Managing Compliance Issues Associated With NIH Career Development Awards

By MICHAEL J. VERNICK

As NIH budgets remain flat and competition for research support becomes more fierce, programs such as the National Institute of Health's (NIH's) Career Development awards (K awards) are becoming increasingly important to promising young scientists.[1] As reflected in NIH's award statistics, these scientists are focusing on three of NIH's K award programs: Mentored Research Scientist Development Awards (K01), Mentored Clinical Scientist Development Awards (K08), and Mentored Patient-Oriented Career Development Awards (K23).[2] The intent of these three programs is to provide a 3-5 year "protected period" of intense, supervised career development aimed at establishing the recipient as a productive, independent NIH researcher.

From an institutional perspective, there is much to be gained by encouraging young faculty members to apply for and obtain K awards. The institution benefits from the 3-5 five years of financial support for its most promising young faculty and the increased likelihood that at the end of the "protected period," the faculty member will be able to attract additional NIH funding to the institution. The receipt of K awards, however, imposes a number of unique compliance burdens on the recipient institution.

This article provides a brief overview of the K01, K08, and K23 programs and then uses those programs to highlight some of the primary K award-related compliance issues.[3] K award level-of-effort and salary limitation requirements—two of the most significant K award-related compliance issues—are afforded special attention. Finally, this article offers some suggested practices for managing institutional K award compliance obligations.

Overview of the K01, K08, and K23 Programs

As mentioned previously, the K01, K08, and K23 programs are intended to help young scientists establish themselves as independent NIH researchers.[4] Although

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[1] The growth of NIH's K award program is not, however, limited to just the past few years. Over the past decade, NIH's K award program has grown significantly in terms of both the number of awards made and the amount of funding provided. From FY 1997 to FY 2006, the number of NIH K awards has increased from slightly more than 2,000 to about 4,200. During that same period, annual NIH K award funding has increased from about $200 million to near $700 million. *See* NIH Investment in Extramural Research and Training Programs, *available at* http://grants.nih.gov/training/outcomes.htm#funded.

[2] In FY 2006, the K01, K08, and K23 programs accounted for approximately 3,000 of the approximately 4,200 new K awards. *Id.*

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[3] In addition to the different K award programs, there also are differences from institute to institute within a specific K award program. The reader, therefore, always should consider guidance from the sponsoring institute when analyzing a K award compliance issue.

[4] *See, e.g.,* K01 Program Announcement, *available at* http://grants.nih.gov/grants/guide/pa-files//PA-06-001.html (stating that NIH's expectation "is that through this sustained period of research career development and training, awardees will

the three programs share that overarching goal, they are directed toward different types of scientists. The K01 program is intended to support traditional research scientists, whereas the K08 and K23 programs are directed more toward clinicians. Of the two clinically-oriented awards, the K23 program is focused on patient-oriented research, which is defined as "research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena for which an investigator directly interacts with human subjects)."[5] NIH explains further in the K23 Program Announcement that "clinically trained professionals or individuals with a clinical degree who are interested in further career development in biomedical research that is not patient-oriented should refer to the Mentored Clinical Scientist Career Development (K08) Award."[6]

Each of the programs recognizes that recipients may be at different points in their careers and that no two recipients are alike in terms of their career goals and objectives. Accordingly, the programs have a substantial amount of flexibility when it comes to the types of activities that they will support. One recipient may, for example, benefit from a period of didactic training that would be unnecessary for another. Likewise, NIH acknowledges in the K23 Program Announcement that even though the program is focused on patient-oriented research, there are some applicants who may want to propose an element of laboratory research to support a career goal involving translational research.[7] Because of the high degree of flexibility and the competitive nature[8] of the programs, NIH expects K award applicants to devote substantial effort to designing and proposing a career development plan that is tailored to their specific needs and that will be most likely to lead to research independence.

Applicants are encouraged to work closely with their mentors when preparing their career development plans. Selection of the applicant's mentor is therefore an important element of a successful K award application. The K award mentor is expected to be an accomplished researcher in the principal investigator's (PI's) field, as well as someone who has demonstrated success in terms of training future independent NIH investigators. If the grant is awarded, the PI will work under the mentor's supervision during the "protected period."

