COVID-19 UPDATE

NIH GUIDANCE CALL ON 03/16/2020

On March 16, 2020, Pitt and School of Medicine leadership participated on a National Institutes of Health (NIH) COVID-19 update call. Dr. Larry Tabak, Principal Deputy Director, NIH. and Dr. Michael Lauer, Deputy Director, Intramural Research, NIH, led the discussion and answered questions from the audience. The following are important points from the call:

NIH has a dedicated COVID-19 webpage that can be found here.

NIH COVID-19 Notices

1- **NOT-OD-20-082 NIH LATE APPLICATION POLICY Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19)**

2- NOT-OD-20-083 General Frequently Asked Questions (FAQs) - Proposal Submission and Award Management Related to COVID-19

3- NOT-OD-20-086 Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19

   COVID-19 Flexibilities for Applicants and Recipient FAQs

    NIH Guidance on Travel and Meetings

4- NOT-OD-20-087 Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected COVID-19

NIH considers safety and participant well-being to be first priority and the funding second in priority.

NIH plans to be as accommodating as possible:

- Late applications will be accepted and accommodated.
- Administrative flexibility will be provided.
- Peer review using a virtual format will be continued.
- Clinical studies will have flexibility.

Responses to Audience Questions:

Shutdown of Research

NIH is not in a position to mandate the shutdown of NIH-funded research. The NIH view is that any mandated temporary shutdowns of research is the purview of the University.

Late Applications

 No NIH permission will be required for the submission of a late application. At the time of submission, a cover letter should be included detailing the closure of the University or circumstances as the result of COVID-19 that prevented an on-time submission, including the closure of a subcontractor. The language in NOT-OD-20-082 has been written intentionally broad.

Late RPPR and Other Reports

NIH will accept all and any reports late because of COVID-19. Details are addressed in NIH FAQs and NIH NOTs.

Administrative Matters

NIH will provide flexibility with administrative matters, including research misconduct cases.

Notice of Award (NOA)

Even though NIH is open for business and the NIH staff are working remotely, time will tell whether NOAs will be delayed.

IRB Study Changes

If clinical study changes need to be made because of patient safety, NIH considers that a priority and thus should be addressed with the IRB first, and then after addressing with the IRB, contacting the program officer. NIH will respond later about whether any temporary changes will require a change in ClinicalTrials.gov.

Cooperative Agreements

If there are delays in milestones because of COVID-19, work with NIH staff already participating in the agreement who have information on next steps.

Salaries

As a general rule, if the institution allows salaries to be paid when faculty and research staff cannot work because of COVID-19, then NIH will allow those salary charges to remain on the grant.

Administrative Supplements

Investigators will have the ability to apply for administrative supplements on a case-by-case basis to assists with the unexpected costs associated with COVID-19. Timing for when applications will be accepted for administrative supplements is unknown. Once the COVID-19 situation stabilizes and begins to normalize, information will be provided by NIH on how to apply for these administrative supplements.

Project Extensions

Researchers should be in touch with their Program Officers if there will be a delay in study recruitment.

Carryover

NIH will be allowing carryover as a result of COVID-19 without preapproval.

Funding for COVID-19 Research

NIH has received some emergency supplemental funding, so if a Principal Investigator has funds already to support COVID-19 research, opportunities for supplemental funding will be available soon.