

March 18, 2020

To: All Clinical Research Study Sponsors

From: University Health Network (UHN) Research Principal Investigator

Re: Guidance Regarding Clinical Research at the UHN Clinical Research Site in the Context of COVID-19

Dear Industry Colleagues.

In light of the rapidly evolving climate of this pandemic, there have been constantly changing guidelines from our national, regional and institutional authorities to ensure the safety of participants and study staff. This in turn creates a rippling effect on clinical trial conduct both for sites and sponsors. Currently, here is the status as it affects your studies.

Participant Visits

- Patient safety and continuation of care is the priority
- Clinical research patients on active treatment trials will be treated in accordance with current UHN policies and pandemic instructions.
- Participants will be treated and managed based on the investigator's medical judgment using all reasonable efforts to manage patients according to the approved study protocol, with patient safety being paramount.
- There may be changes in how patients are being evaluated for study visits i.e. telephone calls and possibly use of external labs. In light of the urgent need for these changes, they will be implemented prior to formal REB approval . We will document how each visit is managed. REB will be notified of the changes.
- There may be delays in data collection, out-of-window visits and missing data. These will be recorded as study deviations. Understand that working within our policies and pandemic instructions, we will strive to ensure the integrity of the study data, and the safety of our studies by prioritizing safety and landmark investigations such as critical study endpoints.
- Some specialized tests (for example peripheral blood mononuclear cell collection) or specific radiographic assessments may not be possible in light of overall institution policies.
- Research staff will maintain contact with all patients on therapeutic clinical research studies via assessment in person or remotely as clinically indicated.
- Participants who elect to withdraw from studies for personal safety concerns will be counselled and managed accordingly. End of study evaluations cannot be guaranteed.

New Studies

- As per UHN directives, there will be a pause in initiation of new studies. The REB will continue to review new studies as per their capacity but initiation delayed. Exceptions for more urgent review of new protocols that address an unmet clinical need may be requested.
- In keeping with TCPS2 guidelines regarding declared emergencies, (Section 6 D) the REB will escalate and prioritize COVID-19 related projects and amendments.

Active Studies

- REB review and approval of routine, non-safety related amendments may be delayed.
- Recruitment to existing therapeutic trials will continue where safe to do so based on pandemic prioritization guidance and PI assessment. Be aware of possible decreases in enrollment rates in response to imperative cautionary measures to prevent the spread of COVID-19 Virus and potential staffing shortages.
- Accrual and follow-up for non-treatment studies is now on hold unless this can be done remotely.

On-site Visits

- In-person visits, including study monitoring visits are suspended until further notice. Limited remote monitoring and data management review may be completed in lieu of onsite visits
- Under special circumstances external study representatives may be required to attend UHN on site, such as to set up technical or other aspects of a study if it is crucial for the patient to receive necessary therapy. This will be assessed on an individual basis.
- Remote access to electronic medical records for monitors is not possible. Transmission of source documents will be limited.
- Remote monitoring may be possible.

Safety of our study participants and study staff is our utmost concern whilst maintaining the integrity of study protocols. We appreciate your understanding during these difficult times. As the COVID-19 pandemic changes, we will re-evaluate the situation.