Unique Legal and Practical Issues in International Contracting

The Sequel (Part 2)

By Janet Simons and David Brady

In the second part of this two-part series, the authors continue their survey of legal and practical issues related to internationally-funded sponsored agreements.

More U.S. Laws of General Applicability and their Implementing Regulations

Foreign Corrupt Practices Act (FCPA). United States (U.S.) institutions of higher learning are growing their collaborations with foreign educational institutions, businesses, and governments. International campuses, collaborative research centers, and other joint ventures are springing up globally. To the extent that an institution engages in payments or gifts of value (e.g., lavish entertainment) to a government official, member of a foreign political party, or an 'instrumentality" of government to facilitate a service or business opportunity, one must be mindful of compliance with the FCPA.

The FCPA's anti-bribery provisions make it unlawful for a U.S. person to bribe a foreign official with money or anything of value for the purpose of obtaining or retaining business. Institutions collaborating internationally must take particular care in light of the U.S. Department of Justice's (DOJ) broad interpretation of who qualifies as a "foreign official", which can extend to commercial or academic officials (Mohraz et al., 2014). This is particularly relevant today, as many foreign colleges and universities may meet the criteria of being an instrumentality, as they are under government control, and perform a function that the government "treats as its own".

For further guidance regarding compliance with the FCPA, one can refer to the DOJ's recent resource guide to the FCPA (DOJ, 2012).

Human Subjects and Animal Care Regulations. Pharmaceutical companies sponsor clinical trials that include sites from around the world. This and other instances of international human research require awareness of applicable regulations on human research participant protection, ethics committee review, privacy regulations, training, shipping of biological specimens, documentation and record retention, indemnity insurance, and clinical trial registry requirements. Animal research similarly involves a set of regulations including ethics reviews, training, shipping of biological specimens, and stringent requirements for animal welfare, care and use. We recommend that you work closely with your institution's ethics review committee or office to ensure that the applicable regulations are understood and can be satisfied. The U.S. Department of Health and Human Services (DHHS) maintains an International Compilation of Human Research Standards (DHHS, 2014). The Association for Assessment and Accreditation of Laboratory Animal Care International offers on their website http://www.aaalac.org/resources/internationalregs.cfm a page of international regulations and resources.

Dual Use Research of Concern. Finally, there is an emerging field of biological research that is being restricted, not by statute, but by recent policies issued by the DHHS and the National Institutes of Health (NIH) (DHHS, 2012, NIH 2013). The policies seek to control certain types of research on certain "tier 1" select biological agents, such as avian influenza. Once restrictions on publication are accepted, technical information generated in the research is likely to be subject to the EAR and licenses for release to foreign nationals and export outside of the U.S. would need to be obtained.

Financial Issues

A number of financial issues are unique to international agreements and require strategies different from those used with a local or domestic sponsor.

Overdue payments or non-payment by a sponsor is always a risk, but collection options related to an international sponsor may be non-existent. In addition to conducting a risk analysis of the sponsor organization, the best situation for the university is to have the sponsor make advance payments. However, many sponsors do not want to accept the risk of non-performance. To reduce the university's risk for cost-reimbursement agreements, a requirement for frequent (e.g. monthly) invoices and payments allow the university to stop work for breach if a payment is not received. When allowable, a milestone-based contract is also a good option, balancing the risk for both parties. The university can monitor payments for each milestone and again, stop or minimize project work if a payment is late or not made.

