Title: Research Compliance: It's Everyone's Responsibility!

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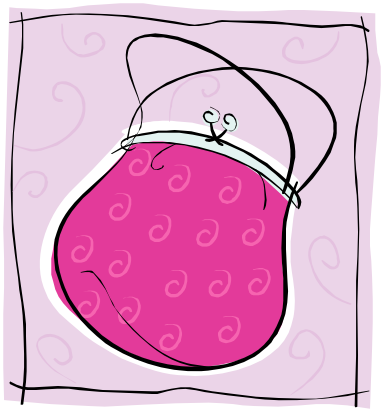
Abstract

Research Compliance is an institution's ability to adhere to regulations established by the federal government. The integrity of an institution's research program lies in the Principal Investigator, the Research Assistant, the Administrators, and the Authorized Official who signs the grant applications. Once an application is funded, among those items that the Institution's Office of Research Administration team members confirm are the appropriate human subject or animal regulatory approvals, adherence to the Bayh-Dole Act by researchers and key personnel, preparation of the Subawards & Consultants Agreements, and any necessary oversight by the institution's Office of Technology Transfer and Bio-Safety Departments. In addition, the Office of Research Administration must ensure that each transaction that posts to the grant is an allowable expense and that all close out documents are submitted on time. Administrators should view the rules of every sponsoring agency as an uncompromising law when adhering to research compliance. Once a grant has ended, there are rules for an institution to follow to ensure the retention of the file is in compliance with the federal government.

What is Research Compliance?



He who holds the purse strings rules the world!
In this case, the purse belongs to funding agencies and the strings represent regulations and general terms and

conditions. To accept a grant from any funding source also means accepting the strings that come attached. Those strings generally cover many areas, such as administrative requirements, reporting timelines and allowable costs. The federal government has produced volumes of books outlining the requirements that accompany funding, while smaller foundations may simply have a set of funding philosophies and guidelines that vary among agencies. Regardless of the platform used to disseminate funding requirements, terms and conditions come with all grants.

As grant administration has grown, so has the need for effective grant management. In response to that growth, and to mitigate risk, institutions have established the Office of Research Administration (ORA) to assist researchers, and those who support them, with the myriad of regulations that are attached to most dollars. In 1988, the Office of Management and Budget (OMB) gave agencies expanded authorities to institute significant administrative oversight, including the power to waive certain prior approval requirements. Ensuring research compliance by understanding this authority and adhering to regulations has become one of the functions of the ORA.

In simplest terms, research compliance is an organization's ability to adhere to regulations. As such, it starts long before an award is funded, before a Principal Investigator (PI) presents his application for review and even before the idea for a specific project is conceived. Research compliance starts with the integrity of the ORA and its ability to effectively interpret and apply regulations. Compliance must be viewed as a team approach in order for an institution to successfully meet the challenges associated with grants management. No one person or group is expected to know all regulations. However, a team of people can become familiar with sections of the regulations, which will lead to greater compliance. A successful team consists of the ORA pre- and post-award staff, Principal Investigators, the departments of Office of Technology Transfer (OTT), Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB), Institutional Biosafety Committee (IBC), as well as the grants management staff associated with the funding agency.

ORAs must serve as a conduit between the PI and the funding agency by accurately interpreting and diligently monitoring projects for compliance. One way to model compliance is by providing a manual to guide PI's and administrators through the lifecycle of a grant. This manual will acquaint researchers and administrators with institutional polices and procedures, inform them of the various services available to them, and serve as a reference for information and assistance.

To effectively manage grants, ORAs must have clear processes for handling standard grants issues such as the A-133 Audit, and Effort Reporting long before the first grant is awarded. Without such processes, the institution loses its ability to mitigate risk. Other standard policies include cost sharing between departments and with funding agencies; policies on cash donations, in-kind contributions and program income; institutional award transfers; and cost transfers.

It is only after framework has been established, that individuals can hope to compete successfully for and effectively manage grant awards.

Principal Investigator Responsibilities

While the PI's goal is scientific advancement through research, that research can only happen within the confines of grant conditions. The PI must ask him- or herself several questions before it can be determined that it is appropriate to seek funding for a particular research project.

