# OSUCCC COVID-19 Supplemental Information for Human Subject Research

March 18, 2020

Dear Colleagues,

We are all concerned regarding the health of our community—our patients and study participants, our staff and basically everyone. The messaging has been clear about hygiene and social distancing (better called "physical distancing" since we still want and need to be social, albeit virtually). Until the COVID-19 surge passes, we will do our best to lock down the transmission of the virus. For human subject studies that involve face-to-face contact, that means reducing all contact opportunities short of decreasing subject safety, and in most cases temporarily suspending accrual and withdrawing subjects.

The Office of Research has posted an update to the "Interim Guidance for Human Subjects Research." We will notify you with updates to this policy, but it is your responsibility to check for updates and know the guidance. The guidance can be found at: https://orrp.osu.edu/2020/03/12/interim-ohio-state-guidance-and-faqs-on-human-subjects-related-research-visits-during-covid-19-outbreak/.

For cancer-related studies, interim guidance from the National Cancer Institute for clinical trials supported by the NCI, such as delegation of visits or procedures to local providers or mailing of oral study drugs, see https://ncicirb.org/announcements/memorandum-interim-guidance-patients-clinical-trials-supported-nci-cancer-therapy.

For those of us in the OSUCCC – James, we are reminded of our 320+ hospitalized cancer patients, most of whom are immunocompromised (and of course patients throughout the system). Thus, please avoid going to any of the hospital or clinical locations unless it is absolutely necessary. Working from home is the best idea and should be done unless there is a reason the work cannot be done at home.

Here are some bullet points to remember, developed in the context of the OSU Office of Research Interim Guidance:

- Each and every human subject study should be reviewed and determined to be essential or non-essential. Currently, the determination of whether or not a research visit is "essential to the health and/or well-being" of a participant is determined by the principal investigator of the research study, the participant and the participant's care provider (when applicable).

- Essential research studies that are essential to the participant's immediate health and/or well-being should continue. This is nuanced by study; for example not all cancer therapeutic trials may be essential. Non-essential study examples include studies seeking to improve standard-of-care therapy that only incrementally are considered in the context of the essential need for additional subject contacts, through screening studies and visits, additional visits, blood draws, increased CTO staff contact and increased clinic visit time. For subjects already enrolled, a decision should be made to continue or withdraw a subject.

- All essential studies should be evaluated for reducing face-to-face visits and the foot traffic to the medical center, e.g., eliminating non-essential visits or blood draws within that study. Reconsider parts of studies that are not central to the primary health outcome.

- Research visits should be performed remotely whenever possible. However, essential in-person research visits (e.g., for therapy, evaluation of serious illness/side-effects) may continue.

- The CTO, investigator and sponsor should work together on how to minimize visits, e.g., having blood draws and scans done locally, shipping of oral drugs to the subject, etc.

- Non-essential studies that require face-to-face visits to Ohio State campus facilities should be postponed until further notice. If these studies can be modified to eliminate all face-to-face contacts without substantially affecting the primary outcomes, they can continue with modifications by amendment to the IRB (and deviation reporting until then).

- Protocol deviations should be carefully tracked, documented, reported and dealt with according to guidance provided by the OSU Office of Responsible Research Practices (https://orrp.osu.edu/).

- Any study can be temporarily suspended without IRB notice.

- Please remember to screen all subjects prior to, or at the beginning of, the face-to-face visit. If they have signs or symptoms, then follow medical center protocols. Participants should be provided with information regarding the current COVID-19 pandemic and how best to reduce their risk of infection.

IRB-related questions should be directed to the IRB at ORRPcovid@osu.edu.

Investigators who want advice about suspending or modifying protocols may contact their Disease Specific Group Leader, Dr. Bill Carson (AD for Clinical Research) at william.carson@osumc.edu, or Dr. Peter Shields (Deputy Director, OSUCCC) at peter.shields@osumc.edu.

For more information on COVID-19 and Ohio State-related updates, visit https://wexnermedical.osu.edu/features/coronavirus/staff-and-students and https://wexnermedical.osu.edu/features/coronavirus/patient-care.

Raphael E. Pollock, MD, PhD, FACS
Director, The Ohio State University Comprehensive Cancer Center
Kathleen Wellenreiter Klotz Chair in Cancer Research

Peter G. Shields, MD
Professor and Deputy Director
The Ohio State University Comprehensive Cancer

The James
THE OHIO STATE UNIVERSITY
COMPREHENSIVE CANCER CENTER