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

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

WHEREAS the Recipient Institution 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 Dr. David Buckeridge, a Professor in the School of Population and Global Health at Recipient Institution, is Scientific Lead Data Management for CITF (herein referred to as "**Recipient Scientist**"; Recipient Institution and Recipient Scientist are collectively referred to as "**Recipient**");

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 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. When uploading the Data to the CITF Database the Provider Scientist will be required to sign an acknowledgement (herein "**Acknowledgement"**) in the form set out in Appendix 4.

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.

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 located 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. Each Party (the "**Indemnifying Party**") shall indemnify and hold harmless the other Party including their respective directors, officers, members, employees, representatives, and any other persons for whom the Party is or may become responsible for in law (collectively, the "**Indemnified Party**") from and against all losses, costs, expenses, damages, claims, demands, awards, judgments, actions and

proceedings including reasonable legal fees and disbursements, by whomsoever, including the Indemnified Parties, made, brought or prosecuted against the Indemnified Party in respect of loss of, damage to, or destruction of property and personal injury, including death, where the damage is caused or contributed to, directly or indirectly, (1) by the negligence of the Indemnifying Party or any person(s) for whom the Indemnifying Party is at law responsible and/or (2) by breach of this Agreement.

4.3. 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 8, 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; or

7.2.2. there is a change in the data custodian and the data governance conditions established in Framework; or

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:

[Organization]

By its authorized signatory:

X _____

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

Acknowledgment by Recipient Scientist

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 Recipient participants are informed of their obligations under said terms and conditions.

X _____

Dr. David Buckeridge
Scientific Lead Data Management, CITF Secretariat
Date:

Provider Scientist

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 Provider participants are informed of their obligations under said terms and conditions.

X _____

Name:
Title:
Date:

Appendix 1

Description of Data Sharing Events

Data collection for study visits completed by the signing date of this document began in [Month/Year] and ended in [Month/Year]. The study team will be able to start sharing those Data with the Recipient once the data sharing agreement is in place. After the initial upload of data, the plan is to provide data every 2 months or no later than 3 months after data collection for each study visit has ended.

Please preface the 'Description of data sharing events' with a brief summary of the Research Project that includes the scope of work, (the technical and scientific description of the Project) with time schedule for milestones and deliverables.

Appendix 2

Description of Core Data Elements and Associated Metadata

Based on Appendix 2, Provider and Recipient will discuss with each other the Core Data Elements and Associated Metadata that Provider will be able to share with Recipient from the Research Project.

(insert CDE for study's funding initiative)

Appendix 3

CITF Data Governance Framework

(see complete PDF)

Appendix 4

Acknowledgment by Provider Scientist when uploading Data to CITF Database: Conditions of Data Contribution

If not otherwise defined herein, the terms used in this acknowledgment shall have the meaning given to them in the Data Sharing Agreement.

Designated Responsible Contact

Provider Scientist agrees to be publicly listed and to remain responsible for responding to any requests from research participants and sample donors regarding the Data, to the exclusion of the CITF. Provider Scientist understands and agrees that the contact information Provider Scientist has provided to the Recipient may be displayed for the purpose of attribution and to allow third parties to contact Provider Scientist.

De-Identification and Data Linkage Documentation

Provider Scientist confirms that all direct identifiers have been removed from the Data and been replaced them with a unique code.

Provider Scientist shall retain the re-identification key (linkage log) required to associate the nominative identity of the research participants and sample donors with the re-identification key, unless doing so would cause Provider Scientist to breach their local ethical, legal, or institutional rules.

Data Withdrawal

Provider Scientist agrees to promptly notify the CITF on becoming aware of any situation requiring the removal of Data from the CITF Database, including a request to withdraw data on behalf of a research participant or sample donor. Provider Scientist is solely responsible for the withdrawal of the Data, as the CITF does not retain linkage logs allowing it to honor data withdrawal requests.

Data Correction

Provider Scientist agrees to notify the CITF of any errors or omissions in the Data upon becoming aware of them. If Provider Scientist changes or modifies the Data, or become aware of such changes, it is Provider Scientist's responsibility to contact the CITF to notify it of these updates.

Data Remediation

The CITF reserves the right to amend, modify or correct, the Data if the data bears inaccuracies or to enhance data interoperability.