Shutting Down Lab Operations AND Limiting Human Subjects Research Including Clinical Trials

Part A: Shutting Down Lab Operations

In response to the rapid spread of COVID-19, it is imperative that we minimize to the greatest extent possible the number of personnel working in our laboratories. Therefore, we are moving policy for research operations to Level 4 – Only work needed to perform essential maintenance activities such as preserving important samples and critical animals may be performed. PI’s must begin to implement Level 4 immediately and have their entire lab in compliance not later than 5pm, Friday, March 20. We will reassess as the situation evolves, but anticipate being at Level 4 for the next 6-8 weeks.

What this means specifically regarding lab personnel and work is as follows:

1)  Lab experiments/operations will shut down completely with virtually no one remaining in a lab or research core after 5pm on Friday, March 20. Only personnel who, in the judgment of their supervisor/PI, are in Level 4 (needed to perform essential maintenance activities such as preserving important samples and critical animals) may access our laboratories. Those who do are reminded that they must still abide by the current published Partners guidance related to social distancing and reporting illness symptoms.

2)  All personnel in Level 1 (work that can be accomplished remotely), Level 2 (work that can be delayed or stopped, i.e., non-essential lab experiments that would require onsite presence to continue), and Level 3 (work to ensure that long-term experiments and vital lab programs remain operational) are directed to stay home and work remotely.

3)  Supervisors/PI’s should have staff members perform tasks that can be done remotely. This could include writing a paper, literature searches on new techniques, assistance with grant applications, online training, updating documentation in Lab Archives, updating online research profiles and lab websites, etc. For clinical researchers, consider updating clinicaltrials.gov records, protocol reviewing/writing/updating, completing OnCore reconciliations, and conducting virtual or phone clinical trial visits. For animal researchers, complete triennial review protocols and review/write/update IACUC applications.

4)  As a reminder to those directed to work from home, we are all hospital employees. As such, we are subject to being called back to work in another support capacity should the need arise as determined by the Hospital Incident Commander.

Salaries. The salaries of personnel directed to stay at and work from home will be covered for a period of time; additional guidance on federal awards can be found at these links from COGR FAQs and the NIH. More guidance from Partners is forthcoming.

Specifying Essential Personnel. Personnel designated by their PI as essential to perform maintenance activities must be submitted using the Redcap form “PHS Petition for Staffing During Research Level 4 Ops”. Forms must be submitted in Redcap by PI’s by EOD Tuesday, March 17. Chiefs must then review/approve in Redcap by EOD Wednesday, March 18. SVP’s will then complete their reviews by EOD Thursday, March 19.

Requesting Exceptions to the Level 4 Policy. We realize that our investigators are working hard to improve our understanding of disease and develop new treatments for our patients. This is essential work that we don’t want to derail, but the urgency of the current pandemic will require that some of this work be temporarily put on hold. Personnel who have projects underway conducting research directly on coronavirus/COVID-19 may petition their Research SVP to allow that work to continue using the same Redcap process, including chief approval, with the same deadlines described above. Also, in rare cases, PI’s may have a long-term experiment underway that is critical to the survival of their lab once operations resume. These PI’s may also petition their SVP using the Redcap process, again with the same deadlines described above.
Part B: Limiting Human Subjects Research Including Clinical Trials

Also, effective immediately, Partners is limiting the conduct of human subjects research including clinical trials. Guidance developed by leadership of Human Research Affairs, the IRB, the Clinical Trials Office, and hospital leadership includes strict conditions under which therapeutic studies may commence or continue, limiting conduct of non-therapeutic studies to those that can be conducted remotely, and suspension of IRB review of new studies (with notable exceptions including COVID-19 research). Please see the attached policy document “Policy on Conduct of Human Research Activities” also provided here.