

Mindful Cross Training: Framing an Effective Approach in the Present to Assist Your Institution's Research Compliance Risks for the Future

HCCA Research Compliance Conference 2019

Ianthe Bryant-Gawthrop, Director RRA & HRPP, Purdue University

Ryan P. Fayhee, Partner, Hughes Hubbard & Reed LLP

Description Overview

- Learn how research regulations can be interconnected. Presenters will develop strategies with workshop participants to engage in interactive examples using export controls and collaboration risks in non-traditional settings as a model.
- The group will develop framework to spark their own research compliance cross-training ideas most appropriate for their institution. It is no longer practical to silo research compliance efforts.
- The constantly changing landscape of research compliance demands awareness in all topics to identify when subtle signs can lead to larger concerns. Teach staff to identify bigger picture concerns including how and when to ask for a subject matter expert.

Assessing Strengths and Recognizing Efforts at your Institution

- How much experience is in your row/table? How many in your department?
- What research is cutting edge or most predominant at your institution?
- Do you categorize your role as high stress? Why?
- Can you summarize the research of 20 investigators at your institution? 50?
- What can we do as research administrators to strengthen regulatory research matters even outside the laboratory or field?
- Where do you go for guidance or help?

What Has Experience Taught Us About the Interconnectedness of Regulations?

- Financial Conflict of Interest disclosures can be connected to recent foreign influence topics.
- Export control regulations/OFAC sanction concerns can appear in IRB protocols or clinical research.
- Animal care and use is undoubtedly connected to biosafety.
- Biosafety is connected to export controls/Dual Use Research of Concern (DURC).
- Data security requirements are of fundamental importance to export controls, human subjects protections, and protection of intellectual property (to name a few).
- Yet, we have multiple sets of regulations that do not contemplate crossover. The connection comes from experience.

What Do We Know About the Management of a Research Project?

- Financial considerations are often organized before administrative or regulatory efforts.
- Regulatory matters must be incorporated or at least considered during study design to move smoothly.
- Research topics might have other specialty concerns that directly or indirectly affect the conduct or the budget of a project (e.g. data protections, participant costs).
- One person (usually the PI) is the hub for folding information together or organizing a complex balance of all these factors.

If You Only Swim in Your Lane... Remember to Look Around You!

- Cross-referencing grants to other regulatory protocols is no longer explicitly required for all regulations, but can be a very useful tool to assess the big picture early.
- Share reference materials on a central source for easy browsing. (Example: Your IBC may be asked about an export controls question. Do they know where to go?)
- Host regular meetings between your risk assessment groups to identify where training or information can be transferred early.
- Hire former scientists or entry level scientists in a variety of disciplines.
- Keep some cross-representation on your regulatory boards in voting or ex-officio status.
- If the time comes to ask the tough questions, you must fine tune your fact finding and minimize the preparation and discovery timeline.

Provide Opportunities to Learn from Current Events and Prevent Losses

- Noncompliance costs money, public scrutiny, most importantly...trust!
 - Several universities recently made public decisions to discontinue engagement with specific companies, citing federal investigations regarding violations of sanction restrictions.¹
 - NIH and NSF are amongst some of the federal agencies requiring consideration of foreign influence and loss of intellectual property.²
- Let's use these recent examples to show how situational considerations evolve and require cross-training.

¹<https://www.cnn.com/2019/04/04/mit-terminates-funding-and-research-ties-with-chinas-huawei-and-zte.html>

²<https://www.sciencemag.org/news/2019/04/universities-will-soon-announce-action-against-scientists-who-broke-nih-rules-agency>

Non-Traditional Espionage

- Universities are increasingly targeted by foreign intelligence services due to their international staff and student bodies and their tradition as a place for the liberal exchange of ideas and information.
 - In a February 2018 Senate Intelligence Committee hearing, FBI Director Christopher Wray warned, "*The use of nontraditional collectors, especially in the academic setting — whether it's professors, scientists, students — we see in almost every field office that the FBI has around the country.*"
- Why are foreign intelligence services targeting universities?
 - Illegally obtain research and technology (technology transfers)
 - Monitor foreign students and professors at U.S. schools
 - Influence university students
 - Establish U.S. credentials for intelligence officers
 - Exploit lax student visas

Focus on University Technology Transfers

- 2019 National Defense Authorization Act
 - Prohibits the head of executive agencies from extending federal funding to institutions that use “covered telecommunications equipment or services”
 - Includes equipment and services from:
 - Huawei Technologies Company
 - ZTE Corp., Hytera Communications Corp.
 - Hangzhou Hikvision Digital Technology Company
 - Dahau Technology Company
 - and subsidiaries/affiliates of any of these companies.
 - Universities that do not comply with the NDAA by 2020 risk losing federal funding

Focus on University Technology Transfers (cont.)

