DATA SHARING AGREEMENT

(herein "Agreement")

BETWEEN: [ORGANIZATION] a corporation under the laws of [JURISDICTION] having its principal place of business at [ADDRESS] (herein "**Provider Institution**")

AND: Prof. [NAME OF SCIENTIST] (herein "**Provider Scientist**")

(Provider Institution and Provider Scientist are collectively referred to as "**Provider**")

AND: The Royal Institution for the Advancement of Learning/McGill University having a principal place of business at 845 Sherbrooke Street West, James Administration Building, Montréal, Québec, H3A 0G4 (hereinafter referred to as "**Recipient Institution**") on behalf of COVID-19 Immunity Task Force (herein "**CITF**") Secretariat, hosted at McGill University

Dr. David Buckeridge (herein "**Recipient Scientist")**

AND: (Recipient Institution and Recipient Scientist are collectively referred to as "**Recipient**")

(Provider and Recipient are hereinafter referred to individually each as a "**Party**" and collectively as the "**Parties**")

WHEREAS Recipient was provided with funding from the Government of Canada through a Contribution Agreement signed on May 29, 2020, to support the activities of the CITF to measure the scope of coronavirus infection in Canada and rapidly provide information needed to manage the COVID-19 pandemic;

WHEREAS the Provider is the recipient of funds from [the Government of Canada through the Public Health Agency of Canada (PHAC)/the Canadian Institutes for Health Research (CIHR)/Other] to carry out the project [NAME OF PROJECT] as described under Appendix 1 (herein "**Research Project**");

WHEREAS the Recipient through the CITF Secretariat, is mandated to coordinate multi-site sero-surveys assessing COVID-19 immunity in the Canadian population and to provide regular scientific updates to the Government of Canada on the state of serologic testing and the evolving understanding of immunity related to SARS-CoV-2 (herein "**Study**");

WHEREAS the Study will include the creation of a database where the Data that is shared by Provider with Recipient will be centralized, harmonized, and stored (herein "**CITF Database)** as defined in the Framework to support the Study (herein "**CITF Data**").

WHEREAS the CITF Data will be securely made available to third parties through the access framework for further research;

WHEREAS Recipient has established the organizational structure, technical elements, and operational policies fundamental to the CITF's mandate as per Appendix 3, the CITF Data Governance Framework (herein "**Framework**");

WHEREAS the Provider is willing to provide Recipient for use in the Study certain data arising from the Research Project as per the terms and conditions set out in this Agreement.

NOW THEREFORE THIS AGREEMENT WITNESSETH that in consideration of the premises and covenants set out in this Agreement, the Parties agree as follows:

1. DEFINITIONS.

In this Agreement, the following words have the following definitions:

1.1. **"Data"** means all personal data (including without limitation medical data and information and other personal health information) and non-personal data and associated metadata that has been collected for the purpose of the Research Project by Provider to Recipient for the purpose of carrying out the Study, as further set out in Appendix 2. The Data will have direct identifiers removed and Provider will code the data where the key for participants identification will only be held by the Provider;

1.2. **"Controlled Access"** means Data that will be held securely and access will only be made available through CITF-approved requests that are in compliance with Framework;

1.3. **"Open Access"** means Data that will be made freely available, to be used and republished;

1.4. "**Effective Date**" means the date upon which the Agreement becomes effective and corresponds to date of the last signature to the Agreement;

2. PROVIDER'S OBLIGATIONS

2.1. Provider shall provide the Data to Recipient to be centralized, harmonized and stored in the CITF Database as further set out in the Framework. The Data shall be provided in accordance with the milestones/deliverables set out in Appendix 1.

2.2. Provider represents and warrants having the necessary authority to share the Data with Recipient in accordance with this Agreement and, without limiting the generality of the foregoing, the Framework. Provider will prepare and furnish Data in accordance with all applicable laws, regulations, guidelines and policies, including, but not limited to laws regarding the privacy or protection of personal or medical information and the Quebec Act Respecting Access to Documents Held by Public Bodies and the Protection of Personal Information ("**Applicable Law**"). Provider has obtained all appropriate participant consents including as described in the Framework. Data will not be collected and/or transferred until Provider's research ethics board

("**REB**") and, if applicable Provider's third-party REB and Recipient's REB, have: a) approved the Research Project protocol, including the transfer of the Data to Recipient for inclusion in the CITF Database; and b) approved the Research Project informed consent forms or waived the requirement to obtain consent.

2.3. Upon transfer of the Data from Provider to Recipient in accordance with the Framework, the Provider will have to acknowledge and agree to the terms of a data sharing agreement.

3. RECIPIENT'S OBLIGATIONS

3.1. Recipient shall only use the Data in compliance with this Agreement and the Framework. Without limiting the generality of the foregoing, Recipient shall not use the Data to attempt to identify or make contact with any of Provider's research participants.

3.2. Recipient, will safeguard the Data in a secure infrastructure physically Gilocated in Canada, or in another secured database in compliance with the Framework and Applicable Law. If CITF were to become inactive, Recipient will be able to transfer the Data to a third party organization for its long-term safekeeping and preservation. This transfer will be subject to a new agreement between Recipient and such third-party organization in compliance with the Framework and Applicable Law.

3.3. Recipient will use reasonable efforts to maintain the confidentiality of the Data and to prevent any unauthorized access, reproduction, disclosure and/or use of the Data. Notwithstanding the above, Provider acknowledges and agrees that the Data and CITF Data may be accessed by third parties for defined uses consistent with the mandate of CITF as more fully described in the Framework, for example, through Controlled Access, and/or Open Access. In addition, Recipient may transfer the Data:

(i) to regulatory authorities, provided that the Recipient gives prior written notice of such intended disclosure to Provider;

(ii) in order to comply with Applicable Law or judicial process, or with a court or regulatory order, provided that Recipient gives prior written notice of such intended disclosure to Provider and takes all lawful actions that are reasonable in the circumstances to minimize the extent of such disclosure and obtain confidential treatment for such disclosure.

3.4. In the event of an actual or reasonably suspected breach of confidentiality, or unauthorized disclosure by mistake or otherwise of Data, Recipient shall promptly give written notice of such to the Provider and shall work with Provider to prevent further disclosure and limit potential damages caused by such disclosure.

4. DISCLAIMER AND LIABILITY

4.1. Except as expressly set out herein, neither Party makes any representations, warranties, conditions or liabilities expressed or implied herewith in relation to any matter hereunder.

4.2. Neither Party shall be liable to the other for indirect or consequential damages.

5. INTELLECTUAL PROPERTY AND RELATED RIGHTS

5.1. The Provider hereby agrees that the Data be treated in accordance with the intellectual property and related rights as described in the Framework. The Provider hereby waives any right to claim any interest in any intellectual property rights that may arise out of use of the Data by third parties pursuant to the Framework.

6. PUBLICATION.

6.1. Any communication with the CITF Secretariat will be as per Section 16, Notices. Provider Institution and Provider Scientist acknowledge that CITF Secretariat may publicize the projects and investigators it supports through the internet, social media, press releases, printed materials released to the public, public reports, speeches, newsletters, and other media, as well as in marketing and promotional materials, in accordance with applicable laws.

6.2. The Provider Scientist agrees to submit, in a timely manner, such information, written material, images, photographs, video, or other content related to the Research Project (the "**Publicity Content**") as may be reasonably requested by the CITF Secretariat to contribute to these publicity efforts. The Provider Scientist consents to the publication of her/his name, as well as names of all co-applicants and collaborators, the title of the Research Project, and the amount of the award, and event photos in association with this award (e.g. on the CITF website).

6.3. The Provider Scientist acknowledges and agrees that (i) all information in submitted Publicity Content shall be accurate, (ii) the Provider Scientist shall notify the CITF Secretariat of any subsequent change that renders such information materially inaccurate, (iii) the Provider Scientist shall notify the CITF Secretariat in writing of any credits that are required to be associated with the Publicity Content, and (iv) any persons that are individually identifiable in the submitted Publicity Content (or, for persons under the legal age of consent in the applicable jurisdiction, their parents or guardians) shall have consented to the uses contemplated herein. Recipient acknowledges that Provider Scientist and/or Provider Institution may also publicize the Research Project on its website, intranet and/or internal newsletters, in accordance with Provider Institution's internal policies and procedures and applicable laws.

6.4. The Provider Scientist shall have the right to publish the results of, or accounts of, the Project. While there is no mandatory requirement for notification of publication or review of publication from funded studies by the CITF to the CITF Secretariat, bi-directional communication is strongly encouraged to support common interpretation of the Data and coordinated public health messaging. More specifically:

6.4.1. The CITF Secretariat will establish a process for providing feedback on manuscripts. Provider Scientist can notify the CITF Secretariat of intent to publish and the CITF Secretariat will endeavor to review the manuscript and highlight any issues that may benefit from discussion.

6.4.2. The CITF Secretariat will also endeavor to engage with Provider Scientist around analyses to synthesize core data elements drawn from multiple studies that have data.

6.4.3. Researchers accessing centralized core data elements from the CITF Data Access Committee (DAC) will not be required to notify the CITF regarding publications.

6.5. The following acknowledgment shall be included in any publications that result from or in relation to the Project that received funding from the CITF "*This project was supported by funding from the Government of Canada, through the COVID-19 Immunity Task Force./ Ce projet a été soutenu par un financement du Gouvernement du Canada, par le biais du Secrétariat du groupe de travail sur l'immunité COVID-19"* unless the McGill CITF Secretariat has advised otherwise. The Parties agree that any scientific publication made pursuant to this Agreement shall be made in accordance with the custom of scientific research and shall acknowledge the contribution of the Parties' scientists, as appropriate. Specifically for

third-party users that are not funded studies by the CITF and have requested and received approval to access centralized core data elements from the DAC, these third-party users will attribute the CITF in publications where the attribution could be a link to a dynamic list of studies contributing data to the CITF, or by citing a central marker paper describing the work and authored by CITF Secretariat individuals that includes Principal Investigators from contributing studies.