Currency issues can also increase the university's financial risk. For example, a Brazilian sponsor issues an award to a U.S. institution. The award is calculated in Brazilian reals. Will the institution accept the Brazilian currency? Is it permitted by policy and practice, and is it a good business decision? What are the ex-

change rate trends? Are there fees to be paid? This case-by-case analysis is needed, and agreement terms to mitigate risks may be appropriate, such as a clause to trigger renegotiation of the award amount, milestones, or project aims in the case of extreme fluctuations of currency. (Brady & O'Neill, 2008)

Expectations for financial documentation and record retention can vary from country to country. John Richey stated in his 1993 article that U.S. institutions can meet most international sponsor accounting requirements by complying with the U.S. government regulations. For the purpose of project accounting, the key is to understand the sponsor's expectations. Consider asking the sponsor to write out the requirements in the contract rather than reference a regulation that may need to be translated or interpreted. Similarly, if there is any doubt or confusion regarding disposition of equipment and other assets on termination or expiration of the agreement, the requirements should be clearly stated in the agreement terms.

Government mandates sometimes apply to both domestic and foreign grantees and contractors. For example, the U.S. Fly America Act (49 USC 40118) mandates the use whenever possible of U.S. flag air carriers for federally funded international travel regardless cost or convenience. Open Skies Agreements have eased this requirement somewhat. In some cases the Buy American Act (41 USC 8301-8305) may also apply, which mandates a preference for U.S. products when purchased with U.S. federal funds.

Finally, financial risk from "hidden" costs must be managed from the time the proposal is developed. In particular, when receiving funds as a subrecipient from an international collaborating partner, the travel budget may need to include visa and insurance costs. Other costs to consider are communications, shipping, and translation.

Legal and Other Issues

If your program involves international project work – a "footprint" in another country – a number of legal issues must be addressed that are beyond the scope of this article. In his recent NCURA Magazine article, Bill Ferreira just scratches the surface of this complex topic (Ferreira, 2014).

Signatures. As part of the agreement discussions, it is worth finding out about any nuances to the contract signature process. Will a blue pen signature in hard copy be required, or is electronic signature acceptable? Will the sponsor accept delegated signature authority, or require the head of institution to sign? Is every page of the agreement to be initialed (more typical in Europe than in the U.S.)?

Governing law and dispute resolution. Little has changed since 2008 when we visited the risks attendant to accepting governance by foreign laws, or being silent on governing law in an agreement. For private institutions, choice of law decisions should always be made in conjunction with choice of dispute resolution. For many state supported institutions, accepting foreign governance is usually not an option for sovereign immunity reasons, nor is arbitration or any other binding dispute resolution an option.

Governing language. Similarly, the 2008 article's advice on language stands. If versions of the agreement are created in two languages, a clause should be inserted in both agreements stating which version of the agreement will govern in case of doubt or conflict between them.

Immunity and consent to jurisdiction. Many academic institutions outside of the U.S. are part of their country's government, and as such may be entitled to sovereign immunity from enforcement or performance under a contract. Strategies for risk mitigation remain in structuring payment schedules requiring advance payment, and express waiver of immunity, granting jurisdiction of U.S. courts in certain circumstances.

Intellectual property. Since the 2008 article was written, there has been a sea change in U.S. patent law. In March, 2013, in accordance with the America Invents Act, the U.S. went from "first to invent" patent system to a "first to file" system. However, the law retains a "grace period" allowing public disclosure (e.g., publish an article) one year prior to filing without jeopardizing U.S. patent rights (Villasenor, 2013). With the grace period, U.S. law still differs from many other foreign laws which have no such relief. As such, publishing before filing can jeopardize foreign patents, and should be carefully considered prior to publishing with international sponsors or collaborators.

Duty of care. As more and more university faculty, employees, and students travel abroad for university educational and research activities, the question of who is responsible for their safety and security has come to the forefront as an issue of "duty of care" (Claus & Yost 2010). For example, when a researcher takes graduate students to a remote African national park to conduct National Science Foundation sponsored research, what are reasonable safety and security precautions that should be taken by the individuals, the university, and the national park? Often

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NCURA MILESTONES

James Casey has been elected to the post of President-elect of the Nonresident Lawyers Division (NRLD) of the State Bar of Wisconsin, effective July 1, 2014. The NRLD represents 6,800 Wisconsin-licensed lawyers, and the President-elect post is the first of a three-year commitment (President, Past President). As President-elect he is also on the Board of Governors, the main policymaking body of the entire organization, and is the Board liaison to the Communications Committee. James has been a member of the Wisconsin Bar since 1990.