For example:

1. Does the project fall within the goals and vision of the institution?
2. Have all necessary protocols been applied for/granted?
3. Can the PI, through effort reporting, stipulate to the fact that she has the time to participate on the project?
4. Are there any conflicts of interest that should be noted?

Only after these types of questions can be answered affirmatively should the PI begin to prepare an application. It is incumbent on the PI to ensure compliance with institutional policies; otherwise, he leaves himself vulnerable without the backing of the institution. Most often, the PI must work closely with departmental administrators to guarantee regulatory compliance.

Pre-Award Compliance Responsibilities

Once an application has been prepared by a PI, but before it can be submitted to a funding agency, pre-award administrators must ensure several things. Let's take a look at three common compliance issues.

First, is the applicant eligible to apply for funding through the institution? Most institutions have policies dictating who can apply for, and who can officially accept, funds. Without such a policy, institutions would be unable to monitor the flow of funds or the integrity of the recipient. If the applicant is unable to apply for funds, is there a work-around established, perhaps a mentoring relationship or another funding mechanism through which the applicant can apply? Pre-Award Administrators must work with the PI to ensure that applications are being submitted through the appropriate vehicle, such as Grants.gov, National Science Foundation (NSF) – Fastlane or by U.S. mail.

Second, pre-award administrators must monitor administrative issues such as indirect cost rates, salary caps and compliance to internal policies.
Every regulation established by funding agencies must have a counter response in the ORA. Otherwise, institutions can quickly find themselves out of compliance.

Third, pre-award administrators must be able to determine if the project, as conceived, complies with standard regulatory requirements such as conflict of interest, drug-free work place, debarment and suspension, certification regarding lobbying and certification regarding nondiscrimination. If the answer is no to any one of these questions, there should be an established response that ensures compliance. While every contention cannot be addressed beforehand, it is very important to have established policies that provide a basis for handling the unique situation.

Post-Award Compliance Responsibilities

Once an application has been awarded, an entirely different set of regulations must be followed to safeguard federal dollars. Post-award administrators must begin by formally agreeing to the terms and conditions accompanying each award. This is most often done when institutions access the awarded funds. Administrators must be certain they are using the established payment systems, such as Payment Management System (PMS), or the Automated Standard Application for Payments (ASAP). Post-award administrators must know the difference between various payment methods (advance payment, reimbursement or working capital) and what is authorized in their terms and conditions to ensure compliance with their funding agency. The inability to adhere to established conditions could ultimately be discovered in site visits or the required A-133 audit, resulting in a variety of sanctions such as loss of future funding or disallowed cost.

Throughout the life of the grant, post-award administrators must monitor the grant to ensure expenditures are allowable, allocable and reasonable, as defined by their funding agency. Such oversight may call for budget revisions, or decisions made through expanded authority.

Additionally, post-award administrators must ensure the reporting of program and fiscal performance. They must be familiar with the requirements listing the frequency of reports. For example, reports cannot be required more than quarterly or less than annually. Administrators are required to know what forms to use and how to submit them. For example, which standard form would be most appropriate for requesting an advance or reimbursement of funds: SF-269, SF-270, SF-271, or SF-272?

Once an award has ended, it is the duty of the post-award administrator to familiarize him- or herself with various funding agencies' file retention requirements. This information should be listed within the file on an "alert sheet" so that anyone reviewing the documents has easy access to the procedures. Depending on the sponsor, a minimum of three years is the requirement for an institution to retain grant documentation; however, on rare occasions, some sponsors require a file retention period of more than five years. In this case, a retention fee can be billed to the sponsor and after the time has expired, the file is then prepared for professional shredding.

Office of Technology Transfer Compliance Responsibilities

The principle "two are better than one," was designed to encourage the act of teamwork where two individuals add their knowledge and experience together in the pursuit of a positive result. In research administration, the collaboration between two institutions allows investigators to combine their expertise and inventions together to further scientific research. Within these collaborations, various agreements and contracts were formed to release and share an institution's discovered material, data, and reagents with one another.