Overview of K Award Compliance Issues

There are several fundamental compliance issues that are generally applicable to K awards (when reference to a specific type of K award will help to illustrate an issue, this article will use the K01, K08, and/or K23 program):

- *Level-of-effort requirements.* The most significant compliance issue related to K awards is that the PI must be able to devote the necessary level of effort to the project. For the K01, K08, and K23 awards, the required percentage of effort per budget period generally is 75 percent.[9]

- *Salary limitation.* K awards limit the amount of the PI's salary that may be charged in each budget period. Although the limitation often is $75,000 per budget period, this is an area where there is substantial variance from institute to institute and from program to program. It therefore is important to check both the Program Announcement and the institute-specific guidance.

- *Uses of K award funds.* In addition to salary support, K awards provide limited funds for other purposes. Allowable uses of non-salary funds generally include (a) tuition, books, and fees; (b) supplies, equipment, and technical personnel; (c) travel to research meetings or training opportunities; and (d) statistical/computational services. K awards generally will not provide salary support for mentors or any administrative personnel. Also significant from an institutional perspective, especially given the compliance challenges associated with K awards, is that K awards provide for only an 8 percent indirect (F&A) cost recovery.

- *Degree requirements.* Different K award programs require different degrees. For example, NIH's K01 program requires that the PI hold a research or health professional doctoral degree or the equivalent.[10] In contrast, a K08 PI must hold a clinical doctoral degree or its equivalent.[11] A limited number of Ph.D.-holders also may be eligible for the K08 program.

- *Citizenship requirements.* K award PIs must be U.S. citizens, noncitizen nationals, or lawful permanent U.S. residents.

- *Requirements related to current or prior sponsored research experience.* K awards often limit awards to applicants with limited sponsored research experience. For example, current or former PIs on NIH R01 grants are not eligible to receive a K08 award.[12]

Most of the compliance issues associated with K awards revolve, at least to some degree, around these issues. Not surprisingly, much of the federal enforcement activity involving K awards also has focused on these issues. For example, one issue in a 2003 False Claims Act (FCA) settlement was compliance with K award effort requirements. A 2004 FCA settlement in-

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launch independent research careers and become competitive for new research project grant (R01) funding).

[5] K23 Program Announcement, *available at* http://grants.nih.gov/grants/guide/pa-files/PA-05-143.html.

[6] *Id.*

[7] *Id.* ("While the focus of the K23 award is on [patient-oriented] research, complementary laboratory research directly related to patient-oriented research may be proposed in the application, thereby providing an opportunity for a career development experience in translational research.").

[8] For example, the success rate for K08 applications has fallen from approximately 50 percent in FY 2002 to less than 35 percent in FY 2006. *See supra*, note 1.

[9] NIH has relaxed the 75 percent effort requirement for the last two years of K01, K08, and K23 programs. During the last two years of the project, a researcher may reduce his or her K award effort in order to work on another NIH research grant. NIH NOT-OD-04-007, "Mentored Career Development Awards: Change in NIH Policy Concerning Concurrent Support from Career Development Award and a Research Grant, *available at* http://grants.nih.gov/grants/guide/notice-files/not-od-04-007.html. To reduce K award effort, the researcher must be the PI or a subproject director on the second grant. If the test is met, the PI may reduce his or her K award effort to no less than 50 percent.

[10] *See supra*, note 4 (K01 Program Announcement).

[11] K08 Program Announcement, *available at* http://grants.nih.gov/grants/guide/pa-files//PA-06-512.html.

[12] *Id.*

volved alleged noncompliance with a similar effort requirement and with a citizenship requirement.

K Award Effort Requirements

A. Overview

The primary K award compliance issue involves what is typically a requirement that the PI devote at least 75 percent of his or her total professional effort to the K award. NIH has made it clear that this requirement is based on effort as opposed to hours, and that institutions are not to calculate effort based on a 40 hour work week if the PI works either more or less than that amount. If a researcher, for example, works 48 hours in a given week, he or she would have to devote at least 36 hours to the K award in order to achieve compliance with the 75 percent requirement. If that same researcher increased his or her workload to a 60 hour week and K award effort remained at 36 hours, that researcher would not be in compliance with the effort requirement. Compliance would be maintained only if K award effort increased to 45 hours.