7. TERM.

7.1. The term of this Agreement shall be as per Appendix 1 and provisions for survival will be as per Section 12.

7.2. Provider may request withdrawal of the Data in the following manner:

- 7.2.1. there is a research participant or sample donor withdrawal request for their own personal data;
- 7.2.2. there is a change in the data custodian and the data governance conditions established in Framework;
- 7.2.3. CITF ceases to exist;

Notwithstanding the above, Data that has already been shared with third parties external to the CITF will not be withdrawn from such third parties; and Data that is being used by a research study, the destruction of which would compromise the integrity of that research study, will not be destroyed from the CITF Database until after the research study is completed, to preserve the scientific integrity of the concerned research.

8. NOTICES. All notices: (a) shall be in writing and shall be deemed to have been given on the date they are: (i) delivered by hand; (ii) received from any reputable delivery service that provides tracking and written verification of delivery; or (iii) transmitted by e-mail, all if given on a business day prior to 5:00 pm failing which they shall be deemed to be given, delivered or made the next business day; (b) shall be given at the following addresses or at such other address as may be indicated by one party to the other by notice as aforesaid:

If to CITF Secretariat:

Olivia Oxlade
Associate Scientific Director (Management)
Email: olivia.oxlade@mcgill.ca

With a copy to McGill:

McGill University
Office of Sponsored Research
James Administration Building
845 Sherbrooke W., 2nd floor
Montreal Quebec, H3A 0G4
Attn: Carole Goutorbe
Associate Director Awards Management
Email: carole.goutorbe@mcgill.ca

If to Provider Institution: To be completed

with a copy to Provider Scientist: To be completed

9. USE OF NAME. Provider shall not use Recipient's name or trademark or any adaptation thereof without the prior written consent of its duly authorized representative.

10. WAIVER OF RIGHTS. No waiver or failure by the Parties to enforce their right or insist on strict performance of this Agreement shall be deemed to prevent the Parties from subsequently enforcing their rights or insist on strict performance under the Agreement. No waiver or failure to strictly enforce rights shall affect the validity of this Agreement.

11. SEVERABILITY. The invalidity or unenforceability of any provision of this Agreement shall not affect the validity or enforceability of the Agreement itself or any of its provisions.

12. SURVIVAL. The provisions of sections 3, 4, 5, 6, 7.2 and 9, shall survive the termination of this Agreement with section 3 surviving termination of this Agreement until CITF ceases to exist.

13. ASSIGNMENT. Neither Party shall have the right to assign this Agreement without the written consent of the other Party. Such consent shall not be unreasonably withheld.

14. HEADINGS. The headings contained in this Agreement are for convenience and reference only and shall not define or limit the scope, or affect the interpretation of, its provisions.

15. AMENDMENTS. Any modification to this Agreement shall be agreed to in writing and approved by an authorized representative of the Parties.

16. COUNTERPARTS. This Agreement may be executed in one or more counterparts, each of which together shall constitute one and the same Agreement. For purposes of executing this Agreement, a facsimile (including a PDF image delivered via email) copy of this Agreement, including the signature pages, will be deemed an original.

17. LANGUAGE. *Les Parties ont requis que cette entente soit rédigée en anglais.* The Parties have requested that this Agreement be drafted in English.

18. GOVERNING LAW. This Agreement shall be governed by the laws of Québec, and Canadian laws applicable therein without regard to their provisions on conflict of Law.

[The remainder of the page is blank. Signature page follows.]

IN WITNESS WHEREOF Provider and Recipient have caused this Agreement to be executed in duplicate by their respective duly authorized representatives.

The Royal Institution for the Advancement of Learning/McGill University

By its authorized signatory:

X_____

Name: Carole Goutorbe
Title: Associate Director, Office of Sponsored Research
Date:

Acknowledgment

I, Dr. David Buckeridge, Scientific Lead Data Management, CITF Secretariat, having read and understood this Agreement, hereby agree to act in accordance with all the terms and conditions herein and further agree to ensure that all Provider participants are informed of their obligations under said terms and conditions.

X_____

Dr. David Buckeridge
Scientific Lead Data Management, CITF Secretariat

[Organization]

By its authorized signatory:

X_____

Name: [ORGANIZATION SIGNATORY]
Title: [TITLE]
Date:

Acknowledgment

I, [SCIENTIST], having read and understood this Agreement, I hereby agree to act in accordance with all the terms and conditions herein and further agree to ensure that all Recipient participants are informed of their obligations under said terms and conditions.

X_____

[SCIENTIST 1]

Appendix 1

Description of Research Project

[Please provide a detailed description of the research project: (use additional pages as needed)]

This Appendix must have the following minimal information which is referred to in this Agreement:

- Scope of Work, (the technical and scientific description of the Project);
- Deliverables
- Responsibilities and duties of Scientific Coordinators;
- Time schedule, including any milestones;

Appendix 2

Description of Core Data Elements and Associated Metadata

COVID-19 IMMUNITY TASK FORCE | GROUPE DE TRAVAIL SUR L'IMMUNITÉ FACE À LA COVID-19

Appendix 2: CITF Core Data Elements, cross-sectional studies, Version 2

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
-	00	Unique participant's identifier	string	single	Guidelines will be provided	-
DEMOGRAPHIC	01	Date of interview	date	single	"YYYY-MM-DD"	Date of interview
DEMOGRAPHIC	02.a	Age of participant (years)	numerical	single	[0, 120]	What is your age
DEMOGRAPHIC	02.b	Age of participant (months)	numerical	single	[0, 11]	What is your age
DEMOGRAPHIC	02.c	Age of participant PNA				What is your age
DEMOGRAPHIC	03	Sex at birth of participant	categorical	single	{01-MALE, 02-FEMALE, 03-PREFER TO SELF-DESCRIBE, 99-PREFER NOT TO ANSWER}	What was your assigned sex at birth
DEMOGRAPHIC	03.a	Sex at birth self-description	string	single		(specify)
DEMOGRAPHIC	04	Current sex of participant	categorical	single	{01-MALE, 02-FEMALE, 03-PREFER TO SELF-DESCRIBE, 99-PREFER NOT TO ANSWER}	What is your sex now
DEMOGRAPHIC	04.a	Current sex self-description	string	single		(specify)
DEMOGRAPHIC	05	Gender of participant	categorical	single	{01-MAN, 02-WOMAN, "03-NON-BINARY, GENDERQUEER, AGENDER OR A SIMILAR IDENTITY", 04-TWO-SPIRIT, 05-PREFER TO SELF-DESCRIBE, 99-PREFER NOT TO ANSWER}	What is your gender (How do you currently self-identify)
DEMOGRAPHIC	05.a	Gender self-description	string	single		(specify)
DEMOGRAPHIC	06	Indigenous identity of participant	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Are you an Indigenous person originating from North America
DEMOGRAPHIC	07	Indigenous group	categorical	multiple	{01-FIRST NATIONS, 02-INUIT, 03-MÉTIS, 04-NON-STATUS FIRST NATIONS, 05-OTHER INDIGENOUS, 99-PREFER NOT TO ANSWER}	Which of the following groups do you belong to [SELECT ALL THAT APPLY]
DEMOGRAPHIC	07.a	Other indigenous group specification	string	single		(specify)
DEMOGRAPHIC	08	Reserve occupation	categorical	single	{01-YES, 02-NO, 99-PREFER NOT TO ANSWER}	Do you live on reserve
DEMOGRAPHIC	09	Ethnicity of participant	categorical	multiple	{01-WHITE, 02-SOUTH ASIAN, 03-CHINESE, 04-BLACK, 05-FILIPINO, 06-LATIN AMERICAN, 07-ARAB, 08-SOUTHEAST ASIAN, 09-WEST ASIAN, 10-KOREAN, 11-JAPANESE, 12-PREFER TO SELF-DESCRIBE, 99-PREFER NOT TO ANSWER}	How would you describe your ethnicity or race [SELECT ALL THAT APPLY] If you are an Indigenous person and answered YES to question 6, select any other that apply.
DEMOGRAPHIC	09.a	Other ethnicity specification	string	single		(specify)
DEMOGRAPHIC	10	Postal code of participant's address	string	single	"\w\d\w" (three-character pattern: letter-digit-letter)	What are the first three digits of your postal code
DEMOGRAPHIC	10.a	Postal code PNA	categorical	single	99-PREFER NOT TO ANSWER	What are the first three digits of your postal code
DEMOGRAPHIC	11	Level of education of participant	categorical	single	{01-LESS THAN HIGH SCHOOL GRADUATION, 02-HIGH SCHOOL GRADUATION, "03-TRADE CERTIFICATE, VOCATIONAL SCHOOL, OR	What is the highest level of education you have completed

