COVID-19 IMMUNITY TASK FORCE

Prospective Consent Guidance

October 7, 2020

Background

The Canadian Immunity Task Force (CITF) draft informed consent materials are structured as follows.
First, there are a series of **Minimum Required Consent Elements** for contributing studies funded by the CITF as well as for external studies that intend to contribute data to the CITF Database.
Second, there is a CITF **Model Informed Consent Form**. This consent form explains the CITF database and its intended data use and data sharing practices. It is a recommended best practice to provide prospective research participants with the CITF Model Informed Consent Form.
Third, the **CITF Principles** have been reproduced in Appendix A. CITF research is intended to be conducted in compliance with the CITF Principles.

Minimum Required Consent Elements

To deposit datasets in the **COVID-19 Immunity Task Force Database**, research consent should be obtained for:
Collection of study data from research participants (survey data and sample data): **Survey data:** COVID-19 infection status, health condition, social distancing practices, demographic information (age, sex, gender, ethnicity, education, etc.), lifestyle, living conditions, and travel habits. **Sample data:** Blood sample analysis results including serological and immunological testing for COVID-19 and related health outcomes.
Sharing of coded study data with approved researchers through a controlled-access mechanism.
International sharing of study data.
Future health research on COVID-19 and related health outcomes.
Use of the study data for commercial and non-commercial research purposes.
Public sharing of anonymized or aggregated data.
Possible storage of study data on centralized servers including outside the province of collection, and on cloud servers.
Indefinite storage of the study data collected.
Withdrawal of study data not possible if already used or published.
Low risk that the participant could be re-identified in the future.

Model Informed Consent Form CITF

The CITF is a national initiative funded by the Government of Canada to perform research related to COVID-19 immunization. The CITF will collect data to share with researchers in Canada and internationally so as to understand the science underlying COVID-19 immunity, COVID-19 infection rates in the Canadian population, and to study related health outcomes.

The CITF studies will be performed in compliance with the CITF Principles. These are twelve guiding principles that are intended to ensure the effective, equitable, and transparent conduct of research. The CITF Principles can be consulted on the CITF website.

What data will be collected about me?

The research team will ask you to complete a survey and answer questions about your COVID-19 infection status, health condition, social distancing practices, demographic information (age, sex, gender, ethnicity, education, etc.), lifestyle, living conditions, and travel habits.

If you do not understand a question, you may ask the study staff for clarification or help.

What samples will be collected from me?

A blood sample [SPECIFY QUANTITY (tbsp)] will be collected from you by the study staff. You may feel slight physical pain or discomfort caused by the blood draw.

What data will be derived from my samples?

The research team or an external laboratory will derive analysis results from your blood sample. Blood sample analysis results include serological and immunological testing for COVID-19, and analysis results concerning related health outcomes.

What data will be included in the CITF Database?

Survey data about your COVID-19 infection status, health condition, social distancing practices, demographic information (age, sex, gender, ethnicity, education, etc.), lifestyle, living conditions, and travel habits will be included.

The CITF will also receive the results of the blood sample you provided, that is, immune response data relating to COVID-19. Other baseline health measurements collected about you may also be provided to the CITF.

How will my data be stored?

The data provided to the CITF will be stored on the CITF Database. The data on the CITF Database will be held under the custodianship of McGill University or one of its collaborators and be shared via the cloud, both nationally and internationally.

For how long will my data by stored?

The data on the CITF Database will be stored indefinitely, or, until it is no longer useful for research, or, an ethics committee decides otherwise.

How will my privacy be protected?

No directly identifying information will be provided to the CITF, nor included in the CITF Database. Your identifiers, such as your name and civic address, will be replaced with a code.

Your data in the CITF Database can be used by researchers outside of the province in which you are located, or in other countries following Data Access Committee (DAC) approval. These transfers will also be made in compliance with Canadian law and research ethics.

A DAC will be responsible for reviewing applications for access to your data and for approving applications that respect the privacy and access policies of the CITF.

How will my data be kept secure?

Your data will be protected using current security safeguards.

However, there remains a minimal risk that the security of your data could be compromised. This could happen if there is a malicious or inadvertent breach of security measures.

What data will be made available to the public?

Data that has either been anonymized (i.e. you cannot be identified), or aggregated (i.e. is accumulated with the data of others), may be made open to the public using a website that anyone can access.

How will my data be made available to researchers?

The CITF will share your coded data with researchers in Canada and internationally. Your coded data will be shared with researchers performing for-profit research and non-profit research. The data will be used to perform research concerning COVID-19 and related health outcomes.

