

## DATA SHARING AGREEMENT

This Data Sharing Agreement (the "**Agreement**") is made effective as of the last signature date below (the "**Effective Date**"), and is made

BETWEEN: **THE RESEARCH INSTITUTE OF THE MCGILL UNIVERSITY HEALTH CENTRE**, a non-profit organization incorporated under the laws of the province of Quebec, Canada, located at 2155 Guy Street, Suite 500 Montreal QC H3H 2R9 Canada

(herein "**RI-MUHC**")

AND: **DR. PIA WINTERMARK**, a researcher with privileges at the RI-MUHC and an address at McGill University Health Centre, Glen Site, 1001 Decarie Blvd, Room EM0.3244, Montreal, Quebec H4A 3J1

(herein the "**Registry Director**")

AND: Newborn Brain Society, Inc, a nonprofit incorporated under the laws of the Commonwealth of Massachusetts, with its registered address at 75 Francis St. #CWN-418, Boston, MA 02115, USA

(herein the "**NBS**")

AND: [Legal name of Provider], located at [complete address] (herein "**Provider**")

The RI-MUHC and Registry Director are herein collectively referred to as the "**Recipient**".

Provider, RI-MUHC and Registry Director are herein individually referred to as a "**Party**" and collectively referred to as the "**Parties**".

## RECITALS

**WHEREAS**, the Registry Director in collaboration with NBS wishes to establish a registry entitled "NBS HIE Collaborative Initiative: Advancing Neonatal Brain Care Together Protocol A Multicenter, Multinational Retrospective Project on Neonatal Hypoxic-Ischemic Encephalopathy (HIE)" (hereinafter referred to as the "Project Registry") to focus on neonatal HIE in a multi-national, multi-center retrospective cohort, as described in Exhibit A (the "Protocol", including any amendments to the protocol duly approved by the research ethics board) and have requested to obtain the Data (defined below), which is proprietary to Provider, for the purpose of the Project;

**WHEREAS**, NBS will serve in a collaborative role in the Project, providing support for coordination, communication, and awareness, and will not participate in the collection, access, storage, analysis, or handling of the Data;

**WHEREAS**, Provider wishes to contribute Data for the purpose of set forth in Exhibit A (the

“Project”);

**WHEREAS**, the Data will be housed at the RI-MUHC, managed and coordinated by the Registry Director and is meant to be shared for secondary use under certain conditions and after approval by the Data Governance Board, as described in the Protocol;

**WHEREAS**, the Provider is interested in providing the Data to the Recipient under the present terms and conditions.

**NOW THEREFORE THIS AGREEMENT WITNESSETH** that in consideration of mutual promises contained herein, and other valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereto covenant and agree with each other as follows:

**DEFINITIONS:**

“**Confidential Information**” means all information disclosed by Provider and (i) identified as being confidential during the term of this Agreement; or (ii) by reason of its nature, a reasonable person in similar circumstances would treat as confidential; or (iii) which is designated as confidential by law, whether such information is disclosed orally, in writing, graphically, electronically or in any other format, and includes, without limitation: Data, experimental results and reports. Notwithstanding the foregoing, any confidential information relating to the Project disclosed prior to the execution of this Agreement shall be subject to the definition of Confidential Information. Notwithstanding the foregoing, “Confidential Information” does not include information which:

- (a) at the time of disclosure, is publicly known or part of the public domain;
- (b) after disclosure, becomes publicly known through publications as set out under **Section 6** or as part of the public domain other than through breach of this Agreement by Recipient;
- (c) Recipient can establish by its written records was in its possession at the time of disclosure or was independently developed by Recipient that did not have access to the Confidential Information and was not acquired either directly or indirectly from Provider;
- (d) Recipient receives from a Third Party under no confidentiality obligations to Provider; or
- (e) is required to be disclosed by law or government regulation or court or governmental agency order, provided that the Recipient immediately notifies the Provider of said order, and takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimize the extent of such disclosure.

