AT THE FOREFRONT UChicago Medicine | Office of Clinical Research

To: Clinical Research Teams

From: Walter Stadler, MD, Dean for Clinical Research and Bethany Martell, Executive Director, Office of Clinical Research

Re: Clinical research activities and COVID-19

Date: March 16, 2020

As we continue to modify work as a result of the COVID-19 pandemic, 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. Additional information is also available on the BSD Coronavirus website.

We consider clinical research activities in three categories, and specific recommendations are as follows.

	Clinical trials for treatment of a disease/condition conducted as part of routine clinical care	**Clinical research studies conducted within the clinical enterprise, but not in the context of routine clinical care.**	**Clinical research conducted in the community**.
Who (subjects)	UCMC patients	UCMC Patients or non-patients	Mainly non-UCMC patients
What (more specifically)	Subjects receiving investigational products (drugs, device, biologic) or follow-up care related to previous treatment with investigational products.	Studies without investigational products, but usually with some kind of clinical activity (research procedures, research labs, etc.).	Community members and may or may not involve collection of biospecimens.
Recommendation	***Activities can continue.*** Research staff and PIs should work with service line leadership to discuss specific visit necessity.	***Place on hold.*** Subjects should be classified as hospital ***visitors***, and thus should be placed on hold.	***Place on hold.***

	The risk/benefit consideration of trial participation may be altered and new enrollments should be evaluated in this context. Further restrictions may be placed in the near future.		

Specific Recommendations for interactions with clinical trial subjects

For Clinicians	Follow all hospital and specific service line clinical operation standards and SOPs with specific reference to guidelines for social distancing for ***clinicians***.
Recommendation for subjects (patients)	Follow hospital-based recommendations regarding restrictions and screening for ***patients***.
Recommendations for clinical research staff	Limit interaction with subjects as much as possible. Interaction should occur only after the patient has undergone hospital-based screening. Interactions should follow all hospital clinical operation standards and SOPs with specific reference to guidelines for social distancing for ***clinicians***.

Clinical research coordinators who work directly with patients on clinical trials can be classified as "essential" for working on campus, but should practice all recommendations for social distancing and minimize face-to-face interactions. Research staff primarily responsible for data management and those who work on non-trial clinical research studies can be classified as "non-essential" for campus based work and should perform work duties from a remote work location.

In this crisis, we encourage ongoing salary support for clinical research staff and to find appropriate work and work arrangements that accommodate not only hospital and public health recommendations, but also take into account the complex family and technology needs precipitated by this pandemic. We can provide guidance in terms of specific funding agencies and their COVID-19 based policies in this context. Additionally, we will provide clinical research managers with suggestions for work tasks that can be done remotely.

As always, protocol deviations that occur in the context of subject safety are allowable. We expect an increased number of such deviations to arise as a result of limiting subject exposure risks. We once again ask that subjects follow all hospital based recommendations regarding restrictions and screening for ***patients,*** even if this leads to protocol deviations. Please work with sponsors and the BSD IRB regarding deviation reporting and amendments.

External monitors and auditors will need adhere to all restrictions and screening in place for hospital based visitors. We are working on solutions to enhance the ability to conduct remote monitoring.

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 will remain available to address specific questions that may be unique to individual projects/protocols.

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 national, state and local entities provide additional guidance.