- Export Control Reform Act of 2018
 - Requires the Dept. of Commerce, Bureau of Industry and Security (BIS) to identify and establish export controls for **emerging and foundational technologies** that are “essential to the national security of the United States.”
 - **Emerging and foundational technology** has not yet been defined by BIS and is currently in the rulemaking process. BIS is seeking public comments on determining criteria for defining and identifying emerging technologies.
 - Emerging and foundational technologies exclude **fundamental research**, which is defined in the EAR as “*research in science, engineering, or mathematics, the results of which ordinarily are published and shared broadly within the research community, and for which the researchers have not accepted restrictions for proprietary or national security reasons.*”

Focus on University Technology Transfers (cont.)

- DOJ's 2018 China Initiative
 - Announced development of "an enforcement strategy concerning non-traditional collectors (e.g., researchers in labs, *universities*, and the defense industrial base) that are being co-opted into transferring technology contrary to U.S. interests."
 - Intended to "[e]ducate colleges and universities about potential threats to academic freedom and open discourse from influence efforts on campus" (e.g., Confucius Institutes, sponsorship of university research).

Huawei – A Cautionary Tale

- Huawei participated in and sponsored research programs at dozens of universities, including UC San Diego, the University of Texas at Austin, the University of Maryland, and the University of Illinois.
- The U.S. government has focused on Huawei because of its goals to develop 5G technology, which it was developing in part with the help of U.S. research institutions.
- To comply with the NDAA, universities have to get rid of all telecom equipment made or developed with Huawei Technologies to avoid losing federal funding.
- The University of California at Berkeley has announced an immediate ban on new research with Huawei, a corporate donor that has provided \$9 million to the university in the last 8 years. Berkeley also had to physically remove Huawei video equipment from an off-campus research site.

Foreign Sponsored Research

- Risk
 - Foreign governments or government-controlled entities underwrite research activities at U.S. universities.
 - As part of the deal, the foreign government or entity may require specific visiting professors or student researchers who are actually intelligence agents be assigned to the project, or may require collaborations with foreign universities or labs to facilitate technology transfers.
- Mitigation
 - Thoroughly vet candidates for research sponsorships or collaborators.
 - Ensure thorough reporting and accounting of all forms of research support.
 - Implement Conflicts of Interest Policies, with input from professionals, that require disclosure of any support from foreign governments and foreign academic institutions.
 - Establish policies requiring independent staffing.
 - Ensure collaborations have an opt-out if they appear to be one-sided.

Research in “Emerging Technologies”

- Risk
 - Foreign intelligence target research in emerging fields to acquire technology before it is identified for export controls.
- Mitigation
 - As noted above, under the Export Control Reform Act, BIS is currently in the process of defining “emerging technology” and creating appropriate export controls.
 - Be aware of how research could ultimately be used; be wary of foreign interest in potential defense or cutting-edge tech fields (e.g., 5G).
 - University compliance officers should closely monitor emerging research and regularly consider whether re-classification may be necessary.

Foreign Travel

- Risk
 - Foreign governments or government-controlled entities encourage or sponsor U.S. academics involved in research to travel internationally to the foreign country.
 - When in the foreign country, devices brought by the U.S. academic may be copied and searched for any valuable research materials. This may occur without the U.S. academic even being aware (e.g., devices left behind in a hotel room).
- Mitigation
 - Educate professors, students and others involved in research on the risks of traveling abroad.
 - Establish travel protocols to avoid taking devices containing research abroad.
 - When possible, provide loaner devices for academics traveling abroad.

Foreign-Made Equipment

- Risk
 - Foreign intelligence agencies donate or otherwise make available computers, servers, cameras, and other equipment needed for research.
 - The equipment has been compromised to serve as spy assets.
- Mitigation
 - As mentioned above, the 2019 NDAA directs universities receiving federal funding to remove telecommunications equipment from leading Chinese manufactures (including Huawei and ZTE).
 - Beware especially of internet or wireless equipment, which may surreptitiously transmit to third-parties.

Deemed Exports

- Risk
 - Foreign national professors and/or students are given access to export-controlled technology as part of their research.
 - Whether intentional or unintentional, the release of controlled technology to a foreign national is “deemed” to be an export to that person’s place(s) of nationality.
- Mitigation
 - Be aware of what controls apply to your equipment and facilities. Know which nationalities would require an export license.
 - Regularly reevaluate the classifications; the classification lists are regularly updated and the license requirements may change.
 - Be especially careful with controlled data, which may require a restricted server to avoid inadvertent deemed exports (e.g., to foreign national IT staff helping to resolve a regular IT issue).

Lab Visits and Tours

- Risk
 - Foreign nationals are provided access to a lab or other research facility containing export-controlled equipment that allows them to recreate the lab or facility in their home countries.
 - Even the visual inspection of controlled-equipment could be considered a “release” of technology and a deemed export.
- Mitigation
 - Establish physical security (e.g., restricted access) for facilities containing controlled equipment or technology.
 - Do not allow photography or video conferencing (e.g., with foreign collaborators) in those facilities.

Start-Ups and Off-Campus Research

- Risk
 - Research that is ready for commercialization is moved to a start-up or incubator off-campus.
 - Because financial and staffing resources are thin, export compliance may be under resourced and the technology may be more vulnerable to transfers.
- Mitigation
 - Educate university staff on the application of export controls, emphasizing the personal responsibility they take when moving the technology off campus.
 - Consider establishing a compliance “starter kit” that could be provided to university-affiliated start-ups.

