Quarterly Compliance Report – Research

This report is for information only.

BACKGROUND

In November 2015, Elizabeth Cherry, Associate Vice Provost, Compliance and Risk Services, presented a report on the University’s new Structural Compliance Program. Over an 18-month cycle, the Board of Regents will receive a quarterly report from each of the six key institution-wide compliance areas:

- Research
- Health & Safety
- Financial
- Information
- Special Areas (e.g. global activities)
- Civil Rights/Employment

Attachments

1) University of Washington Research Compliance
2) UW Research Compliance Priority Item 1: Laboratory Safety
3) UW Research Compliance Priority Item 2: Post-approval Monitoring of Clinical Trials with Human Subjects
With a vision statement that asserts “Discovery is at the heart of our university,” research is undeniably central to the mission of the University of Washington. In fact, since 1979 the UW has received more federal research funding annually than any other U.S. public institution of higher education. In FY 2015 alone, the UW’s colleges and schools secured $1.3B in total sponsored grants and contracts, led by Medicine, Public Health, Engineering, Environment, Arts & Sciences, and Health Sciences Administration. Currently, nearly 4,000 research projects are under way at the UW, linking Seattle, Tacoma, and Bothell to Greenland, Kenya, China, and other locations around the world.

These numbers are broadly indicative of the post-World War II expansion of the American educational enterprise, research in particular. Federal support for research by the National Institutes of Health, for example, increased from $1B to $30B over the last half century; National Science Foundation grants grew from $465M to $7B in the same period. As a recent report by the National Academy of Sciences states, “[R]esearch institutions . . . have been the principal source of a world-class labor force that has made fundamental discoveries that enhance our lives and the lives of others around the world . . . The result of this unique government-academic research partnership is a system of education, mentorship and discovery that is renowned internationally.”

As the importance of the modern research university has grown, so too has the volume of rules and laws attached to federal support. Hundreds of regulations – many with complex data-collection, reporting, and auditing requirements – govern nearly every aspect of research, from scholarly integrity to grants and contracts management. The goals for such regulations are broad: protect government, universities, investigators, and the public; prevent fraud, waste and abuse; minimize risk; and, ultimately, ensure appropriate stewardship of billions in federal tax dollars.

World-class research is accompanied by inherent risks that must be identified, understood, and proactively addressed. Failure to do so can result in fines, loss of eligibility for federal funding, diminution of the University’s reputation, serious injury or fatality, and loss of the public’s trust. Mitigation of risk and compliance with regulations is thus no small task. Indeed, a growing consensus holds that regulatory compliance has become unduly burdensome over the last decade. The U.S. Senate, Lumina Foundation, Association of American Universities, Council on Governmental Relations, American Academy of Arts and Sciences, and even the White House, have all published studies and reports on this pressing concern. Speaking at a recent National Academy of Sciences meeting, the University of Washington’s Vice Provost for Research, Mary Lidstrom, cited excessive regulation as “wasteful, expensive and [a] poor use of taxpayer’s money.” Principal investigators (PIs) responding to the Federal Demonstration Partnership’s Faculty Workload Survey in 2012 estimated that 42% of their research time is devoted to meeting the requirements attached to federally-funded projects.
Regardless of burden or cost, the University must ensure compliance with applicable laws, regulations, standards, and federal agency guidance. Research compliance management requires detailed and current subject matter expertise in the applicable regulations, a basic understanding of the science underlying the research being conducted, and considerable administrative acumen in a higher education environment. Research compliance is a technically- and organizationally-complex task, one which the University of Washington Office of Research does well.

The newly-created UW Structural Compliance Program facilitates and supports this work by providing a unifying governance framework for the University’s diverse compliance obligations and subject matter experts. It employs seven elements to assess and strengthen the effectiveness and maturity of the University’s compliance functions: 1) leadership and oversight, 2) standards of conduct, policies and procedures, 3) education and outreach, 4) monitoring and auditing, 5) receiving reports and investigating, 6) accountability, incentives and corrective action, and 7) response and prevention. The program brings the subject matter experts together to participate in ongoing assessments that emphasize continuous improvement.

Assessment

In December 2015, Research compliance assessment meetings brought together subject matter experts representing research compliance topic areas from across the University: human subjects, animal subjects, export controls, facilities, scholarly integrity, conflict of interest, hazardous materials, radiation safety, infectious disease/biosafety/select agent, and intellectual property. Through those meetings, two research compliance priority items were identified for focused attention over the next 18 months: Laboratory Safety and Post-Approval Monitoring of Clinical Trials with Human Subjects.

