DATA USE AGREEMENT

This Data Use Agreement (“Agreement”) is entered into by and between [ ] (“Covered Entity”) and Beth Israel Deaconess Medical Center, Inc. (“Data User”) and shall be effective as of [ ] [ ], 2020 (the “Agreement Effective Date”).

1. **Definitions**. The parties agree that the following terms when used in this Agreement shall have the following meanings and that the terms set forth below shall be deemed to be modified to reflect any changes made hereafter to such terms by law or regulation. Terms used but not otherwise defined in this Agreement shall have the same meaning as those terms as defined in 45 C.F.R. §§ 160, and 164, Subpart A, Subpart C (“the Security Rule”), Subpart D (“the Breach Notification Rule”) and Subpart E (“the Privacy Rule”), each as amended from time to time. Any ambiguity in this Agreement relating to the use and disclosure of the Limited Data Set by Data User shall be resolved in favor of a meaning that further protects the privacy and security of the information and the definitions in the Privacy Rule and the Security Rule shall govern.
   1. “*HIPAA*” means the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
   2. *“HITECH”* means the Health Information Technology for Economic and Clinical Health Act, enacted as part of the American Recovery and Reinvestment Act of 2009, Public Law 111-5.
   3. “*HIPAA Regulations*” means the regulations promulgated under HIPAA by the United States Department of Health and Human Services, including, but not limited to, 45 C.F.R. Part 160 and 45 C.F.R. Part 164. The term encompasses both the Privacy Rule, the Security Rule, and the Breach Notification Rule.
   4. “*Covered Entity*” means a health plan, a health care clearinghouse, or a health care provider (each as defined by HIPAA and the HIPAA Regulations) that transmits any health information in electronic form in connection with a transaction covered by the HIPAA Regulations.
   5. “*Protected Health Information*”or“*PHI*” means individually identifiable health information, except that Protected Health Information excludes individually identifiable health information in education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g, records described at 20 U.S.C. §1232g(a)(4)(B)(iv), and employment records held by a covered entity in its role as employer.
2. **Obligations of Covered Entity.**
   1. *Limited Data Set.* Covered Entity agrees to share information requested on the PNQIN Perinatal Opioid QI Initiative Data Forms, including the core form and as appropriate, the supplemental forms (the “Forms”). It is recognized that such information will constitute a limited data set, as defined in the Privacy Rule, if at least one of the following data points is included on the Forms: birth date (including month of birth), or treatment date (which includes admission and discharge date) (the "Limited Data Set"). Such Limited Data Set shall not contain any of the following identifiers of the individual(s) who is(are) the subject(s) of the Protected Health Information, or of relatives, employers or household members of the individual(s): names; postal address information, other than town or city, state and zip code; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; Web Universal Resource Locators (URLs); Internet Protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.
3. **Obligations of Data User.**

*Performance of Activities.* Data User may use and disclose the Limited Data Set received from Covered Entity only in connection with the performance of the research activities described below: Limited Data Set will be used to support the PNQIN Perinatal Opioid Project QI Initiative, a statewide improvement project of the Perinatal-Neonatal Quality Improvement Network of Massachusetts (PNQIN). The data set will be used to assess the epidemiology, trends, outcomes, and quality of care of maternal opioid use disorder (OUD) and neonatal abstinence syndrome (NAS) across the state and at participating centers. As a quality improvement initiative, this project will rely on summary metrics measured on a population of patients, and will not rely on individual patient level data reports. Examples of epidemiologic and quality metrics that will be evaluated include: screening and treatment for opioid use disorder in pregnancy; incidence of NAS by hospital; treatment for NAS; average length of stay for NAS patients; use of breast milk in NAS patients; and discharge planning for mothers with OUD and newborns at risk for NAS.

* 1. *Assurances of Data User’s Non-Employee Agents.* Data User shall ensure that any agents, including subcontractors, to whom it provides the Limited Data Set agree to be bound by the same restrictions and conditions that apply to Data User with respect to such Limited Data Set.
  2. *Nondisclosure Except As Provided In Agreement.* Data User shall not use or further disclose the Limited Data Set except as permitted or required by this Agreement or as otherwise required by law*.*
  3. *Safeguards.* Data User shall use appropriate safeguards to prevent use or disclosure of the Limited Data Set other than as provided by this Agreement.
  4. *Reporting.* Data User shall report to Covered Entity any use or disclosure of the Limited Data Set not provided for in this Agreement. Additionally, if Data User is a “covered entity” as that term is defined under HIPAA, Data User will comply with the breach notification requirements applicable to covered entities in the Breach Notification Rule, and will report any breach, as that term is defined in the Breach Notification Rule, to the appropriate individuals, organizations and agencies as required by and in accordance with the law or as it otherwise deems appropriate.
  5. *Identification and Contacting of Individuals.* Data User shall not identify the information or contact the individuals included in the Limited Data Set*.*
  6. *Remuneration*. The parties acknowledge and agree that any remuneration paid by Data User to Covered Entity for access to and use of the Limited Data Set is a reasonable, cost-based fee to prepare and transmit the data pursuant to this Agreement.