Importantly, compliance with K award effort requirements is measured over the course of a budget period, which typically is 12 months, as opposed to over some shorter period of time. That is helpful because it is to be expected that over the course of a budget period, there will be months when K award activity is less than 75 percent. It is, for example, possible that a K award PI who also is a clinician will be "on call" for certain periods of the year. Clinical workloads during those "on call" periods can substantially reduce the amount of time left available for research activity.

As a general rule, NIH will reduce effort requirements only in "unusual and pressing circumstances."[13] NIH guidance provides that such circumstances may include medical conditions, disability, or child or elder care. NIH also cautions researchers that in general a reduction in the effort requirement will not be made to accommodate job opportunities or clinical work.[14]

Given the importance of complying with the applicable K award effort requirement, it is advisable both for institutions and potential PIs to think carefully about their overall professional commitments *before* submitting K award applications. Some disciplines often impose significant clinical obligations on researchers that potentially could make it difficult to meet a 75 percent effort requirement. For example, surgeons might consider whether their clinical obligations can be maintained at a level that will allow them to meet a K award's effort requirements.[15] Individuals with significant institutional administrative responsibilities should factor those obligations in when deciding whether it is advisable to seek a K award.

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[13] *See supra,* note 11 (K08 Program Announcement).

[14] *See id.*

[15] Some institutes have recognized the clinical demands on surgeons. *See, e.g.,* NOT-AR-07-001, "Changes to the Requirements for Physicians Applying to PA-06-512 (Mentored Clinical Scientist Research Career Development Award (K08)) and PA-05-143 (Mentored Patient-Oriented Research Career Development Award (K23)) for the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS)" (reducing K08 and K23 effort requirements for surgeons), *available at* http://grants.nih.gov/grants/guide/notice-files/NOT-AR-07-001.html.

B. What is K award "total professional effort"?

As noted above, K award effort is calculated by dividing the amount of effort devoted to the K award by the PI's total professional effort.[16] For some period of time, it was NIH's view that all of a PI's professional commitments were included in the denominator of the effort calculation, but only activity taking place at the recipient institution could be included in the numerator. NIH's view resulted in individuals operating under some common arrangements at academic institutions, *i.e.*, individuals holding a joint appointment at an affiliated Veterans Affairs (VA) hospital, essentially being ineligible for a K award.

In August 2004, NIH modified its view of total professional effort for K award purposes.[17] NIH acknowledged that there were some common situations at academic institutions that tended to make it very difficult for researchers to meet K award effort requirements, and that as a result the government was not getting as many applications from qualified scientists as it otherwise might receive. NIH, therefore, redefined "total professional effort" for the purposes of meeting K award level-of-effort requirements by stating that the 75 percent effort requirement would be met when an individual has a full-time appointment with the applicant organization and the minimum percentage of K award effort required is met by activity within the scope of that appointment.

This clarification essentially allowed researchers to ignore outside appointments for K award purposes. For example, a researcher with a full-time university appointment and a half-time appointment at an affiliated VA facility could ignore the VA activity for the purpose of calculating compliance with the K award effort requirement.

C. What constitutes K award effort?

To comply with a K award's effort requirement, the PI must complete an effort report at least annually. Accurate completion of a K award effort report can, however, be quite challenging because K awards are different in some important respects from "normal" research grants, largely because of their objective of providing the PI with a comprehensive career development experience.

Learning and developing the skills necessary to become a successful NIH researcher go well beyond the actual conduct of research. For example, the K01, K08, and K23 program announcements each provide that the application must include a description of how the applicant intends to receive training in the responsible conduct of research (RCR). Although RCR training is something a successful NIH researcher must have, it is not the kind of activity that one typically would view as allocable to a federal award. Because it is, however, a required element of the K01, K08, and K23 programs, it is reasonable to conclude that it is allocable to those awards.

There are many other examples that raise similar issues. Learning how to write effective proposals unquestionably is a key skill for a researcher to develop. Gen-

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[16] 40 K award hours/50 total hours = 80 percent K award effort.