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
					APPRENTICESHIP TRAINING", "04-NON-UNIVERSITY CERTIFICATE OR DIPLOMA FROM A COMMUNITY COLLEGE, CEGEP", 05-UNIVERSITY BACHELOR'S DEGREE, 06-UNIVERSITY GRADUATE DEGREE (SUCH AS A MASTERS OR DOCTORATE), 99-PREFER NOT TO ANSWER}	
DEMOGRAPHIC	12	Number of residents in household	numerical	single	[1, 20]	How many people live in your household, including yourself
DEMOGRAPHIC	12.a	Number of residents in household PNA	categorical	single	99-PREFER NOT TO ANSWER	How many people live in your household, including yourself
DEMOGRAPHIC	13	Number of bedrooms in household	numerical	single	[0, 20]	How many bedrooms in your household
DEMOGRAPHIC	13.a	Number of bedrooms in household PNA	categorical	single	99-PREFER NOT TO ANSWER	How many bedrooms in your household
DEMOGRAPHIC	14	Number of bathrooms in household	numerical	single	[0, 20]	How many bathrooms in your household
DEMOGRAPHIC	14.a	Number of bathrooms in household PNA	categorical	single	99-PREFER NOT TO ANSWER	How many bathrooms in your household
COVID-19	15	Participant's COVID-19 self-assessment	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Do you think you have had COVID-19
COVID-19	16	Participant's COVID-19 self-assessment: reason for suspect COVID	categorical	multiple	{01-SYMPTOM REVIEW ONLINE, 02-SYMPTOM PROFILE, "03-NASAL/THROAT TEST RESULT", 04-HEALTH CARE PROVIDER, 05-CONTACT WITH CASE, 06-OTHER (SPECIFY), 99-PREFER NOT TO ANSWER}	Why do you think you have had COVID-19 [SELECT ALL THAT APPLY]
COVID-19	16.a	Other reason for COVID self-assessment specification	string	single		(specify)
COVID-19	17	Participant's hospitalization due to COVID-19	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Were you hospitalized due to COVID-19
COVID-19	18	Participant's previous COVID-19 testing	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Have you ever been tested for an active COVID-19 infection (using nasopharyngeal, throat swab, saliva or gargle test)
COVID-19	19	Participant's number of previous COVID-19 tests	numerical	single	[1, 1000]	If Yes, how many times have you been tested
COVID-19	19.a	Participant's number of previous COVID-19 tests PNA	categorical	single	99-PREFER NOT TO ANSWER	If Yes, how many times have you been tested
COVID-19	20.1					Answer the following questions about the first test (if applicable):
COVID-19	20.1.a	Date of 1st COVID-19 test	date	single	"YYYY-MM"	What was the date of the first test

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
COVID-19	20.1.b	Result of 1st COVID test	categorical	single	{01-POSITIVE, 00-NEGATIVE, 98-UNKNOWN}	What was the result of the first test
COVID-19	20.1.c	Participant's COVID-19 symptom status (1st test)	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW}	Did you have any symptoms of COVID when you had this test
COVID-19	20.1.d	Participant's COVID-19 symptoms (1st test)	categorical	multiple	{01-COUGH, 02-FEVER, 03-SHORTNESS OF BREATH, 04-SORE MUSCLES, 05-HEADACHE, 06-SORE THROAT, 07-DIARRHEA, 08-DECREASED SENSE OF SMELL OR TASTE, 09-OTHER (SPECIFY), 99-PREFER NOT TO ANSWER}	(specify)
COVID-19	20.1.e	Participant's COVID-19 other symptoms (1st test)	string	single		If yes, what symptoms did you have: OTHER [SPECIFY]
COVID-19	20.2					Answer the following questions about the second test (if applicable):
COVID-19	20.2.a	Date of 2nd COVID-19 test	date	single	"YYYY-MM"	What was the date of the second test? [IF APPLICABLE]
COVID-19	20.2.b	Result of 2nd COVID test	categorical	single	{01-POSITIVE, 00-NEGATIVE, 98-UNKNOWN}	What was the result of the second test? [IF APPLICABLE]
COVID-19	20.2.c	Participant's COVID-19 symptom status (1st test)	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW}	Did you have any symptoms of COVID when you had this test
COVID-19	20.2.d	Participant's COVID-19 symptoms (1st test)	categorical	multiple	{01-COUGH, 02-FEVER, 03-SHORTNESS OF BREATH, 04-SORE MUSCLES, 05-HEADACHE, 06-SORE THROAT, 07-DIARRHEA, 08-DECREASED SENSE OF SMELL OR TASTE, 09-OTHER (SPECIFY), 99-PREFER NOT TO ANSWER}	If yes, what symptoms did you have [SELECT ALL THAT APPLY]
COVID-19	20.2.e	Participant's COVID-19 other symptoms (1st test)	string	single		(specify)
COVID-19	20.3					Answer the following questions about the third test (if applicable):
COVID-19	20.3.a	Date of 3rd COVID-19 test	date	single	"YYYY-MM"	What was the date of the third test? [IF APPLICABLE]
COVID-19	20.3.b	Result of 3rd COVID test	categorical	single	{01-POSITIVE, 00-NEGATIVE, 98-UNKNOWN}	What was the result of the third test? [IF APPLICABLE]
COVID-19	20.3.c	Participant's COVID-19 symptom status (1st test)	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW}	Did you have any symptoms of COVID when you had this test
COVID-19	20.3.d	Participant's COVID-19 symptoms (1st test)	categorical	multiple	{01-COUGH, 02-FEVER, 03-SHORTNESS OF BREATH, 04-SORE MUSCLES, 05-HEADACHE, 06-SORE THROAT, 07-DIARRHEA, 08-DECREASED SENSE OF SMELL OR TASTE, 09-OTHER (SPECIFY), 99-PREFER NOT TO ANSWER}	If yes, what symptoms did you have [SELECT ALL THAT APPLY]

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
COVID-19	20.3.e	Participant's COVID-19 other symptoms (1st test)	string	single		(specify)
COVID-19	20.4.a	Participant's other test positive status	categorical	single	{NO, YES}	Have you tested positive for COVID-19 (using nasopharyngeal, throat swab, saliva or gargle test) on a test that wasn't included in the questions above (that is, on the 4th or later test)
COVID-19	20.4.b	Other positive test date	date	single	"YYYY-MM"	If yes, what was the date the first time you tested positive?
EXPOSURE	22	Participant's travel history outside province before January 2020	categorical	single	{01-YES, 02-NO, 99-PREFER NOT TO ANSWER}	Have you travelled outside of your home province since January 2020
EXPOSURE	22.a	Participant's travel history outside province before symptoms	categorical	single	{01-YES, 02-NO, 99-PREFER NOT TO ANSWER}	If you think you have had COVID, did you travel in the 6 months before your symptoms began?
EXPOSURE	23	Participant's travel history by geographic location	categorical	multiple	Provinces: {02-BRITISH COLUMBIA, 01-ALBERTA, 12-SASKATCHEWAN, 03-MANITOBA, 09-ONTARIO, 11-QUEBEC, 04-NEW BRUNSWICK, 07-NOVA SCOTIA, 10-PRINCE EDWARD ISLAND, 05-NEWFOUNDLAND AND LABRADOR, 08-NUNAVUT, 06-NORTHWEST TERRITORIES, 13-YUKON}	What province or country did you travel to [SELECT ALL THAT APPLY]
EXPOSURE	23.a	Participant's travel history by geographic location	categorical	multiple	Countries: ISO 3166-1 (https://www.iso.org/obp/ui/#search/code/)	What province or country did you travel to [LIST COUNTRIES YOU TRAVELLED TO (separated by a comma)]
EXPOSURE	24.a	Participant's work history	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Do you do either paid or unpaid work in an environment where you work in close proximity to other people
EXPOSURE	24.b	Participant's occupation	categorical	multiple	{01-HOSPITAL OR HEALTH CARE FACILITY WORKER, "02-FIRST RESPONDER (PARAMEDIC, FIREFIGHTER, POLICE OFFICER)", 03-CHILDCARE WORKER, 04-CORRECTIONAL OFFICER, 05-TEACHER OR OTHER SCHOOL STAFF, 06-TRANSIT DRIVER, 07-FOOD SERVICE INDUSTRY, 08-GROCERY STORE, 09-PHARMACY, 10-HAIRDRESSER OR BARBER, 11-AESTHETICIAN, 12-FLIGHT ATTENDANT, 13-FACTORY WORKER, 14-OTHER [SPECIFIY], 99-PREFER NOT TO ANSWER}	Have you been working in any of the following occupations or worksites in the past year [SELECT ALL THAT APPLY]
EXPOSURE	24.c	Other occupation specification	string	single		(specify)
EXPOSURE	25.a	Participant's COVID-19 exposures before March 2020	numerical	single	[0, 1000]	How many times have you been in gatherings of more than 10 people since March 2020

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
EXPOSURE	25.b	Participant's COVID-19 exposures before March 2020 PNA	categorical	single	99-PREFER NOT TO ANSWER	How many times have you been in gatherings of more than 10 people since March 2020
EXPOSURE	25.c	Participant's COVID-19 exposures before symptoms	numerical	single	[0, 1000]	If you think you have had COVID, how many times were you in gatherings of more than 10 people in the 6 months before your symptoms began
EXPOSURE		Participant's COVID-19 exposures before symptoms PNA	categorical	single	99-PREFER NOT TO ANSWER	If you think you have had COVID, how many times were you in gatherings of more than 10 people in the 6 months before your symptoms began
HEALTH, HEALTH BEHAVIOURS	26	Participant's smoking status	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Do you currently smoke tobacco
HEALTH, HEALTH BEHAVIOURS	27	Frequency of smoking by participant	categorical	single	{01-LESS THAN DAILY, 02-DAILY, 00-NOT APPLICABLE}	How often do you smoke tobacco
HEALTH, HEALTH BEHAVIOURS	28	Participants current vaping status	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Do you currently use e-cigarettes (vape)
HEALTH, HEALTH BEHAVIOURS	29	Frequency of vaping by participant	categorical	single	{01-LESS THAN DAILY, 02-DAILY, 00-NOT APPLICABLE}	How often do you use e-cigarettes (vape)
HEALTH, HEALTH BEHAVIOURS	30	Participant's Comorbidities				Have you been diagnosed by a physician with any of the following chronic medical conditions [SELECT ALL THAT APPLY]
HEALTH, HEALTH BEHAVIOURS	30.a	Participant's Comorbidities: HYPERTENSION	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Hypertension
HEALTH, HEALTH BEHAVIOURS	30.b	Participant's Comorbidities: DIABETES	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Diabetes
HEALTH, HEALTH BEHAVIOURS	30.c	Participant's Comorbidities: ASTHMA	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Asthma
HEALTH, HEALTH BEHAVIOURS	30.d	Participant's Comorbidities: CHRONIC LUNG DISEASE	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic lung disease
HEALTH, HEALTH BEHAVIOURS	30.e	Participant's Comorbidities: CHRONIC HEART DISEASE HYPERTENSION	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic heart disease
HEALTH, HEALTH BEHAVIOURS	30.f	Participant's Comorbidities: CHRONIC KIDNEY DISEASE	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic kidney disease

