March 13, 2020

Clinical Research Community,

In response to the local SARS-CoV-2 outbreak, King County Public Health has declared a state of emergency and has issued recommendations to avoid visiting hospitals to the extent possible while keeping six feet away from patients. There is a potential for significant exposure of personnel performing clinical research to COVID-19 infection.

We are now experiencing an increasing influx of patients seeking care for suspected and/or confirmed COVID-19 and expect this to continue in the coming weeks. As part of this response and in accordance with UW Medicine and local public health recommendations, **we are suspending all non-COVID-19 clinical study activity** (see exception for studies that deliver immediate care below), **including consenting, that requires presence of research personnel in UW Medicine intensive care units, and emergency departments effective immediately and extending for 2 weeks from the date of this letter.**

This suspension includes all non-COVID-19 related waiver of consent and/or sample collection-only studies. Clinically obtained biospecimens will continue to be available through Northwest Biospecimen (sbowell@uw.edu). The duration of stoppage may be altered depending upon the evolving situation and updates will be posted to the UW Medicine Huddle. We are taking this action out of an abundance of caution to limit potential exposures to personnel as well as to avoid disruption to clinical personnel responding to patient needs.

Ambulatory clinics are not included in this clinical research suspension, but each ambulatory clinic has the authority to determine whether studies in the clinic should continue as patient volume increases. All patients with confirmed COVID-19 infection or requiring potentially aerosolizing procedures should be avoided unless the study is specific for patients with COVID-19.

If your study involves the delivery of immediate patient care that cannot be interrupted and you need access to the spaces above in order to deliver care, please coordinate with the appropriate clinic. This includes randomized controlled trials in which access to patients randomized to the control arm are critical to the research objective.

For clinical studies focused on COVID-19, it is critical to avoid any adverse impact from research activity on inpatient acute care areas. Please, if your study needs to take place in inpatient acute care areas, be respectful and supportive of clinic staff. Make sure that your activity does not add to their burden or stress.

For non-COVID-19 clinical trials, UW Medicine asks that study PI’s develop a COVID-19 mitigation plan for their individual study. Mitigation plans will be reviewed promptly to determine which studies are safe to resume as the suspension is lifted and should be submitted according to the primary area of study enrollment as follows:

- **Emergency Department:** Please submit mitigation plan to Layla Anderson via One Drive or email.
- **Intensive Care Unit:** UWMC: Laura Evans, leevans@uw.edu
  HMC: Bryce Robinson, brobinso@uw.edu

You will be notified directly if enrollment for your study has been determined to be safe to resume.
If your study involves the delivery of immediate patient care that cannot be interrupted and you need access to the spaces above in order to deliver care, please coordinate with the appropriate clinic. This includes randomized controlled trials in which access to patients randomized to the control arm are critical to the research objective.

We realize that this will have a negative impact on research studies recruiting subjects at UW Medicine Hospitals. We will be working diligently to resume all studies as soon as it is safe to do so. Please provide this notification to your funding partners who request justification for research stoppage.

**Guidance for development of COVID-19 mitigation plans for studies enrolling in UW Medicine Hospitals.**

The following items should be addressed in the mitigation plan:

1. All patients with confirmed COVID-19 infection or requiring potentially aerosolizing procedures should be avoided unless the study is specific for patients with COVID-19.

2. Decreasing potential exposure for nonclinical personnel at increased risk of severe illness from COVID-19.

   People at higher risk include:
   - Over 60 years of age
   - With underlying health conditions including include heart disease, lung disease, or diabetes
   - With weakened immune systems
   - Who are pregnant
   - Caregivers of children with underlying health conditions.

3. A protocol for noncontact screening for active symptoms of acute respiratory infection possibly related to COVID-19. This may be accomplished by speaking with care providers, chart review, screening surveys, or other options prior to approaching potential research subjects. Those subjects with active symptoms should be avoided.

   - UW Medicine definition of symptoms of acute respiratory infection are fever, new cough, new shortness of breath, myalgias, etc.

4. Reducing face-to-face contact with research subjects. For example, this may be accomplished by including barriers between research personnel and subjects, and or using technology (e.g. telephone, facetime, intercoms) to conduct interviews.

5. Address PPE training status for nonclinical research personnel who need to be within 6 feet of subjects. Address sources of PPE for research use. Address methods to reduce PPE usage by all personnel, including limiting requests for second blood draws and sample collections by clinical personnel.

Sincerely,

Tim Dellit and John Slattery