

MEMO FROM OCR

From: Office of Clinical Research [ADM]
Sent: Friday, March 13, 2020 5:39 PM
To: Martell, Bethany [OCR]; Stadler, Walter [MED]
Subject: COVID-19 Clinical Research Guidance

Dear Clinical Research Teams,

As we all continue to work through preparations for the evolution of COVID-19, we wanted to provide specific recommendations in regards to our clinical research mission and operations.

Clinical research operations should align with hospital and individual service line operations as well as University guidance (see [Coronavirus Resource Center page](#) and [University of Chicago Coronavirus Updates](#)).

We consider clinical research activities in three categories.

1. **Clinical trials with subjects who are patients here for treatment of a disease/condition as part of their routine clinical care.** These individuals are generally receiving investigational products (drugs, device, biologic) or follow-up care related to previous treatment with investigational products. We recommend that these activities continue, but follow all hospital and specific service line clinical operation standards and SOPs with specific reference to guidelines for social distancing for *clinicians*. We further recommend that clinical research staff interaction with these subjects be limited as much as possible and occur only after the patient has undergone whatever hospital based screening is in place for *patients* at that time.
2. **Clinical research studies with subjects who are patients or non-patients occurring within the clinical enterprise, but not in the context of routine clinical care.** These are studies without investigational products but usually with some kind of clinical activity (research procedures, research labs, etc.), but are not for the treatment of a disease/condition. If deemed necessary by principal investigators and local department/research leadership, these activities may continue, but must follow all hospital and specific service line clinical operation standards and SOPs with specific reference to guidelines for social distancing for *Offices & Labs*. We further recommend that clinical research staff interaction with these subjects be limited as much as possible and occur only after the subject has undergone whatever hospital based screening is in place for *visitors*.
3. **Clinical research that occurs in the community.** There are a number of protocols, including the highly visible NIH funded "All of Us" study, which enroll community members and involve collection of biospecimens from community members. We recommend that clinical research activities here be paused until further notice.

All final decisions and determinations about the continuity of clinical research activities should be made by the principal investigator and department/research and be based on the nature of the research protocols; patient or subject needs; and staff availability. **We are available to address specific questions that may be unique to individual projects/protocols.**

Broadly, clinical research coordinators who work on clinical trials can be classified as "essential" for working on campus while research staff primarily responsible for data management and those who work

on non-trial clinical research studies can be classified as “non-essential” and may perform alternate work duties from a remote work location.

As you know, the situation regarding COVID-19 is changing rapidly. Practices in place today may change tomorrow or by next week as the disease progresses and the CDC and other state and local entities provide additional guidance.

Additional COVID-19 information and updates from the BSD can also be found on this website: <https://biologicalsciences.uchicago.edu/coronavirus>

Walter Stadler, MD FACP
Fred C. Buffett Professor
Depts of Medicine & Surgery
Dean for Clinical Research
Deputy Director, Comprehensive Cancer Center
University of Chicago Medicine & Biological Sciences

Bethany Martell
Executive Director, Office of Clinical Research
University of Chicago Biological Sciences Division
University of Chicago Medicine
773-834-9799
bmartell@bsd.uchicago.edu