GOVERNING DATA & BIOLOGICAL SAMPLES TRANSFER AGREEMENT

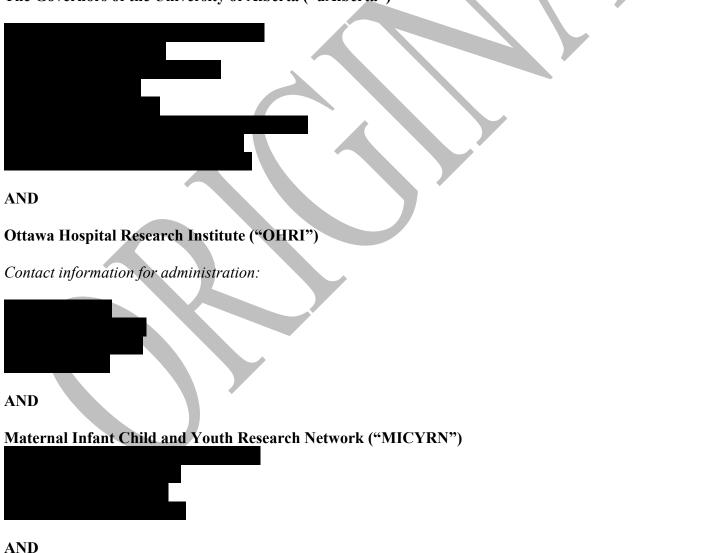
This Governing Data & Biological Samples Transfer Agreement (the "Governing Agreement") is entered into by and between:

McMaster University ("McMaster")



AND

The Governors of the University of Alberta ("uAlberta")



The gDSSA was created by the Accelerating Clinical Trials (ACT) Consortium Contracts Working Group- a Canadian Institutes of 1 Health Research (CIHR) funded initiative

CHU de Québec - Université Laval ("CHUQ-UL")



AND

Dalhousie University ("Dalhousie")



AND

The University of British Columbia ("UBC")



Vancouver Coastal Health Authority ("VCHA")



AND

Provincial Health Services Authority (on behalf of BC Children's Hospital and BC Women's Hospital and Health Centre) ("PHSA")



Provincial Health Services Authority (on behalf of BC Cancer) ("PHSA on behalf of BC Cancer")



AND

Providence Health Care Society ("PHCS")

Contact information for administration



AND

The Research Institute of the McGill University Health Centre ("RI-MUHC")



AND

The University of Saskatchewan ("USASK")

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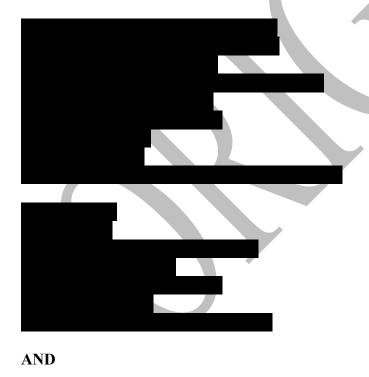


The Saskatchewan Health Authority ("SHA")



AND

Shared Health, the provincial health authority under *The Health System Governance and Accountability Act*, operating the Health Sciences Centre Winnipeg ("**SH**")



The University of Manitoba ("UM")

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Lawson Health Research Institute,

a joint venture of London Health Sciences Centre Research Inc. and Lawson Research Institute ("**Lawson**")



AND

Hamilton Health Sciences Corporation ("HHSC")

