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Agencies Make Allowances for Impact of COVID-19 on Spending, Deadlines

By Theresa Defino

Time can seem both elastic and yet meaningless during a public health emergency like the one the world is experiencing now due to COVID-19. It is almost unbelievable to think that even a month or two ago, institutions —and the federal government—did not have this pandemic on their radar. Universities and others have often had to make difficult decisions without direction from the government (see story, p. 1).[1]

But now agencies are pumping out guidance and, in some cases, responding incredibly quickly when they are told the guidance is lacking. To help keep the research community up to date, the Council on Governmental Relations (COGR) has posted links to both agency and institutional responses to COVID-19.[2]

Among the largest funder of research and, in particular, clinical studies, NIH has been active in issuing guidance. As of *RRC's* deadline, it had issued more than a half-dozen separate documents. Among them:

- NIH LATE APPLICATION POLICY Due to Public Health Emergency for United States for 2019 Novel Coronavirus (COVID-19), issued March 9, http://bit.ly/2x6ZEBY.
- General Frequently Asked Questions (FAQs) - Proposal Submission and Award Management Related to COVID-19, issued March 10, http://bit.ly/2IWZ4JP.
- Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19, issued March 12, http://bit.ly/3b6uysI.
- Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19, issued March 16, http://bit.ly/3de66Yi.

NIH also posted a YouTube video of Michael Lauer, NIH deputy director of extramural research, talking about flexibilities, but there is no transcript (the video is 8 1/2 minutes long).[3]

NSF Promotes Funding Opportunities

For its part, the National Science Foundation (NSF) "encourages the research community to respond to this challenge through existing funding opportunities," Director France A. Córdova said in a March 4 "Dear Colleague Letter," accompanied by an FAQ document.[4] NSF's guidance can be found at http://bit.ly/2Uomk8y.

Among the other documents NSF issued was a resetting of some deadlines for proposals; a few are only a week or so later while others were postponed by several months. A separate FAQ for proposers and awardees instructs individuals in many circumstances to "contact the cognizant NSF program office to discuss the issue."

For example, one question relates to the inability to meet a proposal deadline because individuals have been sent home. "NSF will consider extensions to the submission deadline on a case-by-case basis (and, in a few cases, on

a program-by-program basis), understanding that it may be particularly difficult for individuals impacted to contact NSF," the agency said.

In its guidance, issued March 18, the Food and Drug Administration (FDA) stressed "safety first." For example, FDA pointed out that since "trial participants may not be able to come to the investigational site for protocol-specified visits, sponsors should evaluate whether alternative methods for safety assessments (e.g., phone contact, virtual visit, alternative location for assessment, including local labs or imaging centers) could be implemented when necessary and feasible, and would be sufficient to assure the safety of trial participants."[5]

It also noted that "changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants (e.g., to limit exposure to COVID-19) may be implemented without [institutional review board] approval or before filing an amendment to the [investigational new drug or investigational new device application], but are required to be reported afterwards."