March 25, 2020

Subject: Required Notification of Intent for COVID-19 Research with Human Subjects or Biological Samples

Dear Research Community,

Over the last few days, there has been a tremendous response from the UR research community to the COVID-19 pandemic. This has included many proposals for research involving COVID-19 subjects and samples - such as clinical trials, centralized resources (e.g. biobanks, data repositories), human subjects research, and more.

These activities are a visible demonstration of the strength of our research community.

One emerging area of complexity, especially with respect to interventional clinical trials, is that, in several instances, multiple faculty members have independently contacted the same sponsor. This has led to confusion among clinical research sponsors as to who will be the UR lead on a trial.

Our clinical colleagues are also rightfully concerned that competition for research study enrollment should not interfere with clinical care of COVID-19 patients.

Finally, it is also clear that we do not have the bandwidth to participate in every single COVID-19 trial that may be proposed (e.g. there are already some 20 different vaccines in development!).

For these reasons, we are establishing a central process for evaluating COVID-19 clinical trial and research proposals. All potential clinical trials and research studies will need to first provide a Notification of intent through this form. This will be required prior to RSRB review.

This is especially important for clinical trial opportunities. We realize that many will want to lead or participate in the same clinical trial. We will be working to harmonize effort with the help of a committee led by the Senior Associate Dean for Clinical Research. This group will also prioritize research instances where trials or studies overlap in terms of recruitment populations or resources, or where addition of another trial or study will exceed our research capacity or resources.

We ask for your understanding during this challenging time.

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