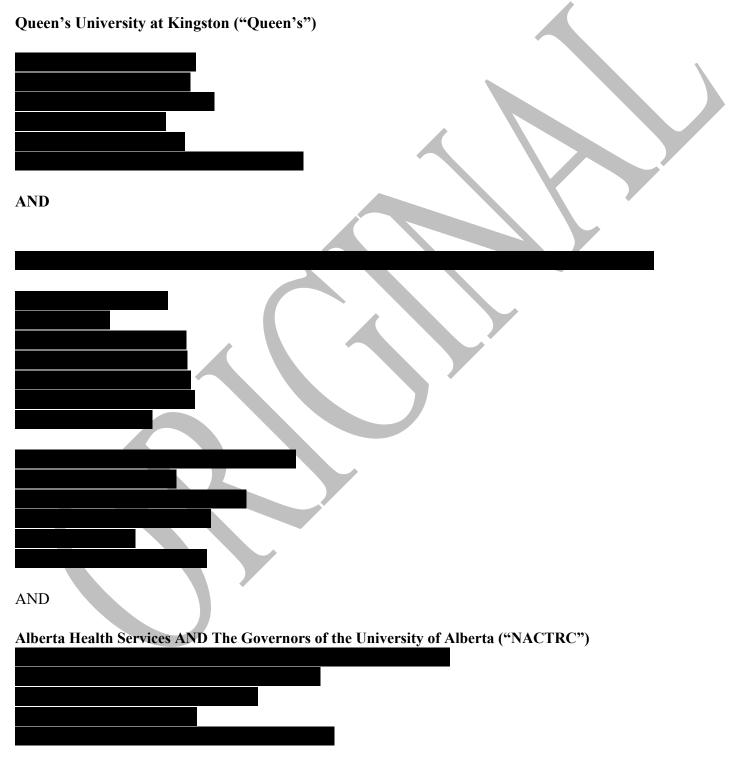
AND

Kingston Health Sciences Centre ("KHSC"), together with its research institute, Kingston General Health Research Institute ("KGHRI"),

-			
		~	
AND			
The University of	f Western On	tario ("We	stern")
			,

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AND

The gDSSA was created by the Accelerating Clinical Trials (ACT) Consortium Contracts Working Group- a Canadian Institutes of 6 Health Research (CIHR) funded initiative

	-

Ottawa Heart Institute Research Corporation ("OHIRC")

AND

University of Ottawa ("uOttawa")

AND

Institut du Savoir Montfort ("Monfort")





WHEREAS,

- A. the Parties (defined below) work together closely and collaboratively on multiple studies requiring transfer of Data and/or Samples (each of which is defined below);
- B. the Parties wish to streamline the contract review and approval process for Data and/or Samples transfer agreements; and
- C. this Governing Agreement is made for the purpose of streamlining the contract review and approval process for Data and/or Samples transfer agreements between the Parties, and in compliance with Provincial Health Privacy Laws (defined below).

NOW THEREFORE, in consideration of the mutual covenants and agreements of the Parties and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

- 1. **Definitions**. As used in this Governing Agreement, the term:
 - a) "Applicable Law" means all applicable laws, regulations, guidelines and policies, including, but not limited to, PIPEDA to the extent applicable, and Provincial Health Privacy Laws;
 - b) "Data" means all data that has been collected for the purpose of the Study by Disclosing Party and is provided to Receiving Party for the purpose of carrying out the Study;
 - c) "Data/Samples" means Data and/or Samples;
 - d) "Disclosing Party" means the Party providing Data/Samples to Receiving Party as outlined in the Transfer Letter attached for each Study;
 - e) "Effective Date" means January 1, 2024;
 - f) "Governing Agreement" has the meaning described above;
 - g) "Lead Investigator" means the Lead investigator outlined in the Transfer Letter attached for each Study;
 - h) "Parties" means McMaster, uAlberta, OHRI, MICYRN, CHUQ-UL, Dalhousie, UBC, VCHA, PHSA, PHSA on behalf of BC Cancer, PHSC, RI-MUHC, USASK, SHA, SH, UM, Lawson, HHSC, KHSC together with KGHRI, Western, Queen's, AHS-UCalgary, NACTRC William Osler, OHIRC, uOttawa, Montfort, and Unity Health collectively;
 - i) "Party" means any of McMaster, uAlberta, OHRI, MICYRN, CHUQ-UL, Dalhousie, UBC, VCHA, PHSA, PHSA on behalf of BC Cancer, PHSC, RI-MUHC, USASK, SHA, SH, UM, Lawson, HHSC, KHSC together with KGHRI, Western, Queen's, AHS-UCalgary, NACTRC, William Osler, OHIRC, uOttawa, Montfort, or Unity Health;
 - "PHI" means "Personal Information" as defined in PIPEDA or Provincial Health Privacy Laws, and "Personal Health Information" or "Health Information" and "Individually identifying Health Information" or similar terms as defined in Provincial Health Privacy Laws, individually and collectively;