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
HEALTH, HEALTH BEHAVIOURS	30.g	Participant's Comorbidities: LIVER DISEASE	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Liver disease
HEALTH, HEALTH BEHAVIOURS	30.h	Participant's Comorbidities: CANCER	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Cancer
HEALTH, HEALTH BEHAVIOURS	30.i	Participant's Comorbidities: CHRONIC BLOOD DISORDER	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic blood disorder
HEALTH, HEALTH BEHAVIOURS	30.j	Participant's Comorbidities: IMMUNE SUPPRESSED	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic kidney disease
HEALTH, HEALTH BEHAVIOURS	30.k	Participant's Comorbidities: CHRONIC NEUROLOGICAL DISORDER	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Chronic neurological disorder
HEALTH, HEALTH BEHAVIOURS	31.a	Participant's weight	numerical	single	[1, 300]	What is your current weight
HEALTH, HEALTH BEHAVIOURS	31.b	Participant's weight units	categorical	single	{01-KG, 02-LBS}	(circle units)
HEALTH, HEALTH BEHAVIOURS	31.c	Participant's weight PNA	categorical	single	99-PREFER NOT TO ANSWER	What is your current weight
HEALTH, HEALTH BEHAVIOURS	32.a	Participant's height (m)	numerical	single	[0.5, 2.5]	What is your current height [in metres]
HEALTH, HEALTH BEHAVIOURS	32.b	Participant's height (feet)	numerical	single	[2, 8]	What is your current height [in feet and inches]
HEALTH, HEALTH BEHAVIOURS	32.c	Participant's height (inches)	numerical	single	[0, 11]	What is your current height [in feet and inches]
HEALTH, HEALTH BEHAVIOURS	32.d	Participant's height PNA	categorical	single	99-PREFER NOT TO ANSWER	What is your current height
HEALTH, HEALTH BEHAVIOURS	39	Participant's access to primary care provider or physician	categorical	single	{00-NO, 01-YES, 98-DON'T KNOW, 99-PREFER NOT TO ANSWER}	Do you have a family physician, primary care provider
HEALTH, HEALTH BEHAVIOURS	34.a	Participant's flu shot	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Do you usually get a flu shot
HEALTH, HEALTH BEHAVIOURS	35	Participant's COVID-19 Protective Behaviours				How often have done the following since March 2020
HEALTH, HEALTH BEHAVIOURS	35.a	Participant's COVID-19 Protective Behaviours: use of mask	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 99-PREFER NOT TO ANSWER}	Worn a mask in public places

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
HEALTH, HEALTH BEHAVIOURS	35.b	Participant's COVID-19 Protective Behaviours: physical distancing	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 99-PREFER NOT TO ANSWER}	Practiced physical distancing in public places
HEALTH, HEALTH BEHAVIOURS	35.c	Participant's COVID-19 Protective Behaviours: crowd avoidance	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 99-PREFER NOT TO ANSWER}	Avoided crowded places, gatherings
HEALTH, HEALTH BEHAVIOURS	35.d	Participant's COVID-19 Protective Behaviours: greeting avoidance	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 99-PREFER NOT TO ANSWER}	Avoided common greetings (such as handshake or hug)
HEALTH, HEALTH BEHAVIOURS	35.e	Participant's COVID-19 Protective Behaviours: contact limit with vulnerable population	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Limited contact with people at higher risk (e.g., an elderly relative)
HEALTH, HEALTH BEHAVIOURS	35.f	Participant's COVID-19 Protective Behaviours: self isolation due to symptoms	categorical	single	{01-YES, 00-NO, 97-NOT APPLICABLE}	Self-isolated because you thought you were infected with COVID-19
HEALTH, HEALTH BEHAVIOURS	35.g	Participant's COVID-19 Protective Behaviours: preventative self quarantine	categorical	single	{01-YES, 00-NO, 97-NOT APPLICABLE}	Self-quarantined because you may have been exposed to COVID-19, but did not show symptoms
HEALTH, HEALTH BEHAVIOURS	36	Participant's COVID-19 Protective Behaviours before having COVID				If you think you have had COVID, how often have you done the following in the 6 months before your symptoms began?
HEALTH, HEALTH BEHAVIOURS	36.a	Participant's COVID-19 Protective Behaviours before having COVID: use of mask	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Worn a mask in public places
HEALTH, HEALTH BEHAVIOURS	36.b	Participant's COVID-19 Protective Behaviours before having COVID: physical distancing	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Practiced physical distancing in public places

CITF Domain	Number	Label	Type	Cardinality	Value constraints	Question
HEALTH, HEALTH BEHAVIOURS	36.c	Participant's COVID-19 Protective Behaviours before having COVID: crowd avoidance	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Avoided crowded places, gatherings
HEALTH, HEALTH BEHAVIOURS	36.d	Participant's COVID-19 Protective Behaviours before having COVID: greeting avoidance	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Avoided common greetings
HEALTH, HEALTH BEHAVIOURS	36.e	Participant's COVID-19 Protective Behaviours before having COVID: contact limit with vulnerable population	categorical	single	{00-NEVER, 02-RARELY, 03-OCCASSIONALLY, 04-OFTEN, 05-ALWAYS, 97-NOT APPLICABLE, 99-PREFER NOT TO ANSWER}	Limited contact with people at higher risk (e.g., an elderly relative)
HEALTH, HEALTH BEHAVIOURS	36.f	Participant's COVID-19 Protective Behaviours before having COVID: self isolation due to symptoms	categorical	single	{01-YES, 00-NO, 97-NOT APPLICABLE}	Self-isolated because you thought you were infected with COVID-19
HEALTH, HEALTH BEHAVIOURS	36.g	Participant's COVID-19 Protective Behaviours before having COVID: preventative self quarantine	categorical	single	{01-YES, 00-NO, 97-NOT APPLICABLE}	Self-quarantined because you may have been exposed to COVID-19, but did not show symptoms
VACCINE	40	Participant's COVID-19 Vaccine Exposure	categorical	single	{00-NO, 01-YES, 99-PREFER NOT TO ANSWER}	Have you been vaccinated against COVID-19?
VACCINE	41	Participant's COVID-19 Vaccine Exposure: dosage	categorical	single	{00-NOT APPLICABLE, 01-1, 02-2, 03-MORE THAN TWO}	How many doses of the COVID-19 vaccine have you received so far?
VACCINE	42	Participant's COVID-19 Vaccine Exposure: date of first dose	date	single	"YYYY-MM-DD"	When did you receive the first dose of the COVID-19 vaccine?
VACCINE	43	Participant's COVID-19 Vaccine Exposure: date of second dose	date	single	"YYYY-MM-DD"	When did you receive the second dose of the COVID-19 vaccine?
VACCINE	44	Participant's COVID-19 Vaccine Exposure: vaccine type	categorical	single	{01-Pfizer and BioNTech mRNA vaccine, 02-Moderna mRNA vaccine, 03-AstraZeneca Oxford Vaccine, 04-Other [Specify the vaccine], 98-Don't Know, 99-PREFER NOT TO ANSWER}	Which vaccine did you receive?
VACCINE	44.a	Other vaccine specification	string	single		(specify vaccine)

Appendix 3

CITF Data Governance Framework

COVID-19 Immunity Task Force Governance Framework

Definitions:

Access: To retrieve, consult, copy, or process a digital, conceptual, or physical asset (including a dataset), in whole or in part.

CITF Data: Coded study data collected from research participants by researchers at local study sites, including survey data and sample data from relevant collections and cohorts. The CITF Data is coded at the local study site before being provided to the CITF. This means that the researchers at the local study site replace all direct identifiers, such as name and civic address, by a code.

CITF Database: The technological platform that holds the CITF Data and is used by researchers to access and download the data. This refers to the physical infrastructure used to host the data, the informational networks that contain the data, and the organizational and professional activities that maintain and direct the functioning thereof.

Core Data Elements: A list of mandatory data elements and data formats that must be included in all datasets provided to the CITF for inclusion in the CITF Database.

Researcher: Researchers include the relevant principal investigator(s), the institution or organization to which they are affiliated for the purposes of their research, and the research team conducting the research.

Prospective Cohort or Collection: A prospective cohort or collection is a group of research participants or other individuals from whom consent is obtained for the specific purpose of contributing their survey data or sample data to the CITF Database.

Retrospective Cohort or Collection: A retrospective cohort or collection is a group or research participants or other individuals from whom consent has not been obtained for the specific purpose of contributing their survey data or sample data to the CITF Database. Such cohorts or collections are generally those that have been collected for other research purposes and subsequently selected for inclusion in the CITF by the Researchers.

1. Governance Framework Mandate and Principles

The COVID-19 Immunity Task Force (CITF) Governance Framework establishes the organizational structure, technical elements, and operational policies that are fundamental to the functioning of the CITF. The Mandate and Principles of the CITF are integral to the operation thereof and guide the conduct of the CITF's activities and of its oversight mechanisms. The Mandate and Principles of the CITF are reproduced below.

1.1. Mandate of the COVID-19 Immunity Task Force

The COVID-19 Immunity Task Force has received funding from the Government of Canada to coordinate and fund research on COVID-19 immunity among the Canadian population.

