



COVID-19
IMMUNITY
TASK FORCE

GROUPE DE TRAVAIL
SUR L'IMMUNITÉ
FACE À LA COVID-19

CITF Data Access Policy and CITF Guiding Principles

Version 1.0

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1. CITF Introduction

The COVID-19 Immunity Task Force (CITF) was created in late April 2020 with the goal of catalyzing, supporting, and harmonizing research into COVID-19 immunity to inform Canadian policymakers, allowing them to make evidence-based decisions.

The CITF has supported numerous studies that aimed to:

- Determine the extent of SARS-CoV-2 infection and vaccination in the general Canadian population and in specific communities and priority populations;
- Understand the nature of immunity arising from SARS-CoV-2 infection;
- Develop improved antibody testing methods;
- Monitor the effectiveness and safety of vaccines as they are rolled out across Canada and in specific sub-groups of the population such as children;
- Determine the need for, and optimal timing of, booster shots;
- Develop models of population immunity to guide public health efforts as the pandemic evolves; and,
- Explore cross-cutting themes.

The CITF was mandated by the Government of Canada to establish and oversee a Secretariat coordinating multi-site sero-surveys assessing COVID-19 Immunity in the Canadian population. The Secretariat has supported researchers in many ways, including:

- a. Coordinating testing to detect COVID-19 antibodies, viral material, and cellular immune response;
- b. Standardizing the data collected across studies through questionnaires about personal characteristics, COVID-19 infection history, and lifestyle;
- c. Facilitating investigators in obtaining consent to permit the sharing of clinical and biological test results and other study data for the purpose of secondary research; and,
- d. Working with researchers and their institutions to allow study data to be deposited in the CITF Databank to enable further research using those data.

2. Guiding Principles

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

- a. 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.



- b. Identify priority issues related to serologic testing and its application, paying close attention to diverse needs for information across the country.
- c. Establish an ethos in which the rigorous gathering and rapid sharing of data to inform Canadians and to advance the broad public interest over-rides any considerations of personal/group advancement.
- d. Mobilize the best science and study designs that are responsive to the rapidly evolving state of the science related to COVID-19 immunity.
- e. 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 CITF, while appropriately managing conflicts of interest.
- f. Work with partners to ensure protection of privacy in data-gathering and safe handling of any and all biological samples.
- g. Collaborate with partners and use existing data- and sample-gathering capacity wherever possible to enhance cost-efficiencies and avoid unnecessary duplication.
- h. Provide a central coordination for the Task Force within a Secretariat 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.
- i. Promote ethical and sound participatory practices that engage relevant stakeholders from study design through to dissemination and application of findings.
- j. 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.
- k. 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.
- l. Communicate the leadership, membership, activities and results of the Task Force with openness and transparency.

3. Definitions

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

Access Applicant: Researcher applying for Access to CITF Data following the Controlled Access Procedure. All applicants must be affiliated with an institution (public or private) and are accepted internationally.

Approved Institution: Institution under which the approved Access Applicant is conducting the Research project.

Access Policy: Policy governing the requirements and procedures to Access CITF Data. To be used in conjunction with the terms outlined in the CITF Access Agreement.

Approved Research Project: Research project being conducted by the Access Applicant which must be reviewed for compliance with Access Policy requirements and CITF Guiding Principles by the Data Access Committee.

CITF Access Agreement: A signed agreement between the Approved Applicant, Approved Institution and McGill University that sets out the terms and conditions in the CITF Access Agreement that allows Access to the requested CITF Data.

CITF Controlled Access Procedure: The process by which researchers can gain Access to individual records contained in the CITF Database. This procedure is in conjunction with the Access Policy and is implemented by the Data Access Office, Data Access Committee and CITF Data Team. It consists of Access Application submission, Access Application validation, Access Application acceptance or rejection, and data acquisition.

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. All CITF Data are coded at the local study site before being deposited in the CITF Database. Coding means that the researchers at the local study site replace all direct identifiers, such as name and civic address, by a code that is unique to each study participant. Individual-level, coded data is housed in the CITF Database and is made available to researchers through the CITF Controlled Access Procedure.

CITF Database: The technological platform that holds the CITF 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 should be included in all datasets provided to the CITF for inclusion in the CITF Database. These make up the CITF Harmonized Data.

CITF Data Team: Team within the CITF Secretariat who specialize in data analysis, curation and management. They are responsible for maintaining the CITF Database and preparing datasets for approved Access Applicants.

Data Access Application: Form submitted through the CITF Data Access Portal to the Data Access Office by the Access Applicant to request Access to CITF Data that requires contact information of the Access Applicant and affiliated institution, research project information and proof of REB approval.

Data Access Committee: Committee with varying areas of expertise that have been assembled to review and make decisions concerning the viability of Data Access Applications. Its composition and responsibilities are outlined in the Data Access Committee Terms of Reference.