- k) "Provincial Health Privacy Laws" means the applicable health privacy laws in each province including as applicable, *Personal Health Information Protection Act, 2004*, S.O. 2004, c. 3 ("PHIPA") (Ontario), the *Act respecting Access to documents held by public bodies and the Protection of personal information, RLRQ., c. A-2.1* (Quebec), the *Health Information Act*, RSA 2000, c H-5 ("HIA") (Alberta); Personal Health Information Act ("PHIA") (Nova Scotia), *The Personal Health Information Act*, C.C.S.M.c. P33.5 ("Manitoba PHIA") (Manitoba), *the Health Information Protection Act* (Saskatchewan) ("HIPA"); Freedom of Information and Protection of Privacy Act ("FIPPA") (British Columbia);
- 1) "PIPEDA" means Personal Information Protection and Electronic Documents Act (S.C. 2000, c. 5);
- m) "Protocol" means the REB-approved protocol, included as Attachment I to the applicable Transfer Letter made hereunder, as well as all other materials provided to an REB as part of the research plan, which may be amended from time to time subject to the approval of the applicable REB and all such amendments shall be incorporated into the Protocol and shall form a part of this Agreement by reference;
- n) "REB" means the applicable research ethics board(s);
- o) "Receiving Party" means the Party receiving Data/Samples from Disclosing Party as outlined in the Transfer Letter attached for each Study;
- p) "Samples" means human biological samples derived from human subjects that have been collected for the purpose of the Study at Disclosing Party and are provided to Receiving Party for the purpose of carrying out the Study;
- q) "Study" means the study identified in the Transfer Letter as approved by all applicable REBs;
- r) "Study Staff" means internal personnel and/or agents of each Party who need access to the Data/Samples for the purposes herein and who are made aware of and will be required to comply with either the confidentiality obligations herein or confidentiality obligations substantially the same as those set forth herein;
- s) "Sub Institution" means the sub institution outlined in the Transfer Letter attached for each Study.
- t) "Sub Investigator" means the sub investigator outlined in the Transfer Letter attached for each Study;
- u) "Transfer Letter" means the fully executed Transfer Letter for each Study, including any attachments thereto, signed by the requisite Parties, as applicable. Each Transfer Letter shall be in a format substantially similar to the form of the Transfer Letter attached hereto as Schedule A (or in such other form as agreed to between the Parties from time to time).
- 2. **Compliance**. Disclosing Party wishes to share the Data/Samples with Receiving Party for the abovereferenced Study. In transferring the Data/Samples, the Parties shall comply with all Applicable Law. Disclosing Party will prepare and furnish the Data/Samples in accordance with Provincial Health Privacy Laws including without limitation obtaining all appropriate consents. The Parties hereto shall use a secure method of provision of the Data/Samples by Disclosing Party to Receiving Party. The Data/Samples will not be collected and/or transferred until Disclosing Party's REB and, if applicable Receiving Party's REB, have: a) approved the Protocol; and b) approved the Study informed consent forms or waived the requirement to obtain consent, to the extent applicable. Disclosing Party retains the right to conduct audits of Receiving Party's compliance with this Governing Agreement, as well as with each Transfer Letter, upon reasonable advance written notice to Receiving Party and at mutually acceptable times. If there is a breach of the Transfer Letter or Governing Agreement by Receiving Party, Disclosing Party may require

that all applicable Data/Samples be returned promptly to Disclosing Party or destroyed in a secure manner, at Disclosing Party's option, to the extent feasible. Disclosing Party retains the right, acting on reasonable grounds, to refuse the transfer of the Data/Samples requested hereunder.

