

Research Compliance Professional's Handbook, Third Edition

12 Grant Management

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Introduction

What does it mean to be compliant in grants management? It means an institution is fulfilling its sponsor-required obligations as part of accepting a sponsor's funds to conduct research or perform an activity. Institution-wide solutions to ensure grant management compliance may include all areas from grant personnel to institutional support functions (such as payroll services) to upper leadership (such as conflict of interest committees). A successful compliance program requires careful documentation and cohesiveness of policies, practices, procedures, and controls, as well as a strong sense of who is responsible for various activities and role delineation.

To understand which laws, rules, and regulations apply to any sponsored study, we must understand the nature of the various funding mechanisms. Grants from government entities are considered public assistance. The funding agency does not direct the science and expects very little in return for the funds—primarily financial and technical reports, as well as disclosure of patents and listing any publication resulting from the sponsored study. The goal of a study funded by a grant is not to provide a specific outcome, but to increase knowledge. Contracts are mechanisms under which the funding entity acquires specific goods, services, and/or technology. Unlike grants and cooperative agreements, and in addition to other laws, rules, and regulations, federal contracts are subject to Federal Acquisition Regulations (FARs), which are addressed in the chapter covering contracts. When a contract is issued, the funding agency is very much involved in developing the research plan, scope of work, and/or protocol as well as management/oversight of the institution's performance. The contract sets specific deliverables and schedules. Federal cooperative agreements are a hybrid of grants and contracts. With these cooperative agreements, the government has a more hands-on approach than with grants, but without the same level of control under a contract. These agreements do set specific deliverables, but the recipient has greater control in how to meet the objectives. Further, these mechanisms are considered public assistance, rather than acquisitions, and are not subject to the FARs. The primary goal of a cooperative agreement is to increase knowledge, but with a higher expectation for a specific outcome than what is expected under a grant. For the purposes of this chapter, the term "grant" will include cooperative agreements.

The vast majority of federal funding provided by grants is issued by the National Institutes of Health (NIH) under the U.S. Department of Health and Human Services (HHS). Therefore, NIH has played a significant role in establishing rules governing studies funded with federal dollars. The NIH is referenced frequently throughout this chapter.

Because consequences for non-compliance associated with non-governmental funding do not typically include penalties mandated by state or federal law, this chapter focuses on grants issued by governmental bodies, primarily federal. This is not to undermine the importance of complying with the rules, guidelines, and policies of our generous non-governmental partners. Many non-governmental sponsors require funding recipients to comply with all NIH requirements; therefore, the requirements discussed in this chapter may be applicable to awards made by state, local, commercial, and nonprofit entities. Even though there might not be legal penalties for non-compliance with the terms of these awards, institutions may have other consequences that are almost as

serious (i.e., destroying your relationship with the sponsors).

Grant awards are made to institutions, not individuals. All recipients of government grant funds must comply with all applicable federal laws, regulations, rules, guidelines, and policies. In addition, grantees must comply with all terms and conditions stated in the NIH Notice of Award (NOA), which may include both standard and special conditions. With NIH awards, pay particular attention to Section IV of the NOA which contains any special terms and conditions. Further, the activities, regardless of funding source, must comply with state and local laws and regulations applicable to the institution, individuals working on the study, and the activity itself. Rarely is an institution required to sign an NOA; however, it is still a legally binding document. In particular, drawing funds from the HHS Payment Management System means that grantees agree to the terms and conditions of the grant award, thereby establishing the legal rights and obligations of the parties.

OMB Circulars, Uniform Guidance, and the Code of Federal Regulations

Historically, the laws, rules, and regulations governing federal funding provided under grants were codified in OMB Circulars. These documents, issued by the federal Office of Management and Budget (OMB), provide the rules applicable to all federal funding agencies each time they distribute public assistance (i.e., issue grants). The funding agencies in turn flow these requirements to all grant recipients. In an effort to streamline funding requirements and make terms consistent among many federal agencies, the requirements in OMB Circulars are now consolidated into a single set of requirements within the Code of Federal Regulations (C.F.R.), namely, 2 C.F.R. Part 200. This set of regulations is referred to as the Uniform Guidance and became effective December 26, 2014. Unlike the OMB Circulars, the CFRs are directly enforceable against institutions and individuals.

According to the Government Publishing Office (GPO) website, which houses federal documents, “The Code of Federal Regulations (C.F.R.) annual edition is the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government. It is divided into 50 titles that represent broad areas subject to federal regulation.”^[2] The Uniform Guidance, cited as 2 C.F.R. Part 200, means that the information is in Title 2, Part 200.

The Uniform Guidance is applicable to all grants awarded after the effective date of the Uniform Guidance, as well as those preexisting awards that have since been amended to add incremental funding. In the rare event an institution has an award issued prior to the effective date (which has not been amended to state that the Uniform Guidance will govern), the OMB Circulars still apply. For the vast majority of awards now in effect, the Uniform Guidance is the roadmap grant recipients use to ensure successful stewardship of their federal funds. Under particular grants, some federal agencies may have more specific rules and/or exceptions, but the Uniform Guidance contains the basic guidelines for any and all federal funding under grants, as well as some rules for federal contracts.

Don’t forget that the funding announcement and notice of award often contain requirements applicable after receiving an award. For instance, the Uniform Guidance and Federal Acquisition Regulations (FARs) both govern federal funding through contracts. Recipients of funding provided under cooperative agreements should follow both the Uniform Guidance and any other regulations and policies issued by the funding entity. For instance, cooperative agreements with the U.S. Department of Defense (DoD) are also governed by the DoD Grant and Agreement Regulations (DoDGARs), codified in Title 32 of the CFR.

Note that the federal government provides separate rules for specific types of entities, broken into broad categories such as federal, state, and local governments; tribal governments; institutions of higher education; and for-profit and nonprofit entities. Therefore, it is important that you understand whether your institution is a for-profit, nonprofit, higher education, or governmental entity to determine which subparts of the Uniform

Guidance govern federal funds received by your institution. If in doubt, ask your office of general counsel to provide you with more information.

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