[17] *See* NOT-OD-04-056, "Determining Full-Time Professional Effort for Career Awards, *available at* http://grants.nih.gov/grants/guide/notice-files/not-od-04-056.html.

erally speaking, however, competitive proposal writing is not an activity that institutions can charge to federal awards. Likewise, the ability to teach students and perhaps even other faculty is an important skill for an NIH PI to possess. There are also certain types of clinical activity that one can envision being closely related to a K award's research objectives. Deciding whether teaching or clinical activity is allocable to a federal award is the kind of difficult question that often comes up in the context of completing an effort report.

Because K award program announcements provide little, if any, guidance on these kinds of issues, institutions can find themselves facing difficult questions when it comes time to complete an effort report. One possible source of guidance on these issues may be the K award itself, specifically its career development plan—if that document is drafted with these kinds of issues in mind. Although it may not provide complete protection against sponsor "second guessing" during an audit or other enforcement action, proposing a certain kind of activity as part of a career development plan and then having that activity undergo peer review and approval would seem to provide a principled basis on which to charge that activity to the K award.

K Award Salary Limitations

Although K award salary limitations vary from program to program and from institute to institute, the most common rule is that a K award will support up to $75,000 of the PI's salary charges during a budget period. The K award salary limitation generally is understood to be conceptually different from the NIH salary cap. Unlike the salary cap, which is a legislatively mandated cap on the salary *rate*, the K award limitation is an administrative limitation on the *amount* of salary that NIH will reimburse per budget period.

That distinction can be seen from the following example. If the K award limitation were treated as a rate cap and a researcher has a salary of $80,000 and spends 80 percent of his or her effort on a K award with a $75,000 salary rate limitation, the grantee could recover only $60,000 ($75,000 x 80 percent). (This essentially is how the NIH cap works, although obviously with a different rate amount.) In contrast, if the K award limitation is treated as a maximum amount of reimbursement, the institution would recover $64,000 ($80,000 x 75 percent). If the base salary is $120,000 and effort is 75 percent, the reimbursement would be limited to $75,000 (because $120,000 x 75 percent exceeds $75,000).

NIH does allow grantees to supplement K award support up to a level that is consistent with the institution's salary policies. That supplementation may not, however, be from federal funds[18] (unless specifically authorized). NIH also cautions institutions that if it supplements a K award PI's salary, that supplementation must not be accompanied by additional responsibilities that interfere with the K award's objectives and requirements. Grantees are entitled to rebudget K award funds to support additional salary recovery, but as a practical matter that flexibility is limited because K awards pay only for a limited amount of non-salary costs.

Suggested Management Practices

Managing K awards can be a challenging component of any institution's sponsored research program. Focusing some special attention on K awards at both the pre-award stage and during each program year will substantially reduce the chances of incurring adverse audit findings and/or monetary disallowances. The following are some suggested methods for managing K awards:

1. Consider who is applying for a K award. Does the potential applicant have significant teaching, administrative, or clinical responsibilities that might interfere with his or her ability to meet the level of effort requirement?

2. Be aware of K award eligibility requirements, including citizenship, degree, and previous sponsored research support.

3. Use the process of drafting the career development plan to your advantage. Carefully consider the kinds of non-research activities in which the applicant will be engaged and determine at this point how (and if) they relate to the objectives of the K award.

4. Develop and implement training programs for K award PIs that focus on the primary K award-specific compliance issues.

5. Consider developing special monitoring for K award recipients. For example, determine whether it is feasible to "check in" with your K award PIs at the mid-point of each budget period to remind them of their effort requirement.

6. At the end of each budget period, confirm that the PI met the effort requirement.

7. Be proactive. If a compliance issue arises, *i.e.*, a failure to meet an effort requirement, work with the sponsor to resolve the situation—do not wait until the end of the award.

Conclusion

K award issues can be complex. It therefore is important to develop and implement policies and procedures that will help your institution manage its K award compliance obligations. By addressing K award-related obligations early on and continuing to monitor the award throughout its life cycle, institutions will increase their ability to meet their compliance obligations.

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[18] Public Health Service funds may not be used.