“**Data**” means the data and all information (including without limitation medical data and information and other personal health information) as described in the Protocol, that has been collected by and at Provider and entered by the Provider in REDCap.

“**Intellectual property**” means any invention, discovery, improvement, idea, process, formula, algorithm, technological advance, prototype, results, industrial design, data compilation, literary works, images, technical information, specification, technology,

machine, system, reagent, chemical compound and derivative, process and method of synthesis of compound or derivative, creation, logo, register, drawing, plan, biobank, domain names, website (including their design and content), software (source code, object code and documentation), micro software and hardware, model, prototype, specification, method, configuration, genetic and biological information, patentable (or not), protectable (or not) by copyright or any other right, as well as: (i) any patent, patent application, continuation, partial continuation, complementary application (divisional application), reissue and re-examination; (ii) any copyright, work or other subject matter of the copyright, and any application for registration, registration, substituted right and extension; (iii) any industrial design, application for registration and registration; (iv) any trade name, certification mark, trade name and trade name, and any registration and registration application relating thereto; (v) all know-how; and (vi) any other type of property right and interest in any such right.

**“Providing Investigator”** is XXXXXXXX;

**“Results”** means any and all results, conclusions or findings arising from the use of the Data in the Project including but not limited to all reports, data and analysis.

**“Project”** has the meaning as provided in the Preamble.

**“Third Party”** means any person or entity other than Provider, Recipient or any of their respective affiliates.

## **AGREED TERMS AND CONDITIONS:**

### **1. PROJECT**

- 1.1. The RI-MUHC and Registry Director request access to the Data at their sole risk and at no expense to the Provider solely for the purpose outlined in Project. This Agreement covers only the appended Project.

### **2. COMPLIANCE**

- 2.1. In transferring the Data, the Parties shall comply with all applicable federal and provincial/state privacy laws, regulations, guidelines (**“Privacy Law”**). The Parties shall make their employees, consultants, students and agents aware of the importance of maintaining the confidentiality of any collected or transferred personal health information or personal information
- 2.2. The Provider will prepare and furnish the Data in accordance with an approved Project protocol (the **“Protocol”**) including, without limitation, obtaining all appropriate consents. The Data will not be collected and/or transferred until the Provider’s Research Ethics Board (**“REB”**) or Institutional Review Boards (**“IRB”**) and, if applicable, the Recipient’s REB, have: (i) approved the Protocol; and (ii) approved the Project informed consent forms or waived the requirement to obtain consent.
- 2.3. The Parties agree that the transfer of Data shall be free of charge.

### 3. OWNERSHIP

- 3.1 The Recipient acknowledges that the Provider retains ownership and all title, right and interest in the Data, subject to the rights of Third Parties, if applicable. No right, title or interest in and to the Data is granted or implied to the Recipient except as stated in this Agreement. Nothing contained within this Agreement shall restrict Provider's right to deal with in any manner as owner to distribute the Data to other commercial or non-commercial entities.

### 4. CONFIDENTIALITY

- 4.1. Only anonymized or de-identified personal data will be shared with the Recipient. Personally identifying information will not be extracted from patient charts at the Disclosing Institution. No data that could reasonably be used to determine the identity of a patient will be disclosed by the Provider to the Recipient. Nevertheless it is agreed that in the event that the Recipient should come into contact with any information that could reasonably be used to identify a patient, the Recipient shall not use such information or disclose it to any Third Parties, except as required by applicable law.
- 4.2. The Recipient shall give access to the Data and the Provider's Confidential Information only to the Registry Director, its directors, officers, employees, medical staff, fellows, students, consultants and advisors (the "Project Personnel") with a need to know for the sole purpose of conducting the Project and who are bound by the same obligations herein. The Recipient shall be responsible for its Project Personnel's compliance with the terms of this Agreement and any breach thereof.
- 4.3. The Recipient agrees that it shall, and shall require its Project Personnel to:
- (a) maintain all Data and Confidential Information in confidence, except as permitted by this Agreement;
  - (b) use all Data and Confidential Information solely for the purposes of the Project and under the Registry Director's direct supervision;
  - (c) reproduce the Data and Confidential Information only to the extent necessary for the purposes of the Project or this Agreement, with all such reproductions being considered confidential;
  - (d) not transfer the Data disclosed under this Agreement to any Third Parties without obligating such Third Parties to comply with confidentiality obligations at least as restrictive as the ones in this Agreement;
  - (e) not use the Data and Confidential Information directly or indirectly for commercial purposes; and
  - (f) use all Data and Confidential Information in compliance with all applicable laws, regulations and guidelines.
- 4.3. Recipient shall not use the Data, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the participants from whom Data were obtained. Furthermore, Recipient shall not make contact or attempt to make contact with an individual participating in the Project.

