

## REVISED OCREB Memo - COVID-19 (Coronavirus) – Collection of infection status and outcome

The Memo was revised to clarify the criteria for the collection of the Covid-19 infection status

OCREB acknowledges the extraordinary impact that the coronavirus is having on the clinical and research environment and the need to collect relevant information about the virus as it affects our participant population.

Due to the concern that oncology patients may be at higher risk for morbidity and mortality if they become infected, especially those who are receiving immunosuppressive therapy or a stem cell (bone marrow) transplant, more information is needed. This information is being generated through standardized testing of patients who are at risk of infection with the guidance of Ontario Health, prior to certain treatments and procedures, which is taking place at many centres.

Criteria for the collection of COVID-19 information for research participants includes the following criteria:

1. Collection of a COVID-19 positive COVID-19 results as part of AE reporting is standard practice for associating an AE with an attribution. Collection of a positive or negative COVID-19 test results as part of a SAE narrative is also considered standard practice (express consent is not required). Capturing COVID-19 status outside of AE reporting requires additional permission.
2. If the sponsor mandates COVID-19 testing for specific research purposes, an amendment to the protocol would be required and new information would be provided to participants to address this change in objectives;
3. New trials do not require the inclusion of information regarding the testing unless the collection of the COVID-19 status are part of the research plan [protocol based].

OCREB is committed to the safety of study participants, and to supporting oncology research teams as much as we can through these challenging times. Please do not hesitate to contact us with any questions. We will do our best to assist your team.



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