

**DATA SHARING AGREEMENT (“Agreement”)
Research Use of Anonymized Data**

BETWEEN: **(‘Provider’)**

(‘Provider Investigator’)

(the Provider Institution and Provider Investigator, together referred to as “Provider”)

AND

McMaster University (‘Recipient’)

1280 Main Street West
Hamilton, Ontario L8S 4L8

Dr. Behnam Sadeghirad **(‘Recipient Investigator’)**

Date: **(‘Effective Date’)**

WHEREAS, RECIPIENT is conducting an individual patient data meta-analysis (IPDMA) and systematic review aimed at developing a artificial intelligence-informed tool for the prediction of chronic post-surgical pain in adult patients undergoing knee replacement surgery (the “Study”) as described in the PROSPER Anonymization Guidelines, on behalf of a third party, PIPRA AG (the “Sponsor”) under a Research Collaboration Agreement;

WHEREAS, PROVIDER is willing to provide raw de-identified data from its studies of adults patients having knee replacement surgery who have undergone evaluation for pain at least 3 months after the procedure using a validated tool (the “Data”) under terms and conditions as set out under this Agreement;

NOW THEREFORE, the parties hereby agree as follows:

1. This Agreement effective as of the Effective Date, is entered into between the parties to govern the transfer of the Data from Provider to Recipient for use in the Study, in compliance with applicable laws. Provider retains the right to refuse transfer of the Data requested.
2. The Provider will prepare and furnish to Recipient the anonymized Data in accordance with applicable privacy legislation (eg. Ontario Personal Health Information Protection Act) , and specifically warrants that transfer of the Data by Provider will be in compliance with REB approved subject informed consent forms (“ICFs”) provided by the individuals from whom the Data was collected, or terms of an REB Waiver of Consent, as applicable. The Data will not be transferred until each party’s REB provides written approval for the Study. All Data must be anonymized by the removal of all personal identifies and the assignment of a study ID to each record. The Provider will retain the nominal file that links the study ID numbers with the patient information. The guidelines for de-identifying the data is described in the PROSPER Anonymization Guidelines.
3. Recipient shall use the Data in compliance with all applicable laws and shall specifically only use or disclose the Data for the conduct of the Study in accordance with the permitted uses of the Data specified in the applicable ICFs or REB Waiver of Consent, or otherwise as required by law. No right, title or interest in and to the Data is granted or implied to the Recipient hereunder.

Recipient may not use the Data for any other Study or any other purpose without the prior written permission of the Provider.

4. Recipient shall have the right to use (1) the analyzed, de-identified data derived from the use of the Data, and (2) de-identified information and results arising out of analysis of the Data or the IPDMA, as part of a publication or presentation of the results of the Study, and shall own such de-identified, analyzed data and results. Recipient shall not include any personally identifying information in any publication or presentation. Provider Investigator's contribution and co-authorship shall be accordance with academic custom and standards. However, the lead authors of the IPDMA publication shall be the Recipient Investigators. The Data provided hereunder will be held by Recipient until peer review of the publication is completed and for an additional one (1) year following publication to allow for time to respond to the findings (eg. Letters to the editor(s)). Following this one (1) year period, no further new analysis may be conducted without an agreement to extend this date by the Provider Investigator.
5. Upon request from Provider, Recipient shall share the progress of the IPDMA with the Provider and share analysis and a preliminary report of the IPDMA. The Provider agrees to maintain the confidentiality of all preliminary results and reports of the IPDMA provided by Recipient hereunder until such time as the final publication of the IPDMA by Recipient pursuant to Section 4 above. The Provider agrees not to publish (including posting on the Internet), nor present in any public forum, nor disseminating through media any results provided by the Recipient hereunder. However, notwithstanding the foregoing, the Provider may produce and or publish results of analysis of their datasets conducted independently from the Study hereunder.
6. Recipient shall use appropriate safeguards to prevent any unauthorized use of disclosures of the Data and shall report to the Provider any unauthorized use or disclosure of which Recipient becomes aware, or of any breach of this Agreement. Recipient shall not use the Data to identify or contact the individuals from whom such Data were collected. Recipient shall securely destroy the Data as required by the Study protocol or Provider and provide a written confirmation of the manner of destruction in a form acceptable to Provider at the completion of the Study. Provider may conduct audits of the Recipient concerning the maintenance of appropriate security safeguards to ensure compliance with this Agreement.
7. Recipient shall give access to the Data only to its staff and collaborators with a need to know for the purpose of conducting the Study (IPDMA), and who are bound by Recipient to comply with the terms of this Agreement.
8. Term and Termination

This Agreement will come into force on the Effective Date and will terminate on the earliest of the following dates;

- a) one year from the Effective Date;
- b) on completion of the Study;
- c) on thirty (30) days prior written notice by either party to the other party; or
- d) immediately by Provider if Recipient has not cured a breach of this Agreement within a reasonable time of being notified.

Upon expiration or termination of this Agreement, Recipient shall Recipient shall securely destroy the Data as required by the Study protocol or Provider and provide a written confirmation of the manner of destruction in a form acceptable to Provider.

9. General Terms and Conditions:

- a) No party shall be entitled to assign or transfer this Agreement or the rights and obligations hereunder to any third party without the prior written approval of other party.
- b) This Agreement, including the attached Schedule(s), represents the entire understanding between or among the parties related to the Study and supersedes all previously or contemporaneously executed agreements related to the Study.
- c) This Agreement shall not be amended, modified, varied or supplemented except in writing signed by each of the parties.
- d) No failure or delay on the part of any party hereto to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof.
- e) The parties hereto are independent contractors. Nothing contained herein shall be deemed or construed to create between 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.
- f) Each party to this Agreement assumes responsibility for its own obligations and liabilities under this Agreement.
- g) No party shall use, or authorize others to use, the names, 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.
- h) This Agreement shall be governed by and construed in accordance with the laws of the Province of Ontario and the federal laws of Canada applicable therein.
- i) This Agreement may be executed by the Parties in counterparts and may be executed and delivered by facsimile or electronically by PDF and all such counterparts, facsimiles and PDF copies shall together constitute one agreement. The parties agree that facsimile or PDF copies of signatures have the same effect as original signatures.

PROVIDER

RECIPIENT

Gay Yuyitung, Executive Director
McMaster Industry Liaison Office

Date

Date

ACKNOWLEDGMENT BY PROVIDER SCIENTIST & RECIPIENT SCIENTIST

I have read and understood this Agreement and agree to act in accordance with all the terms and conditions of the Agreement. I further agree to ensure that all participants working under my supervision or otherwise involved in working with the Data are aware of and abide by the terms of this Agreement.

Dr. Behnam Sadeghirad

Date

Dr. Lawrence Mbuagbaw

Date