Data Access Office: Individual who communicates with Access Applicants, manages and keeps records all Data Access Applications, performs validation of Access Applications and prepares them for Data Access Committee review.

Data Access Portal: Online portal, powered by Maelstrom Research, to which Access Applicants may create an account, explore CITF Data and submit a Data Access Application.

Harmonized Data: The centralized dataset containing the Core Data Elements from all CITF approved studies. CITF Data are harmonized to ensure consistency across studies. Harmonized Data are still considered CITF Data and must be Accessed through CITF Controlled Access Procedure.

4. Access Policy

4.1 Objectives

The CITF Database receives data from CITF-funded studies, including cross-sectional studies and longitudinal cohort studies, as well as the research data of external researchers. Once study data are received, the CITF Data Team works to create a dataset which harmonizes the Core Data Elements collected from all studies. The Harmonized Data in the CITF Database will be made available to researchers in Canada and internationally who request Access to the data following the CITF Controlled Access Procedures.

The CITF Database aims to increase the impact of Canadian Covid-19 research studies. In harmonizing and making these data accessible, the Task Force hopes to provide the research community with a means to Access a wide variety of Covid-19 data in a common format, thus removing important barriers to Access.

4.2 Scope

This Policy includes the requirements and processes by which researchers may Access data stored in the CITF Database. These individual-level (de-identified) data include survey data, individual-level laboratory test results and other baseline health data that the CITF Data Team has harmonized. These data can be Accessed by researchers upon approval of a Data Access Application by the CITF Data Access Office and CITF Data Access Committee.

The list of Core Data Elements, non-core data elements, and metadata fields available for each study dataset are openly available for consultation. Non-core data elements will not be hosted in the CITF Database and the CITF will not be responsible for ensuring Access to these 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.

5. Access Limitations

The data stored in the CITF Database will be available for access to any researcher affiliated with a public or private institution, including institutions outside of Canada. Requests to Access data in the CITF Database may be rejected by the Data Access Committee or deemed invalid by the Data Access Office should the scientific research objectives not follow the CITF guiding principles, or if insufficient information or documentation is given. Access to CITF Data is limited to the Access Applicant and research staff who have been declared as data users in the Data Access Application and CITF Access Agreement, all of whom are bound by the terms and conditions in the CITF Access Agreement. Should updates be made to the research team, an Amendment form must be submitted with the relevant changes to the Data Access Office and Data Access Committee for review.

6. Privacy of Participants

In order to ensure the security of the CITF Data and the protection of the privacy of individual participants for whom data has been collected, all approved users declared on the Data Access Application and CITF Access Agreement must comply with the data security policy (Schedule C – CITF Data Security Policy).

7. Indigenous Data Governance

The CITF recognizes the historic inequitable and harmful nature of research involving Indigenous Peoples and their communities. In addition, the CITF recognizes that in facilitating the sharing of data with researchers, some manipulations and interpretations of the data could have implications for Indigenous Peoples and communities. As such, this document provides a set of principles, which the CITF will use to protect Data Assets.

Currently, the CITF does not intend to centralize data from any studies that focus exclusively on Indigenous Peoples and communities. The following principles therefore apply to CITF-funded studies from across Canada where some participants self-identify as an Indigenous Person or living in an Indigenous community.

As Indigenous Peoples and communities assert the right to govern how their information is used, controlled and disclosed, the OCAP principles are reflected in all applicable agreements, policies and procedures that concern Indigenous Data Assets. As such, researchers wishing to access the data must also comply with these policies. The following policies are actively being implemented:

The full set of principles and policies can be found in Appendix G (*CITF Governance of Data about Indigenous Peoples and Communities*) of the CITF Data Governance Framework.

The CITF recognizes that some of the Core Data Elements could be analyzed in a manner that would risk the identification or stigmatization of Indigenous communities, including harmful psychological, social or other effects on communities or individuals. To limit this risk, Access Applicants are required to provide justification and evidence of REB approval when they request access to the following variables:

- Indigenous identity
- Living on Reserve
- Ethnicity of participant
- Rural FSA
- Postal Code

An expert in Indigenous health research has been appointed as a Data Access Committee Member. They will help to ensure appropriate Indigenous Data Governance when decisions are being made concerning access to data that involves the variables flagged above.

Moreover, if the requested data would allow the identification of communities, the Access Applicant must use appropriate engagement and procedures as dictated by the implicated communities.

8. Access Documents

8.1 Access Application Form

To Access CITF Data, an applicant must register for an account with the [CITF Data Access Portal](#). A single member of the Access Applicant team is responsible for this account. They must then complete and submit the Data Access Application.

Documentation to be submitted along with the application includes:

- Research Summary including justification for the requested variables and statistical analyses to be conducted
- Evidence of approval by a Research Ethics board for the research project or confirmation and justification for why REB approval is not required
- CV of the Researcher applying

This Access Application will be validated for completeness and conformity by the Data Access Office and reviewed by the Data Access Committee.