- 4.4 The Recipient agrees to treat in confidence, for a period of seven (7) years from the date of its disclosure any of the Provider's Confidential Information. Notwithstanding the foregoing, Data consisting of an individual's personal information shall be held as being confidential indefinitely.

## 5. SAFEGUARDS AND NOTIFICATION

- 5.1. The Recipient shall use appropriate safeguards (including without limitation with respect to encrypting identifying numbers, linking files, storing and retrieving files from secured locations) to prevent any unauthorized use or disclosure of the Data and shall promptly report to Provider any unauthorized use or disclosure of which Recipient becomes aware.
- 5.2. Recipient will record and monitor access to the Data in its custody and investigate all reported cases of (i) unauthorized access to or modification of the Data in its custody, (ii) unauthorized disclose or use of the Data in its custody; and (iii) breaches of privacy or security with respect to the Data in its custody or with respect to any computer system in its custody that is used to access the Data. Recipient will report to Provider the results of any such investigations and the steps taken to address any remaining issues or concerns about the security of the Data or computer systems or the privacy of individuals to whom the Data relates.

## 6. PUBLICATION

- 6.1. Should the Results be included in one or more scientific publication(s), the Recipient shall acknowledge in the publication(s) or presentation(s) that the Data was provided by the Provider as well as the contribution of the Disclosing Investigator, where applicable. All publications will include an appendix listing the Providers who contributed Data under the mention "NBS HIE Collaborative Initiative", where applicable. Direct authorship shall be granted only in cases of significant contribution to data analysis and manuscript preparation. The authors list will be followed by "on behalf of NBS HIE Collaborative Initiative ". The Recipient shall provide the Provider with a copy of any such publication. If any publishable Results arise from the collaborative efforts of Provider and Recipient, then publication of the Results shall be a joint publication between the Provider and the Recipient and manuscripts will be written in collaboration between the investigators. Authorship of any such publication shall be in accordance with the ICMJE guidelines. The Recipient shall not disclose the Provider's Confidential Information or any personally identifiable information in any publication(s) or presentation(s).
- 6.2. Any and all publications arising from the Project will be authored "on behalf of the NBS HIE Collaborative Initiative".

## 7. INTELLECTUAL PROPERTY

- 7.1. The Recipient shall be the owner of the Results, but undertakes to provide to the Provider, on request, a written report describing the discoveries and Results obtained in the performance of the Project with the Data. All such Results must be treated confidentially. The Recipient grants to the Provider a royalty free, non-exclusive license to use the aforementioned Results

for academic and research purposes.

## 8. NON-TRANSFERABILITY

- 8.1. This Agreement is not transferable to Third-Parties including other investigators within the Recipient's institution.

## 9. TERM & TERMINATION

- 9.1. This Agreement shall be effective as of the Effective Date until the completion of the Project, unless otherwise extended, renewed, or amended by mutual written consent of the Parties or unless terminated earlier in accordance with the provisions hereof ("Term").
- 9.2. Any Party may terminate this Agreement at any time by giving thirty (30) days written notice to the other Parties. Notwithstanding the aforementioned, any Party may terminate this Agreement immediately for breach where the Party in breach has been given notice of the breach and that the breach has not been rectified within thirty (30) days of written notice thereof. Breach shall be defined as a failure to comply with any provision of this Agreement and the documents incorporated herein.
- 9.3. Termination of this Agreement shall not affect any rights or continuing obligations of the parties that by their nature remain valid after the term of the Agreement.
- 9.4. Any and all provisions, promises and warranties contained herein which by their nature or effect are required or intended to be observed, kept or performed after termination or expiration of this Agreement will survive the termination or expiration of this Agreement. For the avoidance of doubt Sections 3, 4, 5, 6 and 7 shall survive termination or expiry.