The Research compliance assessment was led by:
David Anderson | Executive Director, Health Sciences Administration
Elizabeth Cherry | Associate Vice Provost, Compliance and Risk Services
Joe Giffels | Associate Vice Provost for Research Administration and Integrity, Office of Research | Institutional Official

Subject matter experts:
Philip Campbell | Radiation Safety Officer, Environmental Health & Safety
Damon Fetter | Director, Facilities Maintenance & Construction, Facilities Services
Katia Harb | Assistant Director, Research & Occupational Safety, Environmental Health & Safety
John Kelly | Compliance Analyst, Building and Fire Safety, Environmental Health & Safety
Karen Moe | Director and Assistant Vice Provost for Research, Human Subjects Division
Mark Murray | Assistant Director, Building & Fire Safety, Environmental Health & Safety
Melissa Petersen | Assistant Vice Provost for Research Compliance, Office of Research
Carol Rhodes | Acting Co-Director, Office of Sponsored Programs
Sally Thompson-Iritani | Director, Office of Animal Welfare
Jude Van Buren | Director, Environmental Health & Safety, Health Sciences Administration
Fiona Wills | Director, Technology Licensing, Center for Commercialization
Summary of Priority Items

Priority Item 1: Laboratory Safety
Of the 880 research and teaching labs occupying 3,600 rooms in over 50 campus buildings, surveys conducted by UW Environmental Health & Safety (EH&S) found that a significant percentage fall short of University goals for laboratory safety. Major risk areas include: 1) insufficient safety training; 2) incomplete lab-specific standard operating procedure (SOP), especially around chemical management; and, 3) inconsistent use of appropriate personal protective equipment (PPE) in the laboratory.

To address these risks, EH&S will perform evaluations and provide targeted technical safety monitoring for the 90 academic research labs on the Seattle campus that pose the highest risk for potential accident and injury. Evaluations will include identification of root causes and barriers to maintaining safe lab practices (via lab hazard analysis, chemical inventory review, and assessment of lab safety equipment).

Priority Item 2: Post-approval Monitoring of Clinical Trials with Human Subjects
Compared with other types of research that employ human subjects, clinical trials – of drugs, devices, behavioral interventions, diagnostic or treatment modalities – involve the highest level of risk to participants and the highest level of responsibility for the institution performing those trials. Currently, there are no explicit federal requirements that mandate the active monitoring of clinical trials once they begin.

The UW Human Subjects Division is developing a more robust post-approval monitoring program targeted at clinical trials with the greatest risk factors. The process will ensure that clinical trials are proceeding according to protocols established in the planning, review and approval phases of trial development, with the goal of protecting human subjects and the integrity of the institution’s research endeavors.

Citations
Challenge Statement
Of the 880 research and teaching labs occupying 3,600 rooms in over 50 campus buildings, surveys by UW Environmental Health & Safety (EH&S) found that a significant percentage fall short of University goals for laboratory safety. Major risk areas include: 1) insufficient safety training; 2) incomplete lab-specific standard operating procedure (SOP), especially around chemical management; and, 3) inconsistent use of appropriate personal protective equipment (PPE) in the laboratory.

Context
The American Chemical Society, National Academy of Sciences, and National Research Council acknowledge that inadequate safety in academic labs is a consistent and substantial issue across the country. They have concluded that the two major reasons for preventable accidents in college and university laboratories are the absence of a strong institutional safety culture, and a failure by principal investigators (PI) to assume appropriate responsibility for safety in their labs.

Accidents involving chemicals are far more common than those related to biological and radioactive agents, in part because there is no federally-mandated institutional oversight and approval process, or clear standards, for use of chemicals in labs. The use of chemicals is ubiquitous across the University’s research program, thus increasing the likelihood of accidents and/or injury. The risk to researchers, students, staff and the institution is elevated when safety protocols are not established, understood or observed.

Mitigation Plan
Environmental Health & Safety will perform evaluations of and provide targeted technical safety monitoring for the 90 academic research labs on the Seattle campus that pose the highest risk for potential accident and injury. Evaluations will include identification of root causes and barriers to maintaining safe lab practices (via lab hazard analysis, chemical inventory review, and evaluation of safety equipment). Lab-specific standard operating procedure will be designed and implemented. To monitor progress, baseline laboratory surveys will be conducted in July 2016 and repeated every eight months, for the 24-month life of the project. Lessons learned will be used by EH&S to enhance the support provided to all labs across the institution.

Focus groups of PIs, lab managers, researchers and department personnel, including department chairs, will be convened to increase communication and create best-practices sharing opportunities (list servs, invited speakers, workshops) among safety representatives, and to promote the engagement of leadership in promoting a thriving culture of lab safety at the University of Washington.