8.2 Signed Access Agreement

Once approved by the Data Access Committee, the data requested from the CITF will be shared with the Approved User and their affiliated institution following completion

of the Access Agreement with the Approved User, and signature of the agreement by the Approved Institution and McGill University.

9. Application Review Process

Access Applicants must create an account on the CITF Data Access Portal, where they will be able to explore data variables and submit Data Access Applications. The Access Application form is completed by the Access Applicant of the Research Project and must include all supporting documentation. Once submitted, the Access Application is validated by the Data Access Office for completeness and conformity. If necessary, the Access Applicant will be instructed by the Data Access Office to make changes. The Data Access Committee will review each Access Application according to the Criteria for Approval. An Access Application can be Approved, Rejected or Conditionally Approved. Access Applicants can revise their Access Application according to the comments received from the Data Access Committee, if applicable. Once approved, the Access Agreement is signed by all parties. The Data Management team proceeds with data preparation and processing steps in order to initiate data sharing with the Approved Institution.

Once data sharing has commenced, if there are any changes to the research project or research project personnel from the original Data Access Application that could affect the use of the CITF Data, an Amendment form must be completed by the Applicant, validated, reviewed and approved by the CITF Data Office and CITF Data Access Committee before changes can be carried out by the research team. Should a data breach occur that is known or, with reason, assumed to have affected the CITF Data, immediate notice must be given to the CITF and the CITF data security policy should be followed. Access Applicants accessing the data must also comply with the CITF Publication Policy when publishing research using CITF Data.

10. Criteria for Approval

The following criteria will be used by the Data Access Committee in considering whether to approve requests to Access CITF Data:

- Data Access Office has received all necessary documents.
- Data Access Office confirms availability of CITF Data
- Research is in accordance with the guiding principles of the CITF
- Research has been deemed scientifically sound and the project scope is appropriate
- Justification for the need of the CITF Data is provided
- Proof of REB approval, or justification for REB exemption, has been given
- Should CDEs (Core Data Elements) referenced as “sensitive” be requested, specific justification and study team expertise for the use of these variables is provided in the REB Approval and the Study Protocol.

11. Confidentiality of Applications

All information submitted in the Access Application Form will be kept confidential within the Data Access Office and Data Access Committee. Once Access is granted, general information about the Research Team and the associated Research Project will appear on the CITF Data Access “Approved Projects” Webpage for public view.

12. Publication Policy

Researchers Accessing the data must also comply with the CITF Publication Policy when publishing research using CITF Data.

- Maintaining the confidentiality of the CITF Data in all reports, publications and presentations resulting from the use of the CITF Data. There will be no publishing of any CITF Data or any research outputs, such as derived data that can be potentially identifying.
- Remaining aware of any changes made to the CITF Publication Policy and ensuring continued application with said policy.
- Following the Fort Lauderdale Guidelines, the Toronto Statement, as well as the GA4GH Framework for Responsible Sharing of Genomic and Health-Related Data.
- Recognizing the contribution of the CITF and including an acknowledgement in all reports or publications resulting from the use of data held in the Controlled Access Tier of the CITF Database. The following attribution should be used: The data used in this research was made available by the COVID-19 Immunity Task Force.
- Citing in all publications using data from the CITF Databank a central marker paper describing the work by the CITF Secretariat and Principal Investigators of studies that have deposited data in the CITF Databank.

13. Destruction of Data

Researchers agree to destroy their copy of the CITF Data on or before the date in their CITF Access Agreement. Researchers agree to maintain documentation evidencing the destruction of the CITF Data and to make such records available to the CITF on request.

14. Amendment to Applications

The approved user must inform the Access Office of any changes in the research project, or in the status of approved users or Approved Institution. Should changes to the research project personnel occur that could affect the use of the CITF Data, an Amendment form must be filled out with said changes. This change must be

approved by the Access Office and Access Committee and new members must enter into the Access Agreement with McGill university.

In addition, should changes be made to the research project protocol or events occur during the project that could affect the use of the CITF Data, or the original information provided in the Access Application form, an Amendment form must be completed and approved. If the changes are minor or administrative, the form will be reviewed and approved by the Data Access Office. Should the changes be substantial, the data Access Committee will be required to conduct a full review. However, any suspected threats to the confidentiality and security of the CITF Data must be reported to the CITF and the Data security policy must be followed.

15. Return of Research Results and Incidental Findings

It will not be possible for the CITF nor Access Applicants 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 data in the CITF Database will also be made available in the academic publications of CITF researchers and of Access Applicant having Accessed data in the CITF Database.

16. 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.

17. Derived Data

The CITF does not enforce any routine requirements to share derived data. However, if a researcher creates a variable that could be useful to others, the CITF will consider incorporating this into the CITF Database on a case-by-case basis.

18. Financial Considerations

There is currently no charge for researchers to Access.

Version History

| Amendment No. | Date | Changes |
|---------------|-------------------|--------------------------|
| 1 | November 30, 2022 | First version Completed. |