- 3. Use of Data/Samples. The Parties acknowledge that the Samples may contain one or more infectious agents and may have additional unknown and hazardous properties. Receiving Party shall use the Samples under appropriate containment conditions. The Data/Samples are provided on an "as-is" basis and Disclosing Party makes no representations or warranties, express or implied, including as to its usefulness, efficacy, suitability for any purpose, or that the use of the Data/Samples will not infringe any patents, copyrights, trademarks, trade secrets or other proprietary rights with respect thereto. Receiving Party accepts that there are no representations, warranties, conditions or liabilities expressed or implied herewith in relation to the Data/Samples by Disclosing Party or its trustees, directors, officers, affiliates, investigators, students, employees, servants, authorized representatives or agents.
- 4. **Transfer Letter.** The Parties agree that certain terms of the Governing Agreement may be altered through the Transfer Letter to capture the Parties' intentions for a specific Study. Each Party will maintain a governing list of all Transfer Letters executed by that Party hereunder. The Parties to each Transfer Letter may agree to amend any clause hereunder for the purpose of that Transfer Letter. All Transfer Letters will be signed by the appropriate signing authority for each Party in accordance with that Party's applicable policies and/or procedures.
- 5. **Non-Disclosure of Data/Samples**. Receiving Party shall limit access to the Data/Samples only to its Study Staff with a need to know for the purpose of conducting the Study, and who are made aware and will be required to comply with either the terms of this Governing Agreement or terms no less stringent than those contained herein. Receiving Party agrees that it/he/she shall, and shall require its/his/her Study Staff to:
 - a) maintain the Data/Samples in confidence, and not disclose the Data/Samples except as permitted by this Governing Agreement or as otherwise specified in the Transfer Letter and as applicable to the Study;
 - b) use the Data/Samples solely for the purposes of the Study or other expressly consented purposes, in compliance with:
 - (1) the Protocol as approved by Disclosing Party's REB and as amended from time to time, provided that such amendments are approved by Disclosing Party's REB;
 - (2) any written conditions imposed by Disclosing Party's or Receiving Party's REB;
 - (3) the Study subject's consent consistent with the informed consent form approved by Disclosing Party's REB or, if the authorization has been obtained otherwise in compliance with Applicable Laws, such as from an institutional authorization, or, to the extent applicable if the requirement to obtain consent has been waived, or otherwise determined to be unnecessary, by Disclosing Party's REB, the waiver of consent given by Disclosing Party's REB;
 - (4) any other conditions or restrictions imposed by Disclosing Party relating to the use, security, disclosure, return or disposal of the Data/Samples as set out in this Governing Agreement or as specified in the Transfer Letter.
 - c) not use the Data/Samples to identify or attempt to identify any individuals, unless expressly permitted by the applicable REBs;
 - d) if applicable, use any PHI transferred hereunder exclusively for the purposes of the Study and in accordance with this Governing Agreement and Applicable Law;
 - e) not disclose, transfer, update, distribute, market, sell, or make any other use of the Data/Samples to any third parties without the prior written consent of Disclosing Party. Notwithstanding the foregoing, Receiving Party may transfer the Data/Samples:
 - (1) to regulatory authorities, provided that Receiving Party gives prior written notice of such intended disclosure to Disclosing Party;

- (2) as otherwise permitted by the informed consent form or waiver of consent; or
- (3) in order to comply with Applicable Law or judicial process, or with a court or regulatory order, provided that Receiving Party gives prior written notice of such intended disclosure to Disclosing Party 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.
- f) securely destroy the Data/Samples as required by the Protocol or instructed by Disclosing Party and provide a written confirmation of the manner of destruction in a form acceptable to Disclosing Party; and/or,
- g) in the event that Receiving Party retains a third party to house or maintain the Data/Samples in a database or otherwise transfers the Data/Samples to a third party, with Disclosing Party's consent and in accordance with the informed consent form, that Receiving Party will ensure that any such third party is contractually bound by obligations of patient confidentiality, privacy, security and non-use with respect to the Data/Samples no less stringent than those contained herein. The Receiving Party shall remain responsible for the third party's actions and inactions as it pertains to the Data/Samples. Notwithstanding the foregoing, all such transfers to third parties shall be in accordance with the Protocol.

