

TO: Duke University faculty and grant administrative staff, postdocs, graduate students, business managers, and research administration leaders

FROM: Lawrence Carin, Vice President for Research

DATE: November 22, 2019

RE: Update on University's response to the NIH

I am writing to update you on the University's status with the NIH and our advancement in several key areas related to scientific integrity and research administration processes. Duke has made excellent progress, with all corrective actions promised to the NIH completed, or on track for completion, by the end of this calendar year. Duke provided its sixth quarterly update to the NIH in late September.

Update

Highlights of Duke's recent progress include:

- Conclusion of the work of a panel of external consultants which included recommendations for strengthening research culture and processes
- Creation of the new university-wide [Office of Research](#) led by the Vice President for Research; this new office includes the Duke Office of Scientific Integrity (DOSI), which now serves the entire campus
- Communication to all units regarding the requirement for grant managers to have a reporting relationship to an administrative supervisor linked to the Chair/Director/Dean's office
- Creation of a new faculty committee to evaluate and make recommendations on strengthening administrative processes, reducing administrative burden, and fostering scientific integrity
- Implementation of an electronic attestation process, replacing a paper format
- The move to a university-wide, five-day internal deadline for proposal submissions
- In the School of a Medicine, the release of a new online Intent to Submit form that enables faculty to engage the pre-award office early in the application development and submission process

NIH actions

Yesterday the NIH responded with a plan to restore Duke's Expanded Authority and lifting of the special award conditions imposed within their March 2018 letter to Duke. This is excellent news, reflecting the NIH's restored confidence in Duke, but it is contingent on two important elements:

- 1) Completion of the remaining commitments by Duke as detailed in the April 2018 Corrective Action Plan, before the start of calendar year 2020. Duke is on-target with the remaining plans and we anticipate a successful final report in December.
- 2) Continued focus on scientific integrity and strong administrative processes to ensure adherence with NIH policies and procedures. It is clear that the NIH will be watching to make certain that Duke maintains its emphasis on research culture and accountability with respect to NIH policies.

Procedures related to the removal of Special Award Conditions:

Although the Special Award Conditions are removed effective immediately, we will need a short time period to work out the logistics of changing our work flow processes with the NIH. Additional guidance will be delivered to grant managers as soon as we have finished our discussions with the NIH. The following general guidance may be helpful to understand, with further details to follow:

- Prior approval of requests for Carryover of Unobligated Funds will be discontinued except for those NIH mechanisms that require prior approval for Carryover (e.g., cooperative agreements (U), program centers (P30, P50), fellowships (F), training grants (T), some SBIR/STTRs);

Carryover approvals, except for those noted above, will be handled internally via project spend rate monitoring. We will implement a review/analysis step when spending patterns deviate measurably from the approved budget, and will develop management plans with the project team (PI and GM) as applicable.

- Prior approval of No Cost Extension (NCE) requests will continue under current practices. Institutional review and approval are an expectation of the NIH for all NCE requests.
- Use of modular budgets will be reinstated. However, to avoid situations where sponsored work is underfunded, modular applications will require an approximate budget (without the budget justification) to verify that all costs necessary to carry out the project are included. This information will be entered into the Sponsored Projects System (SPS) for internal review/approval only.

Thank you for your continued cooperation in this very important effort. We welcome your questions and comments at grantsupport@duke.edu.