Tuesday Tips is a new outreach effort by OGCA. The idea behind Tuesday Tips is to convey tips, tricks and other helpful information around the area of research administration. Our goal is to post on (almost every) Tuesdays. If there is something you would like to see covered on Tuesday Tips, email: UAF-GCReATE@alaska.edu. For more Tips visit OGCA website.

Required Submission of Financial Conflict of Interest Policy into the eRA Commons Institution Profile (IPF) Module

Notice Number: NOT-OD-21-002

Release Date: September 30, 2020

Background

NIH policy (see NIH GPS Section 4.1.10 Financial Conflict of Interest) requires institutions subject to the requirements of the FCOI regulation to maintain an up-to-date, written, enforced FCOI policy that complies with the regulation, and to post the policy on their publicly accessible Web site. This requirement applies to all NIH applicants and/or recipients, except Phase I Small Business Innovative Research (SBIR) or Small Business Technology Transfer (STTR) applicants and/or recipients. Fast Track
SBIR/STTRs recipients are subject to the FCOI regulation prior to NIH’s award of the type 4 R44, U44, R42, and UT2 Phase II SBIR/STTR awards.

Automating FCOI Submission Processes for Recipients

Effective November 12, 2020, NIH funded recipients will be required to submit their publicly assessible FCOI policy to NIH via the eRA Commons Institution Profile (IPF) Module (IPF Module). While the automated requirement goes into effect in November, NIH recognizes that recipients will need to modify their internal systems in order to comply. Therefore, applicants and recipients have until December 1, 2020, to comply with this requirement.

A PDF of the FCOI policy must be submitted by the institutional signing official (SO) via the IPF Module under a new tab labeled, “Policy Documents”. The information is provided on an institutional level as part of an institution’s IPF, rather than on a grant-specific level, so it is not necessary to submit the FCOI policy with each grant application.

NIH plans to make future enhancements to the IPF Module which, in addition to a PDF of the FCOI policy, will require institutions to: 1) provide the URL of the FCOI policy and 2) complete an annual institutional FCOI certification of compliance with all identified regulatory requirements. As part of the annual certification, institutions will be required to provide an updated URL and a copy of the revised policy if changes have been made since the last submission. NIH will provide reminder notifications to the IPF SO when the annual certification is required.

NIH plans to conduct FCOI policy reviews to ensure the institution’s policy complies with the FCOI regulatory requirements for grants and cooperative agreements.

Institutions must be registered in eRA Commons in order to use the IPF features. The IPF Module is a central repository of information for all eRA Commons registered applicant organizations. It is designed so that each applicant organization establishes and maintains the profile data concerning
their institution. The IPF Module allows the institutional SO to electronically maintain external organization profile information necessary for all grant applications for their institution.

Consequences for Noncompliance

An institution’s failure to comply with this requirement by December 1, 2020, may cause NIH to delay the issuance of awards, impose specific award conditions or take other enforcement actions to address compliance. These actions may also be imposed as a result of noncompliance with FCOI requirements.

Resources

Instructions for submitting the FCOI Policy into the IPF Module can be found on OER’s FCOI Webpage and eRA Commons Overview of Institutional Profile (IPF).

Institutions are encouraged to refer to the resources NIH has made available on its Office of Extramural Research (OER), Financial Conflict of Interest Web site, including a “FCOI Policy Development Checklist.” This checklist provides an overview of the requirements of the FCOI regulation and serves as a checklist resource for developing, revising or reviewing an institution’s FCOI policy to determine compliance with all regulatory requirements. We encourage institutions to also refer to the “FCOI Training” tutorial and Frequently Asked Questions (FAQs) that are also available on the NIH OER FCOI Web site. NIH’s FAQ G.1 addresses the requirement to post the institution’s FCOI policy on a public website. You can find information on the public accessibility requirements, including the requirement to post your FCOI policy, in Section G., Public Accessibility, of the FAQs.

Inquiries

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