## 10. DESTRUCTION OF INFORMATION

- 10.1. Upon termination of this Agreement, Recipient shall immediately cease using the Data, and shall securely destroy or return the Data to the Provider as required by the Provider. The Recipient shall provide a written confirmation of the manner of destruction in a form acceptable to the Provider.
- 10.2. Recipient may retain one (1) copy of the Data to the extent necessary to comply with the records retention requirements under any applicable law, and for the purposes of research integrity and verification. The Recipient agrees that the confidentiality obligations herein shall survive the termination of the Agreement and continue to apply to such copy.

## 11. REPRESENTATIONS AND WARRANTIES

- 11.1. The Provider makes no representation or warranty, express or implied, regarding the value, usefulness or effectiveness of the Data, and specifically disclaims any implied warranty of non-infringement or merchantability, or the accuracy of the Data for any particular purpose. The Provider makes no representation or warranty that the Data will not infringe any patent, copyright, trademark, or other proprietary rights.

11.2. Each Party shall in no event be liable to the other Party for any loss of profits, be they direct, consequential, incidental, or special or other similar or like damages arising from any defect, error or failure to perform with respect to the Data, even if said Party has been advised of the possibility of such damages.

**12. LIABILITY AND INSURANCE**

1.1. The Recipient agrees to be liable for damages that may arise from the improper storage, security, use or disclosure of the Data by the Recipient. The Provider will not be liable to the Recipient for any loss, claim or demand made by the Recipient, or made against the Recipient by any other party, arising from said storage, security, use or disclosure of the Data by the Recipient. No indemnification for any loss, claim, damage, or liability is intended or provided by either party under this Agreement. For clarity, NBS shall have no responsibility or liability in relation to the storage, security, use, or disclosure of the Data, as it will not be involved in any aspect of data handling or analysis under this Agreement.

1.2. Each Party shall maintain insurance coverage in amounts required by applicable law and sufficient to cover its liabilities and obligations under this Agreement. Such insurance policy shall provide contractual liability coverage for each Party’s obligations herein and, in the event of a claim, each Party shall have recourse to its respective commercial or institutional liability insurance(s) or professional protective association, as the case may be.

**13. MISCELLANEOUS**

13.1. **Notices:** All notices or other communication under this Agreement will have binding legal effect only if written and addressed to any Party at its address provided below, in writing or by email, or at such other address as it may provide notice of from time to time. Each Party may change its address set forth below by notice in writing to the other Party. Notices will be sent to the following addresses:

<p>If to RI-MUHC:</p> <p>Research Agreements Office  The Research Institute of the McGill  University Health Centre,  2155 Guy Street, Suite 500  Montreal, Quebec, Canada H3H 2R9</p> <p>Email: <a href="mailto:contracts@muhc.mcgill.ca">contracts@muhc.mcgill.ca</a></p>	<p><b>If to Disclosing Investigator:</b></p> <p>Name :  Title:  Address:  Tel:  Email:</p>
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<p>If to the RI-MUHC:</p> <p>Dr. Pia Wintermark Address: McGill University Health Centre 1001 Decarie Blvd, Room EM0.3244 Montreal, Quebec H4A 3J1 Tel: 514-412-4452 Email: <a href="mailto:pia.wintermark@mcgill.ca">pia.wintermark@mcgill.ca</a></p>	<p>If to Provider:</p>
<p>If to NBS:</p> <p>Helen Vardanyan Email: <a href="mailto:h.vardanyan@newbornbrainsociety.org">h.vardanyan@newbornbrainsociety.org</a></p>	