The CITF is mandated to oversee a Secretariat coordinating multi-site sero-surveys assessing COVID-19 immunity in the Canadian population.

1. Researchers will perform testing to detect COVID-19 antibodies, viral material, and cellular immune response.
2. Information relating to personal characteristics, COVID-19 infection history, and lifestyle will be collected from participants using questionnaires.
3. Clinical and biological test results will also be contributed by existing collections of data and samples that are subject to appropriate consents to be contributed to the CITF. Longitudinal cohort studies will re-contact and re-consent participants to contribute their data to the CITF Database.
4. Researchers will also be able to contribute their data to the CITF if they hold the necessary ethico-legal permissions to contribute their data.

These studies have two principal purposes. First, to collect accurate population-level data about rates of COVID-19 infection in the Canadian population. Second, to learn more about the science underlying COVID-19 antibody response and immunity.

The CITF Secretariat will identify and approve a select number of studies to be recommended for funding by the Public Health Agency of Canada (PHAC) and/or the Canadian Institutes of Health Research (CIHR). These studies will generally contribute their data to the CITF Database.

The individual-level study data will be coded and held in controlled access. This coded data will be made available to researchers in Canada and internationally who request access to the data following the appropriate procedures. Limited aggregated/anonymized data will be held on an open access database available to all members of the public. Some aggregated/anonymized data that is more detailed than the open access data will be held on a registered access database available to members of the public who create an account. Researchers who contribute data to the CITF database will be able to access the CITF data using an accelerated controlled-access process.

1.2. 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.

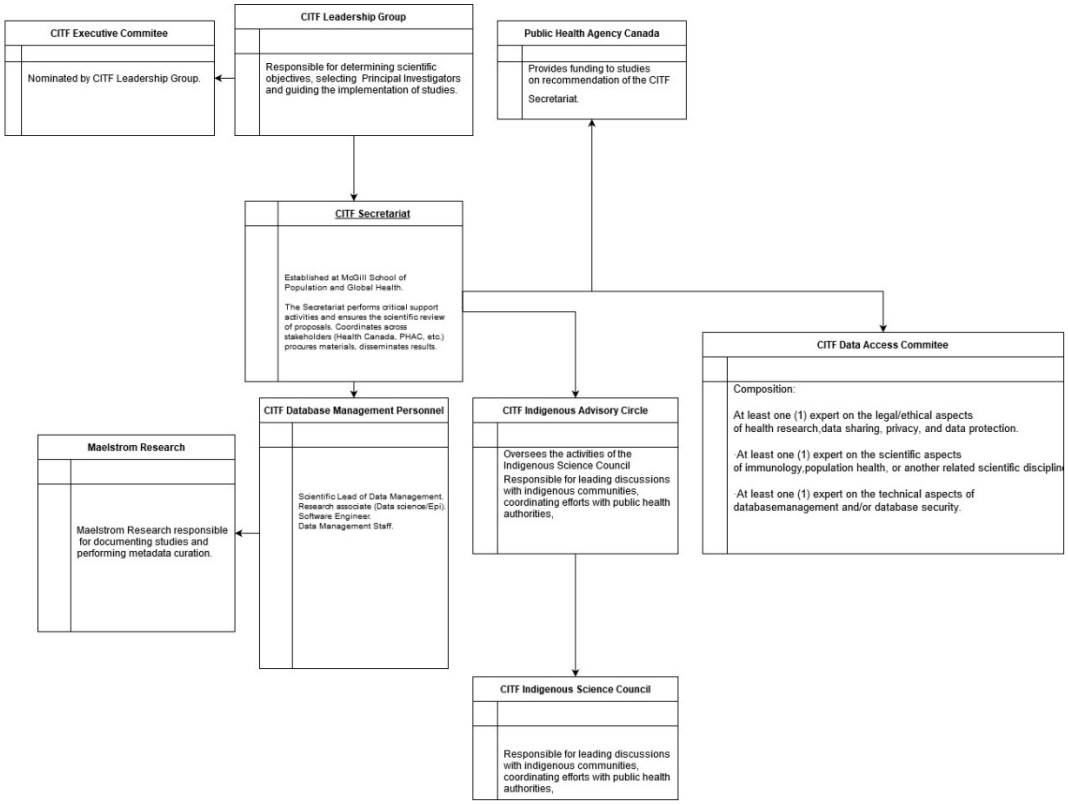
1.3. Purpose of this Governance Framework

This Governance Framework aims to provide oversight mechanisms for the administration, custodianship, and sharing of data deposited in the CITF Database. It establishes the requisite consent and data elements for researchers to contribute data to the CITF Database. It also establishes the access procedures for parties to access the data in the CITF Database. Last, a description of the appropriate data types to include in the public access tier of the database is provided.

The ethical and policy aspects of data storage and data security are described, as well as procedures for the sunsetting and decommissioning of the database. Related matters, such as intellectual property are also accounted for in this document.

2. Governance and organizational structure

2.1 Governance Overview



2.2. Scientific and Administrative Oversight

The Leadership Group is the central governance body of the CITF. The Leadership Group is composed of scientists and officials from Canada's academic research centres, health laboratories, and from among the ranks of the Canadian government. The Leadership Group has created an Executive Committee that supports it in its decision-making activities.

The Leadership Group determines scientific objectives, and selects Principal Investigators, some of whom are affiliated to designated research centres, to lead in the implementation of studies. The CITF selects viable studies and recommends them to the Public Health Agency of Canada and/or the Canadian Institutes of Health Research for funding. The Leadership Group of the CITF is responsible for guiding the implementation of the studies funded and disseminating their results to decision-makers in the field of public health.

The CITF Secretariat is established at McGill University's School of Population and Global Health. The Secretariat is mandated to request proposals for research studies and to ensure the

appropriate scientific review of the proposals received. The Secretariat is responsible for performing critical support activities relating to data management, data storage, study design, and laboratory coordination. The Secretariat is further tasked with coordinating activities among stakeholders such as the Leadership Group, Health Canada, the Public Health Agency of Canada, and Canada's National Microbiology Laboratory. Communication and dissemination of results, procurement of materials, and distribution of funds are also among the Secretariat's functions.

The Indigenous Advisory Circle is responsible for ensuring that the interests and perspectives of Canada's indigenous communities are respected in the conduct of all studies affiliated to the CITF. The Indigenous Advisory Circle will also be directly responsible for the oversight of one of the studies funded by the COVID-19 Immunity Task Force, namely, *Indigenous Journeys through COVID-19: A National Indigenous Seroprevalence Cross-Sectional and Community Sentinel Cohort Study*. The Indigenous Advisory Circle oversees the activities of the COVID-19 Indigenous Science Council, which is responsible for the implementation of the aforementioned study. Both the Advisory Circle and the Council are responsible for leading discussions with indigenous groups and communities, and for coordinating the efforts of the study with public health authorities. Further, these two bodies are responsible for ensuring that research oversight and sample preservation are conducted in compliance with Indigenous research principles.

2.3. Ethical Oversight

The CITF Database will include data from the infection/immunity cross-sectional studies and longitudinal cohort studies that the PHAC and/or the CIHR fund at the recommendation of the CITF. Existing collections of data and samples, as well as cohorts, can also receive funds to conduct new research and contribute the results thereof to the CITF Database.

The data from these funded studies is contributed to the CITF Database by participating Canadian institutions, in compliance with this Framework and following local approvals. For external cohorts and collections, contribution will be possible once the data contributors have validly completed the data contributor agreement. This requires data contributors to demonstrate a valid institutional affiliation, for their host institution to bind itself to the contributor agreement, and for contributors to warrant that all required local ethico-legal permissions as well as those of the CITF have been obtained prior to contribution.

2.4. Management of the Database

The Scientific Lead of Data Management, and the Executive Director of the Secretariat are responsible for the oversight of the CITF Database. A Research Associate specialized in data science and/or epidemiology, hired by McGill University, is responsible for the technical management of the CITF Database. The Research Associate is responsible for data centralization and quality assurance activities, and for providing data access to approved parties. A Software Engineer hired by McGill University will create the database. Maelstrom Research will be responsible for documenting studies and performing metadata curation. The

Data Management Staff of the Secretariat will be responsible for curating, managing, and processing the primary study data.

2.5. Financing

The CITF Database is financed by the Government of Canada. Future funding may be required from other sources to ensure the long-term sustenance and survival of the CITF Database.

3. Types of Data Included in the CITF Database

The CITF Database will receive contributed data from the funded studies, including cross-sectional studies and longitudinal cohort studies, as well as the research data of external researchers. The following sections describe the types of data that can be included in the CITF Database. The CITF reserves the right to add new accepted data types, or to stop accepting or stop hosting data types.

The CITF will receive contributed data that contain the Core data elements. Contributors will be required to provide a list of all data elements available, and to confirm that all of the Core data elements have been provided to the CITF.

The Core data elements and the requirements for contributing data to the CITF Database will be established in a Memorandum of Understanding (MOU) between each data contributor and the CITF Secretariat. The Core data elements will be common across each MOU established. The CITF Secretariat can authorize contributors to deposit data in the CITF Database even if not all Core data elements are available for deposit.

Contributors will also be required to provide a list of all non-core data elements that they wish to make available to researchers that request them directly. Maelstrom Research is responsible for documenting the non-core data elements available for each dataset. The list of Core data elements, non-core data elements, and metadata fields available for each dataset will be made available to the broad public. These non-core data elements will not be hosted in the CITF Database. The CITF will not be responsible for ensuring access to this data, nor will the CITF provide any assurances with regard to the accuracy or quality thereof, its fitness for a particular purpose, or the rights and permissions inherent therein.

For each dataset contributed, the CITF will make available in the open-access tier the list of the non-core data elements provided to it by the data contributor.

