March 16, 2020 Phone Call

Dr. Mike Lauer, Deputy Director for Extramural Research, NIH
Dr. Larry Tabak, Principal Deputy Director of the National Institutes of Health

They are deeply concerned for the health and safety of everybody involved in NIH research and on this phone call will discuss NIH’s efforts to ensure research institutions and scientists are accorded the flexibility needed as they confront COVID-19-related research disruptions.

The following page provides resources and information available to extramural researchers related to the COVID-19 pandemic: [https://grants.nih.gov/grants/natural_disasters/coronavirus.htm](https://grants.nih.gov/grants/natural_disasters/coronavirus.htm):

There are four guide notices on this page as of 3/16, regarding:

- How late applications will be handled (they are being accepted)
- A variety of administrative flexibilities, including delayed reports, rebudgeting, projects extensions, coverage of salaries, refunds of travel costs and canceled registration fees, etc.
- Peer review – which is continuing in a virtual format
- Studies that involve clinical trials in human subjects. Researchers are encouraged to work with IRBs. A number of facilities are shutting down or dramatically decreasing their contact with research participants. Contains information about the kinds of problems researchers are having along with a number of new allowances and flexibilities which are going to be incorporated.

Regarding animal care – NIH’s Office of Laboratory Animal Welfare will be doing a webinar this week on animal care during a time of pandemics (March 19 at 1pm.) Must register.

NIH is approaching this situation in as flexible and accommodating a way as possible. They recognize there will unanticipated costs and will make it possible for researchers to apply for administrative supplements to cover those costs. They want to do what is best to enable research to go forward and deal with individual circumstances in a flexible way.

The rest of the call was in Q & A format. Here is a summary of that information:

Q. Are you encouraging universities to mandate temporary termination of laboratory research activities?
A. That is the purview of the university and not NIH. But NIH will be as flexible as possible if this happens and understands that work would be delayed and additional costs incurred.

Q. How do the late applications handle partial closures?
A. Application instructions are written in a deliberately broad fashion – A brief cover letter can explain that because of “X” circumstances, I am “Y” late in submitting the application. It is expected that 99% of these will be accepted.
Q. Should a program officer be spoken to before the IRB about study changes?
A. IRB takes priority – after that speak to program officer

Q. How does a PI go about obtaining permission for a late submission and obtain a new due date?
A. Advanced permission is not necessary, just submit it late along with a cover letter about why it is late. NIH will be very flexible and expect to approve 99%.

Q. Will RPPRs be accepted after the deadline?
A. Yes, as well as other types of reports, and this is addressed specifically in the flexibilities guide notice.

Q. Will other funding organizations such as PCORI following your guidelines?
A. We can’t speak to what other organizations will be doing.

Q. Do temporary changes require updates to clinicaltrials.gov?
A. Unsure. They will follow up on this.

Q. Is there information about applying for supplementals? How soon will those be available?
A. Probably will be done on case-by-case basis. First we need to get through the immediate set of challenges before putting that in place.

Q. Will there be a tree-approval for late applications?
A. No, it will be done on a rolling, case-by-case basis.

Q. Regarding research misconduct cases that are already underway, can we expect the same flexibility regarding the time frame?
A. Yes, for all administrative matters.

Q. What if we are not closed, but our subcontractor is closed?
A. If that is the reason you are unable to submit, because you need vital information from your subcontractor and cannot get it, tell us that and we will proceed from there.

Q. Do you anticipate delayed NOAs?
A. At NIH, most people are teleworking although we are open for business. Our hope is that we will process applications as soon as we can, but only time will tell. There is likely to be some delay.

Q. Are there any plans or recommendations for standing weekly webinars to discuss this and stay connected?
A. We can work through setting up a regular check-in with the community. We will figure out how best to do this.

Q. Is the NIH COVID-19 new website being pushed out to current grantees?
A. Yes, we are going to include it in the NIH Extramural Nexus – goes out to listserve of about 400,000 people. Most likely tomorrow (March 17)

Q. If subject activities are delayed, what will be the process and timing of seeking project extensions?
A. Researchers should be in touch with program officers and they will guide them through the processes. We also realize that there will likely be unobligated balances because money isn’t being spent for a period of time and carryovers will be allowed without a need for pre-approval.
Q. What is the policy regarding allowing charges for salary and benefits to NIH grants when certain research faculty staff are diverted from research lab work to assisting with increased COVID-19 testing in their clinical labs?
A. As a general rule of thumb, if an institution has as a policy that salary continues to be paid even if they are not able to do the work that they are supposed to be doing, then NIH will cover salary. But in that specific situation, we will have to look into it.

Q. Will the NIH be getting emergency funds from the administration to support research?
A. We have received a supplemental specifically for COVID research, which will go to NIAID and less to NIEHS. That was part of the 8.3 billion supplemental bill passed a week or two ago. Exactly how that will be spent is not yet clear. Along those lines, earlier in February, we put out a notice of special interest for competitive revisions for COVID-19 related research. This is for people who already have funded grants. They will have an opportunity to get additional money to conduct research that is specifically related to COVID-19. Specifics are in that announcement.

Q. For grants that are collaborative agreements, if there are delays in meeting milestones because of these circumstances, how should this be addressed?
A. I presume that you mean cooperative agreements, where the nature of the agreement is that the researchers are working closely with NIH staff. Staff will be well-aware of problems and delays and will work with you regarding those.

Q. Are there criteria for deciding when the first wave of disruption is over?
A. This is still quite early on and we might have a better sense in a week or two.

Q. When can hospitals and researchers apply for new funding opportunities that come out of the first supplemental?
A. Stay tuned to the NIH Guide. There is a Notice of Special Interest out already, for NIAID and NIGMS who are offering for COVID-related research. There are funding opportunities available. Be sure that you subscribe to the NIH Guide where new announcements will be posted.

Q. How much flexibility will be allowed regarding semi-annual IACC inspections of vivaria? Can we install internal flexibility in how we conduct inspections, especially if PPE is normally required to enter a room?
A. OLAW is working on putting together their own guide notice on issues that are specifically related to animal research. We will follow up on this and add it to FAQs.

Q. Is there any guidance on how to handle project-related infections, such as researcher to subject? Will these issues be handled primarily through the general counsel of the institution covering IRB?
A. Yes, I would think so.
Q. Are there special capacities of the science and research community that could be helpful in addition to social isolation and mitigation? How can we help you and the NIH most in light of the public health emergency?
A. Most important is that patients, research participants and researchers should be safe, that concerns about administrative requirements and money should take second place to concerns about safety and participant well-being, that you follow the guidance of public health authorities, the CDC and of your institutional leaders. Many institutions are handling this crisis situation in a thoughtful and comprehensive manner.

Of course there are research opportunities here. What is going to conquer this virus is science. We already notice a dramatic amount of creativity and scientific thought begin published. On the one hand, we deal with the destructions, on the other it is an opportunity for scientific research to shine.

Q. Has the NIH designated an IRB of record for COVID studies and/or will 45 CFR 46.114 be suspended for multi-center COVID research?
A. Will have to look into this.