The transfer of reagents or the exchange of research results must go through an institution's Office of Technology Transfer (OTT). The OTT uses results in basic and

clinical research to provide marketable products. When administering these items, OTT confirms the successful completion of required forms and procedures before the release of any material. A few examples of these forms and procedures are the IDP (Invention Disclosure Procedure), MTA (Material Transfer Agreement), and CDA (Confidential Disclosure Agreement).

The protection of an investigator's research results is the duty of the OTT and following policies that ensure the material has the appropriate copyright or patent before sharing is essential to research compliance.

Institutional Animal Care and Use Committee Compliance Responsibilities

The United States Department of Agriculture (USDA) requires institutions that conduct animal research to establish at least one committee to assess animal care, treatment, and practices. The National Institutes of Health (NIH) and the Office of Laboratory Animal Welfare (OLAW) require institutions to establish and maintain proper measures to ensure the appropriate care and use for all animals involved in research. This regulation is part of the Public Health Service (PHS) policy.

When reviewing protocols for a proposal, the IACUC staff must adhere to standard procedures to ensure institutional compliance. It is imperative for the department to focus specifically on the care and use of the animals and not judge the scientific merit of the proposals; be able to apply the necessary regulatory requirements; inspect facilities; and suspend non-compliant activities.

Another way that the IACUC can remain in compliance is by providing protection for animals through the reporting all non-compliant activities to any federal agency funding the reported grant to the OLAW, PHS and the Animal and Plant Health Inspection Service. Although animals are considered a secondary species, their protection throughout research is just as important as the protection of human subjects.

Institutional Review Board Compliance Responsibility

Maintaining the privacy of data involving research with human subjects is just one role of the Institutional Review Board (IRB). If a PI's proposal presents definite plans for the involvement of human subjects, the PI must comply with her institution's IRB procedures.

In addition to understanding IRB regulatory requirements, the PI and research administrators would do well to familiarize themselves with the laws of the Health Insurance Portability and Accountability Act (HIPAA), the Department of Health and Human Services (DHHS), and the Food & Drug Administration (FDA) so that human subjects protection is achieved.

A way for institutions to assist researchers, administrators, and other personnel with remaining in compliance when dealing with patient information, is to provide annual training and testing that will guarantee that policies and regulations regarding human subjects research are followed.

Institutional Biosafety Committee Compliance Responsibility

Research involving recombinant DNA (rDNA), infectious agents (pathogens), biological toxins, or select agents must be filtered through a qualified committee before an award begins to ensure that the work is in compliance with appropriate guidelines, regulations, and employee safety. Under the NIH Guidelines, each institution that conducts research involving rDNA must establish an Institutional Biosafety Committee (IBC).

The role of the IBC is important, because individuals' lives are at stake. By adhering to the Occupational Safety and Health Agency (OSHA) Blood-borne Pathogens Standard (29 CFR 1910.1030), the IBC must: 1) ensure that employees whose work requires them to come into contact with human blood or other potentially infectious materially are adequately protected against exposure; work with IACUC to ensure that animal experiments with bio-hazardous agents are conducted in a manner that is approved by the federal regulations; And Interact with the institution's health services department to ensure that PIs conducting research involving any hazardous agents receive immunization against the agent being studied.

Individuals who wish to engage in must have appropriate training and certification in place in three Biosafety levels before accessing material. Some examples of materials on those levels are rDNA; infectious agents; human blood, body fluids, and unfixed tissue; organs, or cell cultures of human origin; human gene transfer; sheep (which can carry a virus that causes Q-fever); and biological toxins (the use of toxins and hazardous chemicals may require additional permission from an institution's Biosafety or Environmental Health Officer).

The key to maintaining compliance and safety for the researchers, patients, and the IBC staff is to advocate training along with effective laboratory inspections that will confirm the work is done properly.

Conclusion

While complying with so many regulations may seem daunting, funding agencies want institutions to succeed. Classes are available to new administrators, including certification programs such as the one administered by SRA International and Management Concepts. Federal regulations can be accessed on line through specific agency websites, and grant management staff should always be considered as a resource to discuss particular situations. Funding agencies strive to support successful grant projects. More than merely hold the purse, they want to make sure the strings are as sturdy as possible.