TIGER TIPS RESOURCES FOR AUBURN RESEARCHERS

Changing the Status of a PD/PI: Reminder of the NIH Prior Approval Policyⁱ

Have you wondered what happens when a program director/principal investigator (PD/PI) is no longer available to serve on an NIH grant? Maybe they have accepted a position at another institution? Or perhaps they are unable to carry out their duties for some other reason?

NIH recently issued a Guide Notice (<u>NOT-OD-18-172</u>) to remind the community about the NIH's prior approval policy requirements when an institution seeks to change the status of a PI or other senior/key personnel as designated in the Notice of Award (NOA). This Notice also helps clarify the situations in which NIH's prior approval is required.

In the case of a PI getting a new position elsewhere, Auburn may seek NIH's prior approval to relinquish the grant to the new employer, so the PI can continue to work on the project. Alternatively, Auburn could decide to keep the award and replace the PI with someone else who is qualified to take over the responsibilities of the original PI, as long as the NIH agrees.

Why would this be allowed? For the most part, NIH makes awards to institutions, not people. This may seem counterintuitive since the idea for the research may have come from the investigator. Why is it done this way? The rules for all Federal awards - including uniform administrative requirements, cost principles, and audit requirements anticipate that an institution/organization carries out a Federal award as the "recipient" of the award. The institution designates individuals, including an "authorized organization representative" (AOR) the program director/principal investigator (PD/PI), to assume the responsibilities described below, in fulfilling the terms and conditions of their award. The NIH Grants Policy Statement (NIH GPS), which is a term and condition of all NIH awards, summarizes these responsibilities and the respective roles of the institutions and individuals.

Among other obligations, the applicant organization (Auburn) must certify, and in some cases submit assurances, that they comply with the public policy requirements provided in the NIH GPS. These requirements are intended to ensure fairness, equity, fiscal stewardship, and other protections in activities that receive NIH support. They include measures to promote objectivity in research, civil rights protections, human subjects protections, consideration of environmental impacts, animal welfare, compliance with PHS policies on research misconduct, maintaining a drug-free workplace, prohibitions on lobbying with Federal funds, and many others. While NIH maintains oversight of their awards, they entrust recipient organizations with the responsibility and accountability for successfully administering their grant award, including prudent fiscal management and other requirements spelled out in the NIH GPS.

NIH staff work with designated AORs for compliance matters related to the award. Also known as the Signing Official within the eRA Commons, the AORs are pivotal partners with us, as they are the persons authorized to act for the institutions. They assume the obligations imposed by Federal laws, regulations, requirements, and conditions that apply to grant applications and

There are many scenarios where an institution could replace a PI or reduce a PI's effort on an award with prior approval from NIH. Scenarios include, but are not limited to, situations where the PD/PI withdrew from the project, has been absent for at least three or more consecutive months, or the time the PI has available to dedicate to the project has reduced by 25 percent. Other scenarios may involve restrictions that the institution imposes on such individuals after the time of award, including but not limited to any restrictions on access to the institution or to the institution's resources, or changes in the individuals' (employment or leave) status at the institution. In summary, prior approval is required any time there is a change in status of the PD/PI or other senior/key personnel designated on the award, where that change will impact his/her ability to carry out the approved research at the location of, and on behalf of, the recipient institution on the terms specified in the application and award.

You can learn more about the prior approval policy and requirements in the <u>NIH Grants Policy Statement 8.1.2.6</u>. If you have any further questions about the need for prior approval, contact your <u>Contract Administrator</u> in the Office of Sponsored Programs.

ⁱ Excerpted from the NIH Extramural Nexus, May 2018