Project Leads: Mark Murray, Jude Van Buren and David Anderson
Sample of Relevant Laws and Regulations

- Hazardous Chemicals in Laboratories (WAC 296-828)
- Hazardous Drug Rule (WAC 296-62-500)
- International Fire Code (RCW 19.27, WAC 51-54A)
- Chemical Waste Management (WAC 173-303)
- Chemical Facility Anti-Terrorism Standards: Department of Homeland Security (6 CFR 27)

Additional Reading

https://www.acs.org/content/dam/acsorg/about/governance/committees/chemicalsafety/academic-safety-culture-report-final-v2.pdf

Learning from UCLA: http://cen.acs.org/articles/87/i31/Learning-UCLA.html
Challenge Statement
Compared with other types of research that employ human subjects, clinical trials – of drugs, devices, behavioral interventions, diagnostic or treatment modalities – involve the highest level of risk to participants and the highest level of responsibility for the institution performing those trials. Currently, there are no explicit federal requirements that mandate the active monitoring of clinical trials once they begin. Despite the absence of a federal standard, it is the institution’s duty to do everything possible to ensure the safety of human subjects and the integrity of the University of Washington’s research endeavors.

Context
There are currently more than 500 active clinical trials in Seattle and 30 countries, conducted by nine different colleges and schools. Approximately 40% are funded by industry. All are heavily regulated by the federal government. Non-compliance with laws and regulations can result in fines of up to $10,000 per day; withholding of pending or awarded funds; the University’s inability to bill Medicare/Medicaid for the costs of delivering healthcare associated with clinical trials; or the refusal of the Food and Drug Administration to approve a new drug, device, or diagnostic developed by a UW researcher. Worse yet, adverse reactions to a drug or device, serious illness or mental health issues and even death can result from clinical trials that deviate from an approved research plan.

Mitigation of risks related to clinical trials relies on the University of Washington’s comprehensive compliance system for human subjects, which includes Institutional Review Boards (IRB) – federally-mandated University committees responsible for reviewing and approving proposed and ongoing research involving humans. Other compliance system elements include contract terms negotiated with external sponsors of clinical trials – to clarify roles and enhance participant care – and internal safety committees to review and approve procedures, and the use of biological, chemical or radioactive agents in the research lab.

While research plans are carefully reviewed and require approval by the UW Human Subjects Division (HSD), a unit of the Office of Research, the implementation of those plans is infrequently monitored. Fewer than 6% of clinical trials are visited by HSD annually to assess conformity with the IRB-approved clinical trial protocols. Although there is no federal or state regulatory requirement for conducting post-approval monitoring, the practice is one element of a mature and effective compliance program and is recognized as a best practice in keeping research subjects safe.

Mitigation Plan
The UW Human Subjects Division is developing a more robust post-approval monitoring program that will review significantly more clinical trials, especially those with the greatest risk factors, including trials that are: 1) early in the drug/device development process, 2) conducted on vulnerable subjects (e.g. children, elderly, or prison populations), 3) led by inexperienced PIs, and 4) researcher initiated rather
than industry initiated. The goal of such monitoring is to ensure that clinical trials are proceeding according to protocols established in the planning, review and approval phases of trial development, and to assist researchers in meeting that goal.

Under the more robust program, monitoring will be conducted early in the research study, when education and corrective actions have the most beneficial impact and help researchers stay on track with the IRB-approved research plan. The long-term goal is to provide an appropriate level of monitoring for all high-risk projects within their first year. Monitoring will be tailored to address the varied needs and specific risks of different types of clinical trials. Program operations will be conducted through an educational perspective, rather than a punitive one. HSD will create and deploy a range of structural support tools and systems to help PIs and other research staff ensure compliance and enhance participant safety.

Clinical Trials – Research Process and Compliance Elements

Project Leads: Karen Moe and Joe Giffels

Sample of Relevant Laws and Regulations

- “Common Rule” (protection of human subjects): Department of Health & Human Services (45 CFR 46)
- Protection of human subjects: Food and Drug Administration (21 CFR 50); Department of Defense (32 CFR 219); Environmental Protection Agency (40 CFR 26); Department of Justice (28 CFR 46)
- Investigational new drugs: Food and Drug Administration (21 CFR 219)
- Investigational devices: Food and Drug Administration (21 CFR 812)
- Compliance with health data privacy and security regulations: Health Insurance Portability and Accountability Act (45 CFR 164)
- Genomic Data Sharing Policy: National Institutes of Health
- Policy for Data and Safety Monitoring: National Institutes of Health

Additional Reading