Your data may be used alone or in combination with other data, including other health data. The DAC will ask researchers to confirm that their intended research activities have received necessary ethics approvals.

Your data may also be shared with other COVID-19 research databases that follow similar protections and procedures as the CITF Database.

What information will I receive about the research performed?

[INSERT INFORMATION ABOUT MAIN STUDY PRACTICES REGARDING THE RETURN OF RESEARCH RESULTS AND RETURN OF INCIDENTAL FINDINGS, IF OFFERED BY YOUR STUDY]

The analysis of your sample and data performed by the CITF and by external researchers are for research purposes only and are not intended to be relied on for healthcare purposes. You will not receive any of your test or analysis results.

General information about the research performed by researchers using the CITF data will be made available on the CITF website. Further, the results of such research will be disseminated in academic publications and at academic conferences, amongst other venues. It will not be possible to identify you in any of these publications.

What are the benefits to me?

Participation in the CITF Database is not likely to provide a direct benefit to your health or well-being. It is possible that the research produced will lead to the creation of new treatment options from which you and others might eventually benefit.
Participation in the CITF will help collect accurate data about COVID-19 immunization that will potentially help in the creation of treatments or otherwise improve the quality of COVID-19 healthcare delivery.

What are the risks of participating in this research?

Informational Risks

There remains a minimal risk that the inclusion of your study data in the CITF Database may lead to the disclosure of your identity. This could happen if there is a malicious or inadvertent breach of the CITF Database's security measures. This could also happen if your data is combined with other sources of data to produce new information.

If there is a data privacy breach, it is possible that the data released can cause you to experience discrimination or adverse treatment by employers, insurers, or other individuals.

What happens if I withdraw my consent?

You are free to withdraw your consent to research at any time, even after the research has been completed. To withdraw your consent, you should contact the [MAIN STUDY INSTITUTION] using the contact information provided in this consent form.

If you withdraw your consent to participate in this research, [MAIN STUDY INSTITUTION] will contact the CITF, which will remove your data from the CITF Database.

If some of the data have been shared with other researchers or published, it may not be possible to remove this part of the data.

Will I receive compensation or reimbursement for my participation in research?

No compensation will be paid for participation, and no expenses incurred in participating will be reimbursed.

Research conducted using the data that you have contributed may lead to the creation of new diagnostic tests, drugs, treatments, methods, or other products that are commercial or proprietary. If this occurs, you will not be notified, and you will not receive any share of the profits derived from the sale, use, or commercial exploitation thereof.

What are my rights as a participant in this research?

By agreeing to participate in this research, you do not give up any of your legal rights against the Principal Investigator, the involved research institutions, or the CITF.

Who may I contact with regard to this research?

The study protocol and consent materials related to this research project have been reviewed by the Research Ethics Board of the local research institution. You may contact the Research Ethics Board that conducted the research with inquiries at this phone number.

Appendix A: CITF Principles

The COVID-19 Immunity Task Force embraces the following principles and practices:

1. Partner in all of its work with the Government of Canada and provincial/territorial governments and their agencies, as well as the research community, public health and healthcare professionals/institutions, and a range of community groups
2. Identify priority issues related to serologic testing and its application, paying close attention to diverse needs for information across the country
3. Establish an ethos in which the rigorous gathering and rapidly sharing of data to inform Canadians and to advance the broad public interest over-rides any considerations of personal/group advancement
4. Mobilize the best science and study designs, recognizing the rapidly evolving state of the science related to serologic testing and to the understanding of SARS-CoV-2 immunity
5. Establish fair and transparent processes consistent with principles of equity, diversity, and inclusion (EDI) that offer all interested partners across the country an opportunity to participate in the Task Force, while appropriately managing conflicts of interest
6. Work with partners to ensure protection of privacy in data-gathering and safe handling of any and all biological samples
7. Collaborate with partners and use existing data- and sample-gathering capacity wherever possible to enhance cost-efficiencies and avoid unnecessary duplication
8. Provide a central coordination for the Task Force that facilitates rapid development of studies, their effective implementation, and rapid reporting of results to key audiences, including decision makers and interested stakeholders, and the broad Canadian public
9. Promote ethical and sound participatory practices that engage relevant stakeholders from study design through to dissemination and application of findings
10. Adhere to best practices regarding any authorship of scientific publications eventually arising from this work, while ensuring that all participants understand that this work is in the public interest, requiring rapid dissemination of reliable and relevant results
11. Liaise with relevant entities in other countries and with international agencies involved in serologic surveys and studies to understand immunity related to SARS-CoV-2
12. Communicate the leadership, membership, activities and results of the Task Force with openness and transparency.