6. Safeguards and Notification.

- a) Receiving Party shall use appropriate safeguards, specifically safeguards that are no less stringent than those that Receiving Party employs to protect its own confidential and proprietary information (including, without limitation, with respect to encrypting identifying numbers, linking files, storing and retrieving files from secured locations) to prevent any unauthorized access, use or disclosure of the Data/Samples, and shall promptly report to Disclosing Party any unauthorized access, use or disclosure of which Receiving Party becomes aware. Such safeguards and protections shall be used by Receiving Party for all of the Data/Samples received from Disclosing Party. The above shall apply to any copies of the Data/Samples made by Receiving Party and kept at their premises. Receiving Party shall take appropriate care in the disposal or destruction of the information to prevent unauthorized parties from gaining access to it. The Parties shall make their employees and agents aware of the importance of maintaining the confidentiality of any collected or transferred PHI. These obligations of confidentiality shall survive the expiration or earlier termination of this Governing Agreement for a period of seven (7) years or as required under the relevant Provincial Health Privacy Laws, whichever period is longer.
- b) If approved by the applicable REBs, the Parties may exchange PHI as required for the Study in accordance with this Agreement and Applicable Law. In the event of an unauthorized transfer of PHI to Receiving Party or its employees, contractors, or agents, Receiving Party and its employees, contractors, and agents shall not use or disclose such information and shall: 1) immediately notify Disclosing Party in writing of receipt of such PHI upon becoming aware of same; 2) promptly destroy such PHI in a secure fashion; and 3) promptly certify such destruction in writing to Disclosing Party.
- 7. **Contact with Subjects/Individuals**. Unless expressly permitted by the applicable REBs, Receiving Party shall not make contact or attempt to make contact with an individual or Study subject unless Disclosing Party first obtains the individual's consent or Study subject's consent to be contacted, except to the extent that Receiving Party is otherwise the individual's or Study subject's health information custodian or trustee.
- 8. **Ownership of Data/Samples**. Unless otherwise specified in the Transfer Letter, no right, title or interest in and to the Data/Samples is granted to Receiving Party or implied hereunder. However, all rights to information, analysis of the Data/Sample, and results produced, generated or developed in the course of the Study and arising out of the Study ("Study Results") shall be owned by the Receiving Party.
- 9. The Receiving Party hereby agrees to share the information and results arising from its analysis of the Data/Samples with Disclosing Party and grants to the Disclosing Party a license to use the Study Results

for internal research, quality improvement, clinical, scientific, and educational purposes. Said license is worldwide, non-exclusive, perpetual, royalty free, fully paid-up, irrevocable, non-transferable, non-sublicensable. Patient medical records and internal source documents shall remain at all times the property or under the custody of Disclosing Party or if the Disclosing Party is not the trustee or custodian of medical records, then patient medical records shall remain in the custody and control of the trustee or custodian of such medical records.

Intellectual Property

- 10. Receiving Party shall promptly inform Disclosing Party of the creation of any patentable intellectual property arising from any use of the Data/Sample ("New IP"). If New IP results from the sole contribution of a Party, the property rights and obligations pertaining thereto belong exclusively to that Party in accordance with that Party's policies and collective agreements. If it is determined that a Party is sole owner of New IP, this Party will grant to the other Party a royalty-free, irrevocable, non-exclusive, worldwide, without limit of time or without the right to grant sublicense, license to use such New IP for internal academic, training, clinical, and research purposes If the New IP results from the contribution of more than one Party, the property rights and obligations are divided according to the relative inventive contribution of the inventors of each Party and their applicable respective internal policies and collective agreements. In the case that the Parties' internal policies conflict with one another or the Parties are unable to agree as to their relative inventive contribution, the Parties shall negotiate ownership rights acting reasonably and in good faith.
- 11. Each Party shall retain the rights in its respective Background Intellectual Property. This Governing Agreement is not intended to and shall not infer any license grant or assignment, whether expressed or implied, with regard to such Background Intellectual Property. "Background Intellectual Property" means any intellectual property that was owned or controlled, directly or indirectly, by a Party prior to the date of this Governing Agreement or after the date of this Governing Agreement but that is developed by a Party independently to any Study.
- 12. **Financial Terms.** All financial terms associated with any transfer of Data/Samples shall be addressed as Attachment II to each Transfer Letter.
- 13. **Publication**. Unless otherwise specified in the Transfer Letter, Receiving Party shall have the right to use: a) the analyzed, de-identified data derived from the use of the Data/Samples; and b) information and results arising out of analysis of the Data/Samples, as part of a publication or presentation of the results of the Study. The Parties agree that the de-identified Data/Samples may be made publicly available for publication purposes to the extent required by the applicable publication. Receiving Party shall not include any personally identifying information, including PHI, in any publication or presentation. Disclosing Party's contribution to the Study shall be acknowledged appropriately in any such publication or presentation in accordance with academic standards.

14. **Obligations/Liability**

- a) Each Party shall be responsible and assume liability for any damage or loss to the extent that such damage or loss arises out of or as a result of its own negligence or willful misconduct or breach of this Governing Agreement or a Transfer Letter or the negligence or willful misconduct or breach of this Governing Agreement or a Transfer Letter of or by those for whom in law it/he/she is responsible.
- b) No Party or its trustees, directors, officers, employees, and agents (the "First Party") shall be liable to any other Party (the "Second Party") for any costs, suits, or claims made by the Second Party or

made against the Second Party except to the extent caused by negligence or willful misconduct or breach of this Governing Agreement or a Transfer Letter on the part of the First Party of or by those for whom in law it/he/she is responsible..