1. **Material Breach, Enforcement and Termination.**
   1. *Term.* This Agreement shall be effective as of the Agreement Effective Date and shall continue until the Agreement is terminated by the parties or in accordance with the provisions of this Section 4. All of Data User’s confidentiality obligations herein shall survive the expiration or termination of this Agreement indefinitely.
   2. *Covered Entity’s Rights of Access and Inspection.* Upon a reasonable determination by Covered Entity that Data User has intentionally breached this Agreement, and upon reasonable notice, Covered Entity may inspect the facilities, systems, books and records of Data User to monitor compliance with this Agreement. If the audit involves sensitive and confidential information or is subject to attorney client privilege, then the Data User may withhold such sensitive and confidential information until there is an appropriate confidentiality agreement or other assurance of confidentiality or joint defense agreement in place, as applicable.
   3. *Termination*.
      1. Without Cause. This Agreement may be terminated by either party without cause upon thirty (30) days’ advance written notice.
      2. For Cause. Upon material breach by either party of its obligations under this Agreement, the other party may terminate this Agreement if the breach remains uncured for more than ten (10) days after a party gives written notice to the other party of the breach.
      3. Pursuant to Section 5.a. of this Agreement.
   4. *Reporting to United States Department of Health and Human Services and Others by Covered Entity*. If any pattern of activity or practice by Data User constitutes a material breach or violation of this Agreement and it is not feasible for Covered Entity to cure or end the violation, Covered Entity may discontinue disclosure of the Limited Data Set and report Data User’s breach or violation to the Secretary of the United States Department of Health and Human Services.
   5. *Disposition of Records.* Upon termination of this Agreement for any reason, including, but not limited to Data User’s decision to cease use of the Limited Data Set, Data User agrees to return or destroy all Limited Data Set data within its possession. If Data User elects to destroy the Limited Data Set, Data User shall certify in writing to the address given in this Agreement for notices to Covered Entity that the Limited Data Set has been destroyed within thirty (30) days of termination.
   6. *Indemnification.* Each party agrees to indemnify, defend, and hold harmless the other party from any claim, liability, or loss (including reasonable attorneys’ fees and expenses of litigation) arising out of or resulting from the acts or omissions of the indemnifying party, or any of its agents or employees or its, or their performance of or failure to perform the provisions of this Agreement. Indemnifying party’s indemnification shall not apply to any liability, damage, loss or expense to the extent that it is attributable solely to the negligent activities, reckless misconduct or intentional misconduct of the indemnified party. Indemnifying party agrees, at its own expense, to provide attorneys reasonably acceptable to the indemnified party to defend against any actions brought or filed against any party indemnified hereunder with respect to the subject of indemnity contained herein, whether or not such actions are rightfully brought. The parties’ respective rights and obligations under this Section 4.f. shall survive termination of the Agreement.
2. **Miscellaneous Terms.**
   1. *Amendment.* Covered Entity and Data User agree that amendment of this Agreement may be required to ensure that Covered Entity and Data User comply with changes in state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set.
   2. *No Third-Party Beneficiaries.* Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Covered Entity and Data User, and their respective successors and assigns, any rights, obligations, remedies or liabilities.
   3. *Order of Precedence.* To the extent that any provisions of this Agreement conflict with the provisions of any other agreement or understanding between the parties with respect to use of the Limited Data Set provided hereunder, this Agreement shall control.
   4. *Notices*. All notices required or permitted under this Agreement to be in writing may be delivered personally, by electronic facsimile (with confirmation), or by registered or certified mail, postage prepaid, addressed to a party indicated below:

**If to COVERED ENTITY**:

[INSERT]

**If to BIDMC**:

Beth Israel Deaconess Medical Center, Inc.

Office of Sponsored Programs

Attn: [\_\_\_\_\_\_\_\_]

330 Brookline Avenue, BR 264

Boston, MA 02215

Email: resadmin@bidmc.harvard.edu

Facsimile: 617-667-1110

Phone: 617-667-1803

Notices shall be deemed to have been given on receipt of communications personally delivered or transmitted by electronic facsimile (delivery confirmed) and, for communications made by United States mail, on the third (3rd) day after mailing. The above addressed may be changed by giving written notice as described in this section.

**IN WITNESS WHEREOF**, the parties hereto have duly executed this Agreement as of the dates set forth below.

**[INSERT NAME OF COVERED ENTITY]**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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

**BETH ISRAEL DEACONESS MEDICAL CENTER, INC.**

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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