

Dr. Larry Tabak and Dr. Mike Lauer Call 3/16 3:30 EDT

Comments from NIH in *Italics*. Questions for NIH in **Bold**.

- *Deeply concerned about health and safety of everyone involved in NIH research. Mike Lauer – Guide Notice on clinical trials human subjects is out today: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html>*
- *Gave overview of NIH Guidance to date – look to grants.nih.gov and click on COVID-19 for the latest.*
- *OLAW will have Animal Care webinar March 19, 1pm: <https://olaw.nih.gov/news/special-olaw-webinar-march-19-pandemic-contingency-planning-and-its-impact-animal-care.html>. Registration is required but not sure if there are any restrictions in who can participate. Check OLAW's website*
- *We are going to approach this as flexible and accommodating as possible. We recognize there will be unanticipated costs, and we are working on putting together a way for institutions to apply for administrative supplements to cover costs. NIH understands that each circumstance will be unique*
- *Late application cover letter – the language is deliberately broad, it is not tied to a specific number of days the institution is closed for example. Applicants need to include a cover letter with a late application, describing circumstances for the delay, specifying COVID-19's impact. 99% of these requests will be approved*
- **Should we speak to PO before or after IRB for study changes?** *NIH – IRB takes priority, then speak with PO.*
- **Are you encouraging universities to mandate temporary termination of research activities?** *NIH - Under purview of universities. Will be flexible, understand it will delay work and that additional costs will be incurred, but NIH is not in the position to recommend that universities suspend work.*
- **Looking at late applications web site, which requires cover letter with enough detail to say how long closure is. USF is only partially closed, only most essential experiments can continue and everyone else is working from home. How do you frame that partial closure for late submissions?** *NIH - Applications may come late because of closure or unable to submit grant applications due to the effects of COVID-19. Deliberately vague. Could say because of xyz circumstances we are xyz late submitting and likely almost all will be accepted. (Gave 99% figure twice)*
- *NIH will accept RPPR, financial, close out reports late. Not a problem. Specifically addressed in guide notices and FAQs*
- **Will other orgs such as PCORI follow NIH guidelines?** *We can't speak on what other organizations will do*
- **Do temporary changes require updates in CT.gov?** *NIH will follow up on that question*
- *Administrative Supplemental funding – will be case by case basis. They are still trying to figure out.*
- **Will the same spirit of flexibility be extended to misconduct cases already in the works?** *Yes, we will be flexible and accommodating for such administrative matters.*
- **If subrecipient is closed and they have vital piece of information or role in the project, is a reasonable cause for delay?** *Yes, that is a reasonable cause for delay.*
- **Will NOA's be delayed?** *NIH - Most of NIH is teleworking, but they are open for business and hope is that applications will be processed as quickly as possible. Facing some of the same challenges that academic and research community is facing and likely will have some delays but patience appreciated and intent to continue is clear. We don't know yet, time will tell.*
- **Can NIH think about setting up 'regular' check ins like this with the broader community?** *Yes, we will work this- more to come on that.*
- **Is information on Open Mike, etc. being pushed out to grantees –Yes, Extramural Listserv is monthly, probably next one will be issued tomorrow**

- **As subject activities are delayed how do we get extensions?** *NIH - We anticipate it will happen reasonably often. Researchers should be in touch with POs to help guide them through the process. May be unobligated balances and will allow carryovers without prior approval.*
- **Some of us have research staff that have been diverted to hospitals for help with COVID-19 testing, can we charge salary /fringe etc when they've been diverted?** *NIH - If an institution has as their policy that salary can continue to be paid then NIH will pay. This specific question/case may need further clarification.*
- **Will NIH be getting emergency funds from the administration to support research?** *NIH - They have received supplemental COVID-19 funding, particularly for NIAID and NIEHS. Exactly how it will be spent, they are working on that.*
- **For grants that are cooperative agreements, if there is a delay in milestones, how do we inform NIH?** *NIH: Because the nature of the cooperative agreement is to work closely with NIH and they'll already be well aware.*
- **Is there criteria for when the first wave of disruption is over?** *NIH – To quote Dr. Fauci, this is fog of war, we may have a better sense of that in a week or two.*
- **What about vivarium inspections – especially if PPEs are required to enter a room?** *NIH - OLAW is working on putting together a guide notice on issues for animal research, if it's not specially answered within that guide notice Mike will follow up with OLAW.*
- **Any stop travel orders coming from NIH?** *Not that Mike is aware of*
- **What if a project requires an immediate change that affects the outcomes or trajectory of the project – do the changes need to be approved by the Program Officer ?** *NIH - If you need to make changes because of safety, that's top priority. The first administrative authority would be IRB. Do what you need to do. Then please get in contact with your Program Official. Please don't let administrative concerns with the agency get in the way of public health or patient safety.*
- **How can we help NIH in light of this emergency?** *NIH: What 's most important to NIH is patients and researcher's safety. Administrative requirements and money should take second place to safety. Follow the guidance of public health authorities and institutional leaders. We are well aware of what a number of institutions are doing around the country and are very impressed with the institutional response – thoughtful and comprehensive manner.*
- **Is there an IRB of record for COVID-19 studies -?** *NIH will get back to us.*

Closing Comments: *Only going to be through scientific research is how we'll get on top of this problem. This is a time for science to shine. Must deal with disruptions, but opportunities for scientific research are important. Only through science will progress be made against COVID-19. Mike provided the example of the HIV crisis.*