COVID-19 IMMUNITY TASK FORCE

Retrospective Consent Guidance

October 29, 2020

Background

This document aims to help researchers determine if Retrospective Datasets can be included in the Canadian Immunity Task Force (CITF) Database. Retrospective Datasets include, for example:

- Datasets that are generated from pre-existing tissue samples (e.g. archival samples, blood samples originally donated for the purpose of transfusion, and other samples originally collected for purposes other than research).
- Datasets that are generated before the creation of the CITF Database.
- Datasets that are created for the purposes of a different research project, which are subject to research consent permissions that may differ from those required to submit data to the CITF.

The coded research data submitted to the CITF will be held in a controlled access database.

- Only accredited researchers that require the data for bona fide research purposes and demonstrate their affiliation to a recognized research institution will be able to access the data.
- Non-identifiable aggregate data generated from the coded research data will be held in a public access database that is available to the broad public. CITF researchers will generate this aggregate data.

The CITF recognizes that external research projects may use different consent language than the CITF. This consent language could be reflective of the time and context in which the data or samples were collected. It could also reflect local or institutional informed consent practices that differ from those of the CITF.

To determine if the ethico-legal permissions applicable to your data are suitable for inclusion in the CITF, it is a recommended best practice to seek guidance from your local Research Ethics Committee (REC), Institutional Review Board (IRB), or equivalent.

The following assessment tool can help you determine if data is subject to appropriate approvals to be included in the CITF Database.

STEP I:

Is there an appropriate authorization in place to generate the intended data from the concerned biological sample or samples? (For example, a valid research ethics consent, a research ethics committee waiver of consent requirement, or an applicable regulatory or statutory authorization allowing for the contribution of the data).

- If the question is **Not Applicable** because the biological sample has already been analyzed and the concerned data has already been derived, please proceed to **STEP II**. Further, if all of the data concerned is survey data or other data that has not been generated from a biological sample, please proceed to **STEP II.**
- If the answer is **Yes**, please proceed to **STEP II.**
- If the answer is **No,** the tissue sample cannot be used to generate data for the CITF without first obtaining an appropriate approval or ethics waiver. Proceed to **STEP III.**

STEP II:

Question 1: Has the sample donor or research participant provided informed consent to general research use:

Does the consent form indicate that:	Yes	No
a) Data can be used for any future, unspecified research purpose?		
b) Data will be shared through a registered access or controlled access database that allows researchers in any part of the world to access the data for any approved research purpose?		

- **If you have answered yes to <u>both</u> questions**, your datasets can be deposited in the CITF Database.
  (Please note that some institutional policies may require local ethics committee approval, or other regulatory approval, before data can be deposited in the CITF Database).
- **If you have answered no to either question,** please proceed to Question II, below.

Question 2: Has the sample donor or research participant provided informed consent to all of the following:

The informed consent form or other valid record of consent indicates consent to the following:	Yes	No
a) The intended serological, immunological, and other tests can be performed using the collected samples?		
b) Data will be shared internationally?		
c) Data may be stored on centralized servers including outside the province or country of collection, and on cloud servers.		
d) Data will be stored for an indefinite period of time?		
e) The withdrawal of data is not possible if already used or published.		
f) There is a possible risk of re-identification in the future? g) Data can be used to perform future health research on COVID-19 and related health outcomes?		
h) Data can be used for commercial research purposes? i) Coded data can be shared with approved researchers through a controlled access mechanism? j) Public sharing of anonymized or aggregated data?		

- **If you have answered yes to all of the above,** your data can be deposited directly in the CITF database.

- **If you have answered no to any of the above**, please proceed to **Step III** to determine if re-consent of donors is possible, or whether a consent waiver should be obtained from the appropriate research ethics committee or equivalent body.

Step III:

Question 1:

Re-contact / re-consent	Yes	No
a) Does your consent form or other applicable local policy allow for re-contact of donors/research participants?		
b) Is it feasible for you to re-contact and re-consent your donors/research participants for inclusion in the CITF Database?		

- **If you have answered yes to <u>both</u> questions**, please re-contact and re-consent the donors and include the CITF Minimum Required Consent Elements in your consent materials. The CITF Model Informed Consent Materials can be used to obtain this consent.

- **If you have answered no to either question**, please proceed to **Question II,** below.

Question 2:

Consent waiver	Yes	No
a) Is it possible for you to apply to a local ethics committee (or equivalent) to obtain a waiver of consent requirement to deposit your dataset in the CITF Database?		
b) Is it possible for you to apply to a local ethics committee (or equivalent) to obtain an authorization to "anonymize"/de-identify the data to deposit it in the CITF Database?		

- **If you have answered yes to <u>either</u> questions**, please request and obtain a consent waiver according to your local procedures, or "anonymize"/de-identify your dataset following local requirements.
- **If you have answered no to both questions**, your data cannot by deposited in the CITF Database.