- c) The Receiving Party assumes full responsibility for any damages that may result from the Receiving Party's use or disclosure of the Data/Samples, except to the extent permitted by law when caused by the negligence or willful misconduct of the Disclosing Party or those for whom in law it/he/she is responsible. The Disclosing Party shall not be liable to the Receiving Party for any loss, claim or demand made by the Receiving Party, or made against the Receiving Party by any other Party, arising from the Receiving Party's use, access to, or disclosure of the Data/Samples except to the extent permitted by law when caused by the negligence or willful misconduct of the Disclosing Party or those for whom in law it/he/she is responsible.
- d) Further, the Receiving Party assumes full responsibility for any damages that may result from the Receiving Party's use or disclosure of the Study Results, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Disclosing Party or those for whom in law it/he/she is responsible. The Disclosing Party shall not be liable to the Receiving Party for any loss, claim or demand made by the Receiving Party, or made against the Receiving Party by any other Party, arising from the Receiving Party's use, access to, or disclosure of the Study Results except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Disclosing Party or those for whom in law it/he/she is responsible.
- e) During the term of this Governing Agreement and for the duration of its obligations surviving expiration or termination of this Governing Agreement, each Party shall maintain in full force and effect a policy or policies of insurance sufficient to cover its obligations hereunder. The obligation to maintain the insurance shall survive the completion or termination of this Agreement. The amount of insurance is not a limit on each of the Parties' liabilities as set out herein. Each Party acknowledges and agrees that it is its sole responsibility for determining the adequacy of its insurance coverage. As applicable, the Lead Investigator and Sub Investigator shall maintain active membership in good standing in the Canadian Medical Protective Association during the course of the Study.
- f) Except as a component of third-party claims and except for damages arising from a Party's gross negligence or willful misconduct, no Party shall be responsible for any lost profits, lost opportunities, or other indirect or consequential damages suffered by another Party as a result of a Study or the performance of this Governing Agreement.

12. General Terms and Conditions.

- a) **Term:** This Governing Agreement shall become effective as of the Effective Date and shall automatically renew each year, unless all Parties withdraw from this Governing Agreement. The term of this Governing Agreement may be amended by an amendment document, agreed to and signed by all Parties.
- b) Withdrawal: A Party may withdraw from this Governing Agreement with thirty (30) days' written notice to the Ottawa Hospital Research Institute. Such withdrawal shall not affect any Transfer Letters that are currently in effect at the time of withdrawal. Further, such withdrawal will not affect the validity of any provisions that are, expressly or by implication, to survive or to take effect after such withdrawal. Withdrawal from this Governing Agreement shall be without prejudice to the accrued rights and liabilities of the Parties under this Governing Agreement.

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- c) **New Parties.** New Parties may sign onto this Governing Agreement by executing the Joinder Letter, attached here as Schedule B, as set out in Schedule B. The Ottawa Hospital Research Institute shall update all Parties when new signatories sign the Joinder Letter.
- d) Assignment: This Governing Agreement shall enure to the benefit of and be binding upon the Parties and their respective successors, heirs and permitted assigns. No Party shall be entitled to assign or transfer this Governing Agreement or the rights and obligations hereunder to any third party without the prior written approval of the other Parties.
- e) Entire Agreement: If there are any conflicts between the terms of a Transfer Letter and the terms of this Governing Agreement, the terms of the Transfer Letter will govern with respect to Study-specific matters and this Governing Agreement with govern with respect to all other matters. If there are any conflicts between the Protocol and the Transfer Letter, the Protocol will govern with respect to all other matters.
- f) **Amendments:** This Governing Agreement shall not be amended, modified, varied or supplemented except in writing signed by each of the Parties.
- g) **Waiver:** A failure by any Party to take any action with respect to any default or violation by another Party of any of the terms, covenants, or conditions of this Governing Agreement shall not in any respect limit, prejudice, diminish, or constitute a waiver of any rights of such Party to act with respect to any prior, contemporaneous, or subsequent violation or default or with respect to any continuation or repetition of the original violation or default.
- h) **Independent Contractors:** The Parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between or among the Parties hereto a partnership or joint venture or employment or principal-agent relationship. No Party shall have the authority to act on behalf of any other Party or to bind another Party in any manner.
- i) Use of Name/Symbols: No Party shall use, or authorize others to use, the name, symbols, or marks of another Party hereto or its staff for any endorsement purposes without prior written approval from the Party whose name, symbols or marks are to be used., except as described in Article 13, Publication.
- j) **Governing Law:** This Governing Agreement shall be governed, construed and interpreted pursuant to and in accordance with the laws of the Province of the Party defendant in litigation, and the laws of Canada applicable herein. The provincial or federal courts having jurisdiction in the Province of the Party defendant in litigation shall have exclusive jurisdiction over all matters pertaining to this Governing Agreement.
- k) **Force Majeure Clause:** Noncompliance by a Party with the obligations of this Governing Agreement due to force majeure, including laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labor disturbances, shortage of materials, disease, epidemic, public health crisis, failure of public utilities or common carriers, or any other causes beyond the reasonable control of the applicable Party, shall not constitute breach of this Governing Agreement and such Party shall be excused from performance hereunder to the extent and for the duration of such prevention, provided it promptly notifies the other Parties in writing of such prevention and that it uses reasonable efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