- 13.2. **Independent Contractor.** The relationship between the Parties is that of independent contractors and nothing in this Agreement shall constitute an agency relationship, employment relationship, partnership or a joint-venture between the Parties or any two of them. No Party shall have the authority to act on behalf of any other Party or to bind another Party in any manner.
- 13.3. **No Waiver.** The failure of a Party to enforce at any time for any period any provision hereof will not be construed to be a waiver of such provision or of the right of such Party thereafter to enforce each such provision, nor shall any single or partial exercise of any right or remedy hereunder preclude any other or further exercise thereof or the exercise of any other right or remedy.
- 13.4. **Governing Law and Jurisdiction.** This Agreement shall be governed by and construed in accordance with the laws of the domicile of the defendant without reference to conflicts of law principles. The Party who decides to process with a suit shall do so in the jurisdiction of the defendant to entertain any complaint, demand, claim or cause of action whatsoever arising out of this Agreement.
- 13.5. **Use of Name.** No Party shall use the name, insignia, logo or other identifying characteristic of the other Party or of its affiliates, directors, officers, appointees or employees without the other Party's express written consent.
- 13.6. **Counterparts.** This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which taken together shall constitute one and the same instrument. Signatures to this Agreement transmitted by facsimile, email, and portable document format (PDF) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as the physical delivery of the paper document bearing original signatures. Further, an electronic signature shall have the same force and effect as an original signature written by hand by such Party and shall be considered a valid and binding obligation of the executing Party.
- 13.7. **Amendments.** This Agreement may only be amended by a document signed by the



- authorized representatives of the Parties and no other purported amendment is effective.
- 13.8. **Severance.** If any portion of this Agreement is held invalid by a court of competent jurisdiction, the invalid portion must be severed and neither the decision that it is invalid nor the severance affects the validity of the remainder of this Agreement.
- 13.9. **Whole Agreement/ Headings.** This Agreement is the entire agreement between the Parties and it terminates and supersedes all previous communications, representations, warranties, covenants and agreements, whether verbal or written, between the Parties with respect to the subject matter of this Agreement. The descriptive headings of the sections and subsections of this Agreement are for convenience only, and do not affect this Agreement's construction or interpretation.
- 13.10. **Preamble.** The Preamble is deemed to form an integral part of this Agreement and is incorporated by this reference into this Agreement.
- 13.11. **Language.** The Parties declare that they have accepted that this Agreement and all other documents and notices related thereto be drawn up in English. *Les parties aux présentes déclarent avoir accepté que cette convention et tous les documents et avis afférents soient rédigés en anglais.*

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Signature page follows



**IN WITNESS THEREOF** the Parties have signed or caused this Agreement to be executed by their respective duly authorized representatives, effective as of the Effective Date.

**THE RESEARCH INSTITUTE OF THE MCGILL  
UNIVERSITY HEALTH CENTRE**

**(PROVIDER)**

By: \_\_\_\_\_

By: \_\_\_\_\_

**Name:** Rhian M Touyz MBBCh, PhD,  
FRCP, FRSE, FMedSci, FRSC  
**Title:** Executive Director and Chief Scientific Officer

**Date:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**REGISTRY DIRECTOR**

**NEWBORN BRAIN SOCIETY**

By: \_\_\_\_\_

By: \_\_\_\_\_

**Name:** Dr. Pia Wintermark  
**Title:** Researcher

**Name:** Gabriel Variane  
**Title:** President

**Date:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Disclosing Investigator**

I have read and acknowledge the obligations herein this Agreement:

By: \_\_\_\_\_

Date: \_\_\_\_\_



## Exhibit A

### Project

Project Title: NBS HIE Collaborative Initiative: Advancing Neonatal Brain Care Together Protocol A  
Multicenter, Multinational Retrospective Study on Neonatal Hypoxic-Ischemic Encephalopathy  
(HIE)

(Protocol incorporated by reference and provided under a separate cover)