(i) **Population Survey Core Data Elements**	**Description**	
a. Survey data collected from individual participants or their authorized representative	Survey data collected from the individuals represented in participating cross-sectional study cohorts and longitudinal study cohorts. The survey data includes individual identity (age, sex, gender, ethnicity, education, etc.),	Required for contributing cross-sectional studies or longitudinal cohort studies that collect primary consent from participants.

	location of residence and living conditions, COVID-19 infection status, travel practices, lifestyle, and occupation. The survey data has been either anonymized/aggregated for the open access tier or coded for the controlled access tier. The survey data has been coded but is not necessarily anonymized. The relevant data elements can be gathered from a different source, such as a medical record or administrative health record, if the data contributor obtains the required consents and other ethico-legal permissions to collect and contribute such data.	
(ii) **Laboratory Analysis Data**	**Description**	
a. Blood test, immune response test, and serological test results	All studies will be required to collect human blood samples for the purposes of performing serological and immune response testing and to include Core data elements and metadata elements related thereto in the CITF Database. . These elements generally relate to the patient's physiological characteristics, medical status upon admission, co-morbidities, past medical history, symptomology, and medicines prescribed to the patient. Blood sample analysis results include serological and immunological testing for COVID-19 and results related to other health outcomes.	Required.
b. Metadata elements	All studies will be required to collect human blood samples for the purposes of performing serological and immune response testing and to include Core data elements and metadata elements related thereto in the CITF Database. These elements generally relate to the patient's physiological characteristics, medical status upon admission, co-morbidities, past medical history, symptomology, and medicines prescribed to the patient.	

	The relevant data elements can be gathered from a different source, such as a medical record or administrative health record, if the data contributor obtains the required consents and other ethico-legal permissions to collect and contribute such data.	

4. Data collection and deposit in CITF Database

The CITF Database will accept data from studies funded by the CITF, and from studies conducted by external researchers that are specifically consented for inclusion in the CITF Database. The inclusion of retrospective cohort and collection data in the CITF database that are not specifically consented for inclusion therein is permissible under certain circumstances. This can be done if the cohorts or collections to be contributed meet the Minimum Required consent elements detailed below. Researchers that desire to contribute Retrospective cohorts that potentially do not meet the Minimum Required consent elements should consult the CITF Retrospective Consent Filter, reproduced in Appendix D.

Data contributors are free to establish different inclusion or exclusion criteria for their studies, however, the data contributed to the CITF Database must conform to the inclusion and exclusion criteria listed here.

Inclusion criteria:

1. Individuals of any age, including:
2. Adults capable of consenting to participate in research.
3. Adults who have been rendered incapable of consenting to participate in research due to COVID-19 (sudden and temporary incapacity), in compliance with applicable local ethico-legal requirements.
4. Adults who lack the capacity to participate in research due to a condition other than COVID-19, in compliance with applicable local ethico-legal requirements.
5. Minors capable of providing primary consent to participate in research. Alternatively, minors whose parents or guardians provide consent and who are capable of providing assent.
6. Individuals having provided or contributed samples to select government services such as the Canadian Blood Services (CBS), or HEMA-Quebec.
7. Individuals having participated in previous studies or longitudinal cohort studies who consented to being re-contacted and who are re-contacted and consent to having their pre-existing or freshly collected data included in the CITF Database in compliance with the recontact policies of the original study.

8. Other individuals, if an ethics waiver of consent has been obtained from a relevant REB and all other local ethico-legal permissions have been obtained.

Exclusion criteria:

1. Individuals who are known to have been included in the CITF Database already as part of a different study.
2. Individuals that have provided consent that does not satisfy the Minimum Required consent elements, and with regard to which an ethics waiver of consent has not been obtained.

Recruitment Sites:

Participants will be recruited at different participating sites across Canada. The local site must have all required ethics approvals in place for the project prior to collecting samples or data in relation to COVID-19.

Identification of Potential Participants:

The Principal Investigator or a delegated and duly authorized individual ensures that recruitment methods, and methods of identifying individuals for prospective recruitment are compliant with local ethico-legal requirements and have received requisite REB approval.

Requisite approval must in certain circumstances be obtained to consult health records or other sources of personal data to identify and recruit prospective research participants, as established in local ethico-legal requirements.

4.1. Process for depositing data from local research cohorts

4.1.1. Prospective cohorts and collections

Consent to the collection of survey data and biological samples should be obtained by the researchers at local sites. If individuals are recruited through solicitation via postal communication, e-mail, or re-contact, or if a single member of a family or other social groups is responsible for transmitting consent for multiple individuals, additional steps should be taken to ensure the validity of their consent.

It is a recommended best practice that any individuals who have not or were not able to provide consent directly or through an authorized representative at the research site be required to provide written confirmation of their verbal consent.

For individuals from whom verbal confirmation of consent is sought, such verbal confirmation should be obtained via telephone or videoconference and witnessed by a person independent from the research team and research institution. The witness should not be a person who is enrolled in the study.

In the event that a research participant elects not to provide verbal confirmation of their written consent, that a research participant does not respond to the request to provide verbal confirmation of their written consent, or that such confirmation is not obtained for other reasons, the original written consent remains valid.

Prospective cohorts and collections obtaining consent to research prospectively should include the following **Minimum Required Consent Elements** to ensure that datasets used in the CITF Database are interoperable and can be reused for broad secondary research purposes in Canada and internationally:

Minimum Required Consent Elements for Prospective Cohorts and Collections

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.

If any of the items listed above are not included in the consent documents, datasets should not be deposited as-is in the CITF Database without obtaining appropriate approvals from the relevant local research ethics committee and from the CITF.

4.1.2 Retrospective cohorts and collections

- Research cohorts and collections being retrospectively approved for inclusion in the CITF Database, which are included on the basis of consents that were granted prior to the

creation of the CITF, may use consent language that differs from the above consent elements.

- Alternatively, retrospective cohorts and collections may include data generated from samples collected prior to the creation of the CITF Database, which were collected for purposes other than research and are not governed by an informed consent form for research purposes.

4.1.3. REB Approval

Approval from the cohort or collection's local REB and from the CITF (i.e. must verify that the data meets the CITF core elements) is to be obtained prior to the deposit of the cohort's data in the CITF Database.

Datasets hosted in the CITF Database will be hosted on servers located within Burnside Hall, at McGill University in Montreal, Quebec. It is possible that the data will instead be hosted using a public cloud based in Canada, or another storage mechanism at a different location in Canada.

4.1.4 Data Security Policy

The CITF Data Security Policy is included in Appendix C, below. The Data Security policy is intended to apply to CITF Researchers and to external Researchers that access CITF data.

5. Data access

CITF data will be made available through open and controlled access tiers.

5.1. Overview of CITF Data Access Tiers

TIER 1: OPEN ACCESS	
Data available under Tier 1 (Open Access)	Data with a very low risk of re-identification and that does not relate to sensitive attributes ("open data"), such as aggregate data revealing statistical patterns created from the individual-level data contributed by the research participants.
Who can access?	Openly accessible to anyone.
Access mechanism	Open access.
Access Process	Open to the general public without restriction.
TIER 2: REGISTERED ACCESS	
Data available under Tier 2	Data with a low risk of re-identification, with more granularity than the data in the Open Access Tier, such as aggregate data concerning individuals with particular combinations of common attributes (e.g. gender, age, and sex).

(Registered Access)	
Who can access?	Registered users from among researchers accessing CITF data.
Access mechanism	Registered access.
Access Process	Accredited researchers must register and create an account to access the data.
TIER 3A: CONTROLLED ACCESS	
Data available under Tier 3A (Controlled Access)	Individual-level survey data or analysis data.
Who can access?	Researchers approved by the CITF DAC.
Access Mechanism	Controlled access.
Access Process	Researchers: Access to data by external researchers requires submission of an application to the CITF DAC (as detailed in Appendix A). Access requests must, amongst other, include: A summary of the research project (scientific abstract and lay summary); Justification for the types of data requested; Ethics approval from the Principal Investigator's institutional REB, or confirmation that no ethics approvals are required at the local institution; Acknowledgment of the data use conditions, and the signature of an institutional representative from the Principal Investigator's institution, who is capable of binding the concerned institution to the terms of access;
TIER 3B: ACCELERATED CONTROLLED ACCESS **(CITF Contributor Researchers)**	
Data available under Tier 3B (Accelerated Controlled Access)	Individual-level survey data and analysis data.
Who can access?	Cohort or collection affiliated Researchers who have contributed cohort data to the CITF Database will receive accelerated access to the CITF Database as the validation of their institutional affiliation and academic credentials does not need to be performed. Cohort or collection affiliated researchers who have previously been approved to access CTIF data may also receive accelerated access to the

	CITF Database as the validation of their institutional affiliation and academic credentials does not need to be performed.
Access Mechanism	Controlled access
Access Process	Cohort or collection affiliated Researchers who have deposited data in the CITF Database receive accelerated access to CITF data upon providing ethics approvals and supporting evidence of affiliation with a CITF cohort or collection to the CITF DAC.

5.1.1. Open Access Data

Aggregate data in the CITF Database is available to the general public in the Open Access Data section of the CITF Data Portal.

Lists of the non-core data elements that are available on application to the original research teams will also be made available in the Open Access Data section.

5.1.2 Registered-Access Data

Accredited researchers that create an account and register to access the registered-access tier of the CITF Data Access Portal will be able to access the data held in the Registered Access Data section of the CITF Data Portal.

Such data will be similar to the data held in the Open Access Data section of the CITF Data Portal. However, it will be possible for users to query the data to obtain results that are more granular than the data held in the Open Access Data section. For instance, information corresponding to individuals sorted for two or three variables, such as age, gender, and sex will be available. Further, it will be possible for users to access data not available in the open access tier, such as data about the categories of serological or immunological tests conducted.

The Registered Access portal allows researchers to use an API to perform limited queries of the aggregate Registered Access data. This allows researchers to filter for summary-level information regarding COVID-19 prevalence relative to certain demographic traits or other relevant characteristics.

5.1.3. Controlled-Access Data

Individual-level (de-identified) survey data, individual-level (de-identified) laboratory test results and other baseline health data collected are held in the Controlled-Access Tier of the CITF Database. This data is made available upon approval of an application to the CITF DAC.

CITF personnel will be able to conduct health surveillance activities and quality assurance activities on behalf of public health authorities and other authorized healthcare bodies without being required to request the CITF DAC, in compliance will ethical and legal requirements.

5.1.4. Accelerated Controlled-Access Data

Cohort or collection affiliated Researchers who have contributed cohort data to the CITF Database will receive accelerated access to the CITF Database for REB-approved projects, as the validation of their institutional affiliation and academic credentials does not need to be performed.

5.2. Researcher Derived Data

It will not be possible for Researchers to return derived data to the CITF Database for inclusion in the CITF Database.

5.3. Data sharing with other databases

The data in the CITF Database can be integrated with external research databases.

This is contingent on the fulfillment of the following conditions:

1. The external research database must hold the individual-level coded and de-identified in a controlled-access database that provides access to the data to external researchers in conditions that respect the Minimum Required consent elements of the CITF Database. The access conditions of such a database can be more restrictive than the access conditions of the CITF Database but cannot be less so.
2. The external research database must maintain security safeguards that are compliant with the security safeguards provided for in this Governance Framework. Further, the standard of data privacy ensured by the external database must be equivalent to that provided for in Canadian research ethics and law, regardless of the country or countries in which the database is hosted.
3. The external research database and the entities responsible for its oversight and maintenance must bind themselves not to use intellectual property rights or other legal mechanisms to preclude the access to, and use of, the CITF Data by the CITF or by researchers approved to access the data by the CITF DAC.
4. The external research database and the entities responsible for its oversight and maintenance must further bind themselves not to use intellectual property rights or other legal mechanisms to preclude the lawful use of open access CITF data by any persons.
5. The external research database and the entities responsible for its oversight and maintenance must bind any third parties accessing or using the CITF data to conditions 2-4 listed in this section. Such parties must not release the controlled-access CITF data to third parties without the authorization of the CITF DAC or an analogous body responsible for overseeing access to the external research database.
6. The external research database must retain the CITF data on servers or other storage platforms physically located in Canada.

6. Database Maintenance and Database Closure

Data hosted in the CITF Database is hosted under the custodianship of McGill University. The responsibilities for database maintenance and oversight related thereto have been delegated to the CITF Secretariat.

If the CITF Database were to cease activities, the CITF data custodian would make efforts to transfer the CITF data to another data custodian in Canada that manages the data in compliance with the conditions set out in this Governance Framework. Such a transfer will need to be approved by the McGill REB responsible for ethics review of the CITF Database.

If no custodian can be found that is willing and able to govern the CITF Database in compliance with the conditions set out in this Governance Framework, the CITF custodians can nonetheless transfer the CITF Data to another data custodian.

In this instance, the original data contributors and their institutions will be notified and will have the opportunity to withdraw the data from the CITF Database, such that it will not be transferred to the new data custodian. Even if the new data custodian does not govern the data in compliance with all of the conditions set out in this Governance Framework, the new data custodian must nonetheless respect the Minimum Required consent elements, the data security requirements, the access requirements and tiers, and the data sharing and intellectual property requirements established in this Data Governance Framework and associated documentation.

7. Potential Benefits and Risks

The potential benefits and risks of research participation listed below are examples that are recommended for inclusion in the informed consent materials of data contributors.

7.1. Potential Benefits

Participation in the COVID-19 Immunity Task Force (CITF) is not likely to provide a direct benefit to the individual health or well-being of research participants.

Participation in the CITF will help collect accurate data about COVID-19 immunity that will potentially help in the creation or use of tests and treatments or otherwise improve the quality of COVID-19 healthcare delivery.

Participation in the CITF will also help collect accurate data about COVID-19 seroprevalence and infection rates among the general population. This can potentially help in the creation of treatments or otherwise improve the quality of COVID-19 healthcare delivery.

It can also help form an accurate picture of COVID-19 incidence and immunity among the general population, which allows healthcare bodies and public health authorities to develop a more accurate pandemic response and to allocate healthcare resources more effectively.

7.2. Potential Physical Risks

There are no physical risks associated with participation in the CITF. However, there may be minor physical risks involved in the participation in the studies that are contributing data to the CITF Database, such as a minor risk of physical pain from any blood draws required. The researchers conducting the associated studies are responsible for the disclosure of such risks to research participants.

7.3. Potential Informational Risks

There is a small risk that the data held in the CITF Database will lead to the re-identification of a research participant, or to the disclosure of their sensitive health attributes. This can happen if there is a malicious or inadvertent breach of the CITF Database security measures. This can also happen through the intentional or inadvertent re-identification of a research participant.

If there is a data privacy breach as described above, it is possible that the data released can lead to adverse treatment or discrimination by employers, insurers, or other third parties or groups.

In the event of a data privacy breach, the CITF will communicate the occurrence to the contributing researchers and institutions affiliated with the affected cohorts. The researchers and institutions concerned will be responsible for disclosing such breach to the affected research participants. The affiliated researchers and institutions affected may also elect to disclose the breach to local data privacy authorities voluntarily or as required by their local data privacy laws.

8. Protection of Participant Privacy and Data Security Measures

Prior to the contribution of data to the CITF Database, contributing researchers will be required to remove direct identifiers and code the data in accordance with their local requirements. The CITF will receive the coded data and the associated code (participant identification number). The key to link the participant's CITF Database participant identification number is held locally by the data contributor (i.e. the institution and Principal Investigator that contribute the data).

Data contributors will be required to hold re-linkage keys and linkage logs securely in order to comply with their local data withdrawal or data breach notification requirements, and to ensure that any successive waves of data collection from longitudinal cohort studies are added to the associated records in the CITF Database.

The participant identification number is the only remaining link between the coded or anonymized research participant data held in the CITF Database and the nominative identity of the research participant retained in the linkage log.

In storing, using, and disseminating individual-level coded data, the CITF will comply with the CITF Data Security Policy (Appendix C). Researchers that access and use such data must comply with the CITF Data Security Policy, and a copy of the Data Security Policy will be incorporated to the Data Access Agreement that researchers must sign.

The Government of Canada and the Research Ethics Boards responsible for reviewing ethical compliance can access CITF Data to ensure legal compliance, perform quality assurance, derive statistical data, and for other purposes as provided for in Canadian law.

9. Data Access and Release Oversight

The data custodian for CITF data and the CITF Database is McGill University.

Data from the CITF Database will be made available through open, registered, and controlled-access tiers.

Data access and release under the controlled access tier will be overseen by the Immunity Task Force Data Access Committee ('DAC'), as described in Appendix A.

The Terms of Reference of the DAC are detailed in Appendix A (including, for instance, the frequency of its meetings and the process for the review of access applications). The Data Access Committee will be composed of at least (5) voting members, including:

- At least one (1) expert on the legal/ethical aspects of health research, data sharing, privacy, and data protection.
- At least two (2) experts on the scientific aspects of immunology, population health, or another related scientific discipline.
- At least one (1) expert on the technical aspects of database management and/or database security.
- At least one (1) member of the broader community.

The Data Access Committee can integrate additional voting or non-voting members to its activities at the discretion of the Chair of the Committee, on a permanent or temporary basis. The role of non-voting members is to provide expert insight for applications that involve ethical, legal, social, or scientific issues outside of the expertise of the Committee.

10. Data Conservation

The CITF Data will be stored in the CITF Database indefinitely (or another database if justified in the circumstances). The data may also be withdrawn from the database at the instigation of the data contributor for a valid reason (for instance to comply with a participant's withdrawal request). The data may also be withdrawn from the database if there is a change in the data custodian and the data governance conditions established in the Data Governance Framework will no longer be adhered to, in accordance with the provisions on Database Closure.

11. Management of Participant Withdrawal

Consent to participation in the CITF Database is voluntary. A prospective research participant's decision not to participate in the CITF Database, or to withdraw their consent to participate, is entirely voluntary and will not affect the standard of medical care received by the participants.

If a participant decides to withdraw from participation in the study, the participant is responsible for informing the original study researchers of this fact. The research participant is not required to justify their decision to withdraw their data. The original study researchers are in turn responsible for notifying this request to the CITF, who will destroy the participant's associated records.

Data that has already been shared with Researchers external to the CITF will not be withdrawn from the Researchers.

Data that is being used by a research study, the destruction of which would compromise the integrity of that research study, will not be destroyed from the CITF Database until after the research study is completed, to preserve the scientific integrity of the concerned research.

12. Participant Recontact

The original data contributors are required to determine whether participant recontact was foreseen in their study protocol and associated consent materials, and under what circumstances participant recontact is anticipated.

Participants who were minors at the time of their contribution may come of age during the lifetime of the CITF Database. In some instances, data contributors will become aware that incapable persons for whom an authorized representative provided substitute consent has regained the capacity to consent to research.

For these categories of participants, it is a recommended best practice for the data contributors to recontact participants via notification of existence of the study to confirm the continued validity of the consent obtained. If it is not possible to successfully initiate contact with such participants, or if no answer to such a request is obtained, the consent initially collected remains valid (subject to local ethico-legal requirements).

13. Return of Research Results and Incidental Findings

The information collected in the CITF Database is not intended to provide medical information nor healthcare to research participants. Furthermore, the testing data and survey data that is being collected is not anticipated to create large quantities of material incidental findings. Research results and incidental findings will not be returned to study participants by the CITF Database or Researchers.