- 1) Counterparts: This Governing Agreement may be executed by way of electronic signature and in any number of counterparts with the same effect as if all Parties had signed the same document. All of these counterparts will for all purposes constitute one Governing Agreement, binding on the Parties, notwithstanding that all Parties are not signatories to the same counterpart. A faxed or emailed PDF copy or photocopy of this Governing Agreement executed by a Party in counterpart or otherwise will constitute a properly executed, delivered and binding agreement or counterpart of the executing party.
- m) **Dispute Resolution:** The Parties shall make reasonable efforts to amicably resolve any issues, claims, disputes, controversy or inconsistencies involving this Governing Agreement or the Protocol and to escalate the matter to senior management prior to the commencement of any legal proceedings.
- n) Languages: In accordance with the Québec's Charter of the French Language, RLRQ. c. C-11, this Agreement can be written in the English language only. En conforvité avec les dispositions de la Charte de la langue française, RLRQ. c. C-11 du Québec, ce contrat peut être rédigé en anglais uniquement.
- o) Severability: The invalidity or unenforceability of any particular provision, or part of any provision, of this Governing Agreement shall not affect the other provisions or parts hereof, and this Governing Agreement shall be construed in all respects as if such invalid or unenforceable provisions or parts were omitted.



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IN WITNESS WHEREOF, each of the Parties has caused this Governing Agreement to be executed as follows:

Institution

Name: Title:

Date:

I have authority to bind the organization.

SCHEDULE A

TRANSFER LETTER

This Transfer Letter is entered between ______ ("Participating Institution"), Dr. ______, a physician professionally affiliated with Participating Institution ("Participating Investigator"), the ______ ("Lead Institution"), and Dr. ______, a physician professionally affiliated with Lead Institution ("Lead Investigator"), and is effective as of the last signature date below ("Transfer Letter Effective Date"). This Transfer Letter is a part of the Governing Data and Biological Samples Transfer Agreement ("Governing Agreement"), which the Lead Institution and Participating Institution are party to and which is effective on ______. ("Effective Date") The Parties agree that terms used in this Transfer Letter not otherwise defined will have the same meaning as set forth in the Governing Agreement.

The Parties hereby agree as follows:

1. Scope

This Transfer Letter constitutes a "Transfer Letter" as defined at 1(v) of the Governing Agreement. The transfer of any Data/Samples for the purposes of the Study, in accordance with the Protocol, attached as Attachment I to this Transfer Letter, is to be conducted, in accordance with the terms and conditions of the Governing Agreement.

2. Study Details

Study team to complete. Plea	se fill out the information requested in the table below:
Study Title:	
Participating Institution	
REB Number:	
Lead Institution REB	
Number:	

Attachments to this Transfer Letter:

- Attachment I: Protocol
- Attachment II: Financial Terms

3. Financial Terms

Any financial terms, including but not limited to fees for transfer, related to the transfer of the Data/Samples under this Transfer Letter are described in the Financial Terms, attached as Attachment II to this Transfer Letter.

4. Description of Data/Samples to be Transferred

a. Direction of Data/Samples Transfer:

SI	uay leam to complete. I lease check applicable box.	
]	The Data/Samples shall be transferred:	
	From Participating Institution to Lead Institution.	
	From Lead Institution to Participating Institution.	
	From Participating Institution to Lead Institution, and from Lead Institution to	
	Participating Institution.	