Michele Codd has retired from George Washington University, where she was the Director of Research Quality Improvement. Michele's career included many years at Vanderbilt University, plus positions at Massachusetts Institute of Technology and Meharry Medical College. She also served as an NCURA travelling workshop faculty member and a peer reviewer. Michele recalls, "My career as a Research Administrator was thoroughly satisfying and allowed me to work with wonderful colleagues, both at the universities and through NCURA."

Nancy Daneau recently joined New York University as its Director of the Office of Sponsored Programs. With over 25 years of experience at both public and private institutions in both department and central administration positions, Nancy is excited to be at NYU and part of the team of administrators supporting the research enterprise. Nancy can be reached at Nancy.Daneau@nyu.edu

Rashonda Harris became the Administrative Director of the Center for Cellular and Molecular Therapeutics at The Children's Hospital of Philadelphia on September 2, 2014, supporting Dr. Beverly Davidson, the new Center director. The Center's mission is to use pioneering research in cell and gene therapy to develop novel therapeutic approaches for hitherto untreatable illnesses. Prior to joining CHOP, Rashonda served for eight years as the Associate Director of Research Accounting Services at Temple University.

Cindy Hope, Assistant Vice President for Research and Director, Office for Sponsored Programs at The University of Alabama has been elected chair of the Federal Demonstration Partnership (FDP) for the initial three years of Phase VI. Phase VI begins October 1, 2014 for a six year period and includes 155 institutions and 10 federal agencies working to reduce administrative burdens associated with research grants and contracts. Cindy is an active NCURA member and has served as past regional officer, traveling workshop faculty, national program committee member and FRA conference co-chair. She was recently recognized for her service as a 2014 awardee of the NCURA Julia Jacobsen Distinguished Service Award during the 56th Annual Meeting in August.

Leerin Shields is now the Manager, Grants and Contracts at the Translational Research Institute, Florida Hospital. Prior to her move, Leerin had been the Region II Chair and the Manager of Contracts and Grants at the University of Maryland, Baltimore.

Brian Squilla was appointed Vice President of Administration and Chief of Staff in the Office of the Provost at Thomas Jefferson University effective July 1, 2014.

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a contractual relationship needs to be established with a foreign state or regional authorities, or with a foreign collaborator, delegating some safety and security responsibilities for university personnel and property to those authorities physically able to perform such functions that the university cannot perform due to distance.

A number of universities have sought enterprise-wide solutions to the issue of duty of care, in some cases hiring third party firms to provide additional insurance options such as medevac.

Conclusions

Finally, a challenge of many international agreements lies in the conduct of negotiations. An internet search of "cross-cultural communication" or "international negotiations" will result in an abundance of advice. A few items for consideration include the method of communication (telephone, email, Skype), and practical issues such as scheduling calls over multiple time zones and translation of documents. Educate yourself regarding the sponsor organization, the funding program, and the cultural beliefs and values in that country.

It has been exciting and challenging to participate in the increasing globalization of research and, by extension, research administration. As our investigators learn to collaborate creatively, we too must balance our risks against the value of our international collaborations and continue to share our experiences and successes.

Janet Simons, MBA *is the Director, Research Policy and an Export Compliance Officer at the University of Maryland, Baltimore. She has over 30 years experience in both central and department research administration, and serves on NCURA's Global Community Subcommittee. She can be reached at* jsimons@umaryland.edu

David Brady *is the Director of the Office of Export and Secure Research Compliance at Virginia Polytechnic Institute and State University (Virginia Tech) and an Empowered Official of the university, with ten years' experience implementing export and sanctions compliance at a major research university. He is also formerly a senior contract negotiator at Virginia Tech, and can be reached at* dbrady@vt.edu