Data contributors may however elect to return their own research results or material incidental findings to research participants in compliance with the research consents gathered and their local practice. Such decisions should be made according to local ethico-legal requirements in collaboration with the concerned REB.

Generally, it will not be possible for the CITF nor Researchers accessing CITF Data to return research results of incidental findings to research participants.

General information regarding the scientific research performed and the outcomes thereof will be made available on the CITF website. Information about the use of CITF Data will also be made available in the academic publications of CITF researchers and of Researchers having accessed CITF Data.

14. Intellectual Property and Related Rights

Intellectual property rights, sui generis database rights, and related rights cannot be claimed on the CITF Data by parties other than the CITF. Intellectual property, sui generis database rights, and related rights claimed on the CITF Derived Data should not impede the use of primary CITF Data by the CITF, nor by researchers and other persons authorized to access and/or use the CITF Data.

The CITF commits to invoking intellectual property rights, sui generis database rights, and related rights only for the purpose of safeguarding the access of data contributors, the CITF, and other authorized parties to the CITF Data and associated resources.

Patent protection will not be sought by the CITF for any innovations, such as functional assays or scientific approaches it creates. The CITF believes that Open Science delivers the most rapid and accessible scientific results for research participants. Nonetheless, it remains possible for data contributors or External Researchers to claim intellectual property protection on the innovations they create or the Derived Data they generate.

APPENDIX A: CITF Data Access Committee Terms of Reference

1. Role:

The role of the CITF Data Access Committee (DAC) is to receive access requests for projects proposing to use controlled-access CITF data. The DAC assesses the feasibility of the proposal and its compliance with the CITF Governance Framework, Minimum Consent requirements, Data Access Agreement, and Data Access Committee Terms of Reference.

2.Term:

These Terms of Reference are effective from [DATE].

3.Membership

The Committee shall be composed of a minimum of five (5) members. One member shall serve as the Committee chair on a voluntary basis.

- At least one (1) expert on the legal/ethical aspects of health research, data sharing, privacy, and data protection.
- At least two (2) experts on the scientific aspects of immunology, population health, or another related scientific discipline.
- At least one (1) expert on the technical aspects of database management and/or database security.
- At least one (1) member of the broader community.

The Data Access Committee can integrate additional voting or non-voting members to its activities at the discretion of the Chair of the Committee, on a permanent or temporary basis. The role of non-voting members is to provide expert insight for applications that involve ethical or scientific issues outside of the expertise of the Committee.

4. Responsibilities

All members of the Committee agree to:

- Attend all scheduled DAC meetings, or, in case of absence, to provided detailed notes and decisions to the DAC ahead of the meeting.
- Share relevant communications with all Committee Members.
- Make decisions within a reasonable time and with necessary expedience.
- Fulfill their role with diligence, prudence, and fairness.

Members of the Committee are entitled:

- To be provided with all of the information required to render a decision on each data access application required to them for review

- To have the opportunity to confer with other members of the Committee to ensure that their understanding of each application is complete and accurate, and that their proposed decision is reasonable under the circumstances.
- To have a reasonable amount of time to review each application and give a decision relative thereto.

5. Meetings:

The Committee will appoint a Chair from among its members to preside over meetings and to review applications submitted for accelerated controlled access approval.

A meeting quorum is 5 members of the DAC, in person or by video/phone.

Decisions are made by consensus. If consensus is not possible, a majority decision will be taken. The Chair can break a tie.

The Chair can affirm decisions and respond to applicants if at least five voting members (including the Chair) have provided written or oral reasons, even if no meeting is convened.

The five voting members forming quorum, or providing reasons out of session, must correspond to each of the roles listed at section 3, above.

Meeting agendas and minutes are drafted by a delegated Member of the Access Committee, whether voting or non-voting. Reasons and decisions are drafted by the Chair, or by a delegated Member of the Committee and subsequently approved by the Chair.

Meetings are to be held every two weeks in person, by teleconference, or by videoconference.

6. Amendment, Modification, or Variation

These Terms of Reference may be amended, varied, or modified in writing after consultation and agreement by the DAC. The modifications will be submitted to the McGill REB for approval as it modifies an Appendix of the Governance Framework.

Appendix B: Examples of Consent Clauses for the Prospective Minimum Required Consent Elements

	Minimum Required Consent Elements	Example of consent clause language:
Research data	Collection of survey data. COVID-19 infection status, social distancing practices, demographic information (age, sex, gender, ethnicity, education, etc.), lifestyle, living conditions, and travel habits.	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.
	Collection of sample data. Blood sample analysis results including serological and immunological testing for COVID-19 and related health outcomes.	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.
	Collection of sample data. Blood sample analysis results including serological and immunological testing for COVID-19 and related health outcomes.	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.
	Collection of study data from research participants (survey data and sample data).	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.

Data sharing and location of data storage.	International sharing of study data.	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.
	Possible storage of study data on centralized servers including outside the province of collection, and on cloud servers.	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.
Future research use	Future health research on COVID-19 and related health outcomes.	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.
Commercial use	Use of the data collected for commercial and non-commercial research purposes.	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.
Controlled access	Sharing of coded study data with approved researchers through	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.

	a controlled-access mechanism.	Your data may also be shared with other COVID-19 research databases that follow similar protections and procedures as the CITF Database.
Open Access	Public sharing of anonymized or aggregated data.	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.
Duration of storage	Indefinite storage of the study data collected.	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.
Data withdrawal	Withdrawal of study data not possible if already used.	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.
Re-identification	Low risk that the participant could be re-identified in the future	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.
Data Privacy	Not a Minimum Required Consent Element.	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.
Data Security	Not a Minimum Required Consent Element.	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.

Appendix C: CITF Data Security Policy

1. **Encryption and Password Protection.** Researchers agree that the CITF Data will be stored primarily on password-protected desktop computers or servers. If stored on mobile devices, such as laptop computers or remote storage devices, the CITF Data will remain encrypted when at rest.
2. **Physical Safeguards.** Researchers agree to keep desktop computers and servers holding the CITF Data in private rooms that can be locked and to lock the doors thereof if the researchers are not on site to monitor the use of the CITF Data.
3. **Data Safeguards.** Researchers agree to use a recognized virus and malware protection software on the desktop computers, laptop computers or remote storage devices (provided these can be outfitted with such protection) that will host the CITF Data.
4. **Organizational Safeguards.** Researchers agree to implement and adhere to organizational practices that enhance data security. Access to data must be limited to authorized personnel. Authorized personnel must remain demonstrably accountable to institutional leadership and senior personnel, as well as to the institution itself.
5. **Data Destruction.** Researchers agree to destroy the CITF Data at the time determined in the Data Access Form or equivalent document. Researchers agree to use an auditable method of data destruction to destroy the CITF Data. Researchers agree to maintain documentation evidencing the destruction of the CITF Data and to make such records available to the CITF on request.
6. **Training.** Researchers agree to ensure that the principal investigator, authorized personnel, authorized students and other persons at their institution that access the CITF Data are provided with training that addresses data security and data privacy, to a degree that is appropriate to their role and responsibilities.
7. **Record-keeping.** Researchers agree to maintain records of who has access to the CITF Data under their control or in their possession. Researchers agree to record the time interval and scope of data elements accessible to each approved user. Records must also be maintained detailing data destruction.
8. **Monitoring and Audit.** Records regarding CITF Data access and destruction shall be stored using technological means that allow for audit internally and by external researchers. Audits of user activity shall be conducted on a regular basis and shall be conducted immediately when irregular user activity occurs.
9. **Data Breaches.** Researchers shall use industry-standard technological mechanisms appropriate to protect health data to prevent data breaches, and that allow for data breaches to be detected. If a data breach occurs that is known or suspected to affect CITF Data, the CITF must be informed immediately and all known information about the data breach must be provided to them.
10. **Vulnerability Management**. Researchers agree to immediately take measures to patch and/or remediate all software and other security vulnerabilities that are discovered which could affect the CITF Data. Researchers agree to have policies in place to ensure the prompt and ongoing patching of vulnerabilities and to implement that policy effectively.

11. **Third Party Service Providers**. Researchers agree to use all contractual and other measures necessary to ensure that Third Party Service Providers comply with the terms of this Policy and are demonstrably held accountable to the CITF.

12. **Cloud Storage and Cloud Computing**. Researchers agree to adopt all contractual and other measures necessary to ensure that all Cloud Storage and Cloud Computing providers that will use or access the CITF Data remain accountable to them and to the CITF. These measures shall include, but not be limited to, providing specific details as to, and guaranteeing the auditability of: the jurisdictions of storage of the CITF Data, data retention and destruction practices, segregation of the CITF Data from other data, implementation of appropriate security measures, maintenance of adequate access logs, and adoption of appropriate procedures for resisting compelled access to the CITF Data.

Appendix D: Assessment of Consent Elements for Inclusion of Datasets from Retrospective Collections (Retrospective Consent Filter)

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 I: 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 <u>either</u> question,** please proceed to Question II, below.

Question II: 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 <u>all</u> of the above**, your data can be deposited directly in the CITF database.

- **If you have answered no to <u>any</u> 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* I:**

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 <u>either</u> question**, please proceed to ***Question* II, below.**

Question* II*:

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 <u>both</u> questions**, your data cannot by deposited in the CITF Database.

Version History

Amendment No.	Date	Changes
1	October 12th 2020	First version of Governance Framework completed
1.1.	November 4th 2020	Core consent elements and access tiers finalized
1.2.	December 2nd 2020	DAC Terms of Reference and appendices finalized
1.3.	December 7th 2020	Language changed to reflect location of data storage and to clarify DAC composition.
1.4.	December 15th 2020	Language changed to reflect potential for Government of Canada Access to CITF data.