Study team to complete. Please check applicable box:

b. Type of Data/Samples to be Transferred:

Study team to complete. Please check applicable box:

Receiving Party shall not receive any PHI. The Parties agree that Receiving Party may receive PHI and that the transfer of such PHI has been approved by the applicable REBs.

Study team to complete. Please include any additional details about the Data/Samples in the box below:

Other Details.	

5. Modifications to Governing Agreement

 Study team to complete. Please check applicable box:

 The Parties agree to the following amendments to the Governing Agreement for the purposes of this Transfer Letter which may include additional terms and conditions:

 6.

 Term:

The term of this Transfer Letter will commence on the Transfer Letter Effective Date and will continue until the termination of the Study in accordance with the Protocol or termination of this Transfer Letter per Clause *The gDSSA was created by the Accelerating Clinical Trials (ACT) Consortium Contracts Working Group- a Canadian Institutes of* 18 *Health Research (CIHR) funded initiative*

7 below.

7. Binding on Investigators:

The Lead Investigator and Participating Investigator expressly agree to be bound by all terms and conditions of the Governing Agreement. [include if the Lead Investigator or Participating Investigator are a Party to the Transfer Letter. Adapt as needed] Lead Investigator and Participating Investigator agree that he/she has had the opportunity to seek independent legal advice with respect to this Transfer Letter and the Governing Agreement, has either sought such advice or has declined to do so, and is signing this Transfer Letter voluntarily and with a full understanding of its contents and the contents of the Governing Agreement.

8. Termination:

The Parties may terminate this Transfer Letter by providing thirty (insurn30) days prior written notice to the other Parties. Termination or completion of this Transfer Letter will not affect the validity of any provisions that are, expressly or by implication, to survive or to take effect after such termination or completion. Termination or completion of this Transfer Letter shall be without prejudice to the accrued rights and liabilities of the Parties under this Transfer Letter or the Governing Agreement.

9. <u>Amendments</u>:

Amendments to the Governing Agreement apply directly to this Transfer Letter. No modification, amendment, or waiver of this Transfer Letter shall be effective unless in writing and signed by a duly authorized representative of each Party, in accordance with Section 12(e) of the Governing Agreement.

10. Counterparts:

The Transfer Letter shall be executed in accordance with the applicable counterpart clauses of the Governing Agreement.

11. LANGUAGES

(If Applicable) In accordance with the Québec's *Charter of the French Language, RLRQ. c. C-11*, this Agreement can be written in the English language only. *En conforvité avec les dispositions de la Charte de la langue française, RLRQ. c. C-11 du Québec, ce contrat peut être rédigé en anglais uniquement*

IN WITNESS WHEREOF, each of the Parties has caused this Transfer Letter to be executed as follows:

Lead Institution

By:

Name:

Title:

Lead Investigator

By:

Dr.

Date:

Date:

I have authority to bind the organization.

Participating Institution

Participating Investigator

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By:		
Name:		
Title:		

<u>By:</u> Dr.

Date:	

Date:

I have authority to bind the organization.

Schedule B

Letter Joinder Agreement to GOVERNING DATA & BIOLOGICAL SAMPLES TRANSFER AGREEMENT ("Letter Joinder Agreement")

Form of Letter Joinder Agreement for a new party that wishes to sign onto and join the Governing Data & Biological Samples Transfer Agreement (the "Governing Agreement").

TO: Please return an executed copy of this Letter Joinder Agreement to: Ottawa Hospital Research Institute ("OHRI") c/o Jennifer Cox, Manager, Research Contracts at <u>jencox@ohri.ca</u> and to <u>contracts@ohri.ca</u>. OHRI will maintain signed originals and the official list of signatory organizations.

Name of New Party: (hereinafter "New Party"), Address of the New Party: Contact Information: Name and title: Email:

WHEREAS a number of research institutions and hospitals are parties to the Governing Agreement. In consideration for receiving the **Data/Samples**, and for other good and valuable consideration, the receipt of which is hereby acknowledged, the undersigned hereby declares and agrees as follows:

1. This Joinder Letter Agreement dated and effective ______ binds the New Party to all terms, conditions, rights, and obligations in the Governing Agreement as if they had been an original party to that Agreement.

EXECUTED by "name of the New Party" through its duly authorized representative(s).

Per:
Name/Title:
Date: