, and the MSU Center for Serious Naturally Occurring Toxins is funded. Congratulations!

Shortly thereafter, you receive a draft subaward from TSU for collaborative animal research involving MSU and TSU researchers, as well as researchers from Weapons-R-U's. During negotiations for the subaward, you learn that animals will be transferred for testing between TSU and MSU facilities and scientists from Weapons-R-U's will be participating in these research activities at MSU and at TSU.

You further learn that Weapons-R-U's does not have an animal care and use program or an animal handler occupational health program; however, the company's legal counsel insists that the subaward include full indemnification and hold-harmless provision for Weapons-R-U's's role in the animal research.

While handling the animal use issues, you also receive a proposed subaward for clinical research at the ESU Medical Center. The research will include toxicity studies on healthy volunteers as well as patients who are being treated for exposure to the toxin. ESU plans to further subcontract some of the toxicology studies to the nongovernmental organization, Médecins Sans Chéquier (Doctors without Checkbooks), which runs the hospital at ESU's new offshore campus in the developing country of Nöwaristan.

You learn that Nöwaristan has a high incidence of poisoning from the naturally occurring toxin in the general population. As part of the clinical studies, personally identifiable healthcare information from subjects will be exchanged between the PI and investigators at MSU, PPU, ESU, and Nöwaristan. You also receive a request from ESU and Doctors without Checkbooks to have the project guarantee treatment costs for the clinical trial subjects at the hospitals.

### **Case Study Part 4**

After handling the animal care and human subject issues, you learn from your PI that IM Tenured has already received a Small Business Innovation Research (SBIR) award from the Defense Advanced Research Projects Agency (DARPA) to develop new sensors using project technology provided by PPU. DARPA considers the PPU technology to be controlled under the International Traffic in Arms Regulations (ITAR). To complicate matters, while your PI is a US citizen, all of the graduate students who will be using the PPU technology are foreign nationals.

While pondering these issues, you receive a call from the MSU General Counsel's office, which has received a complaint from the federal Department of Transportation. Apparently, MSU sent samples of the freshwater algae toxin to the co-investigators at ESU and Nöwaristan without providing a Shippers Declaration of Dangerous Goods and without placing the toxin in a certified protective package. You next learn from the MSU biosafety officer that the material sent to ESU and Nöwaristan is quite toxic and included on the United States Department of Agriculture Animal and Plant Health Inspection Service's (APHIS) Select Agent and Toxins List.

### **Case Study Part 5**

Finally, you receive a proposed PPU subaward for basic science research on toxicology sensors. PPU plans to further subaward monies to IM Tenured, Inc. Under the terms of the award, IM Tenured's faculty inventor will participate in the research both as a PPU co-investigator, as well as an IM Tenured research scientist.

While reviewing the proposed subaward, you note that the project scope and deliverables for both the PPU and IM Tenured subawards seem nearly identical. You also recall from the preliminary collaboration discussions that IM Tenured is receiving DARPA SBIR funding for similar activities.