Bottom Line

- Education and awareness is key
- Be vigilant for unusual or suspicious activity
- Be cautious of deals that are too good to be true.

Train Staff to Spot a Subtle Sign and Assimilate New Considerations Into Process

- Teach staff to resist the urge to bury their heads in the sand!
- Train the staff to eliminate Imposter Syndrome or “I am just...” speech. What they notice might be the beginning of the solution.
- Communicate that the goal is NOT to over scrutinize activities, but instead to know the scope of what to expect and identify the strategies needed if something falls outside of that.
- Assign them the task to discover where they subject matter expertise within the organization.
- Look for more internal assistance and guidance. However, this does not need to mean more eyes or more staff.
- If you get the opportunity to engage with other institutions on their best practices, translate those opportunities to contextualize. Organizations should try to identify common ground rather than compete.

Reframe Challenging Situations: How do we Mindfully Frame Research Compliance?

- Accept the reality that challenges arise as everyday situations and that the goal isn't always absolute perfection.
- See the situation from multiple perspectives.
- Recognize the situation as it is and sort what you can/can't influence.
- Take the wide perspective. What is at stake for others, for you, for the team?
- Recognize the potential for growth. Is the growth a learning experience or an opportunity for change?

*Derived from The Mindful Day by Laurie J Cameron (2018)

Practical Methods to Apply Mindfulness to Compliance Activities.

- Encourage staff to e-mail and text mindfully:
 - Designated times for digital communication- avoid quick responses when quick solutions are not known.
 - Consider what bothers or worries you about responding or not responding.
 - Seeks to ease the problem rather than be "right".
- Find ways to add mindful listening to your training:
 - Staff should plan conversations at times where they can devote attentiveness without additional distraction
 - Encourage staff to have an understanding of the research itself, rather than just ways to regulate it.
- Remind compliance staff to keep an open mind:
 - Observe the tendency to make judgements before they present - approach with flexibility first.
 - Silence the tendency for cynicism (i.e. that will never work or that is a bad idea) and fear (i.e. there are negative consequences)

*Derived from The Mindful Day by Laurie J Cameron (2018)

When to Call in a Subject Matter Expert

- Know when you feel overwhelmed. Use your years of experience in the field to understand when something is bigger.
- You can no longer find documented procedures or designated departments anywhere in your institution to handle the scenario.
- You've assembled a group and can no longer see a clear path forward.

Apply These Principles to Common Compliance Scenarios: Miscellaneous Agreements

- Common “miscellaneous agreement” types:
 - Material/Data Transfer
 - Nondisclosure/Confidentiality Agreements
- How do we typically think about these agreements?
- What information might benefit both contract negotiations and compliance?
- If we routinely require this information up front, detection becomes easier
- Setting up this method mindfully to think about each area in advance allows you to have information in front of you when the time comes for signature.

Example: One- Stop Compliance and Negotiation Questions

Up-Front Example Questions to Facilitate Compliance and Contractual Needs			
Information about the recipient and provider	What is the purpose of the exchange?	How will you protect data?	What is the material being transferred? What is intended use?
Is either party OUS or establishing research OUS?	What is the relationship (if any) to funded projects?	Did you perform a Restricted Party Screen?	Does the use involve deliverables or the potential for funded work?
Is information confidential or proprietary? If yes, who will receive it?	Potential for military/space applications?	Is there a relationship to a potential conflict of interest and/or management plan?	Does it relate to humans, animals, rDNA/biohazardous material, radioactivity?

A Hypothetical, (Yet Realistic) Example!

- A researcher approaches you because they need your support to assist them with a new initiative. Their team will receive donated mini lapel cameras from a company. Their goal is to use the cameras in everyday situations to travel to different areas of the world and will ask volunteers to play the streaming videos.
- Categorize yourself based on your current job
 - Financial
 - Compliance/Regulatory
 - Other (Support, technical, other administration)
- Switch the role. See anything?
- Change your role to be the researcher. What changes?

Consider the Many Ways to Connect Research Administration Considerations

Financial	Regulatory	Other
Donation Parameters?	Human Subjects?	Confidentiality
Is a budget needed?	Any FCof?	Travel?
Funding source/work expectations	Any export controls considerations? What company?	Academic project?
		Material Transfer?

These are just a few. Yet all of them need to be considered before the project begins. If we don't see outside our area, we miss the opportunity to help this project succeed.

Take-Home Points

- Use real-world examples to train staff on multiple research administration considerations to allow establishment of a standard expectation.
- Thinking about your framework now trains new staff for future research administration challenges.
- New ideas and concepts emerge within law/regulation and technology, and business. Knowing where to embed them in your process keeps your team aware and efficient.

Thank you!
Any Questions?

Contact Information:
Ilanthe Bryant-Gawthrop
ibg@purdue.edu

Contact Information:
Ryan Fayhee
Ryan.Fayhee@hugheshubbard.com
Phone:
(202) 721-4691 (Office)
(571)-228-0304 (Cell)