

DATA USE AGREEMENT

This Data Transfer Agreement (this “Agreement”) is made as the last signature day of the Party (the “Effective Date”) by and between Lahey Clinic, Inc., having its principal place of business at 41 Burlington Mall Rd., Burlington, MA 01805 (“Lahey”), and Motol University Hospital, having its principal place of business at V Úvalu 84, Prague, Czech Republic (the “Institution”). Lahey and Institution are referred to herein collectively as the “Parties” and individually as a “Party”.

WHEREAS, [REDACTED] (“Institution Investigator”) and [REDACTED], MD (“Lahey Investigator”) are collaborating on a research study under a protocol titled “International ICD in HCM” (“Research Project”) for which Lahey Investigator will need to use Institution’s Patient Data (as defined below); and

WHEREAS, Institution wishes to share the anonymous Patient Data as mentioned in this Agreement with Lahey Investigator for use in the Research Project;

NOW THEREFORE, the Parties hereby agree as follows:

1. DEFINITIONS.

- a. “HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191.
- b. “HIPAA Regulations” shall mean the regulations promulgated under HIPAA and HITECH (as defined below) by the United States Department of Health and Human Services, including 45 C.F.R. Parts 160 and 164.
- c. “HITECH” shall mean 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.
- d. “Limited Data Set” shall have the same meaning as the term in 45 C.F.R. §164.514(e)(2) and specifically shall exclude the following direct identifiers 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.
- e. “Patient Data” shall mean PHI (as defined below), if any, and all other patient data and information, that Institution provides to Lahey under this Agreement.

f. “PHI” shall mean “protected health information” as such term is defined under the HIPAA Regulations.

g. “Subjects” shall mean individuals who are the subjects of the Patient Data.

2. **OBLIGATIONS OF INSTITUTION.** Institution will transfer to Lahey the anonymous Patient Data and provide other assistance with respect to the Research Project as described on Exhibit A, which Patient Data are, to Institution’s knowledge and belief, a limited data set under the HIPAA Regulations. Institution will disclose to Lahey the minimum data necessary to conduct the Research Project only as mentioned in the Protocol. To the extent Institution’s collection and preparation of the Patient Data cause it to be “engaged” (as such term is used in 45 C.F.R. § 46.103(a)) in human subjects research, Institution will obtain and provide written evidence of its approval of the Research Project by an institutional review board or research ethics board with appropriate authority, if required. Institution shall provide all necessary and qualified personnel, equipment, materials, and facilities, as applicable, to accomplish the Research Project as set forth in the Protocol attached to this Agreement as Exhibit A and all applicable laws and regulations. Institution understands that Lahey is obtaining data from multiple institutions, however Institution will not receive nor request access to patient data from any other institution nor the complete dataset. The contracting parties declare that no biological samples will be handed over as part of this research.

3. **OBLIGATIONS OF LAHEY AND LAHEY INVESTIGATOR.**

a. Compliance with Applicable Laws and Policies and Institutional Review Board Approval. When using and disclosing the Patient Data, Lahey will comply with all applicable laws, regulations, and guidance (including laws, regulations, and guidance concerning the conduct of human subjects research and the disclosure of conflicts of interest and the HIPAA Regulations and all other laws governing the privacy and security of Patient Data) and all applicable policies of Lahey. To the extent required, Lahey will obtain an approval from its institutional review board (or rely on an approval granted by Institution’s institutional review board or research ethics board, if applicable) that complies with the standards of the federal research regulations at 45 C.F.R. Part 46 before using the Patient Data for the Research Project.

b. Use and Disclosure of Patient Data. Lahey and Lahey Investigator will use and disclose the Patient Data for the conduct of the Research Project in accordance with the protocol in Exhibit A or for any subsequent expansions or derivative studies and use appropriate safeguards to prevent the use or disclosure of the information other than as provided for in this Agreement. The foregoing restrictions are not intended to prohibit Lahey from publishing the results of the Research Project in accordance with Section 7.a.

c. Custodian of Patient Data. While Institution shall remain owner of Patient Data it provides to Lahey, Lahey Investigator will be the custodian of the Patient Data at Lahey and will

oversee the use and disclosure of the Patient Data. Notwithstanding the foregoing, Lahey shall hold all title and ownership of aggregated Patient Data, analysis, and results.

- d. Contacting Subjects or Re-identifying Information. Lahey shall not contact or attempt to contact the Subjects. Only fully anonymized data will be transmitted, therefore any re-identification is excluded according to current scientific and technical possibilities.
- e. Improper Use or Disclosure of Patient Data. Lahey and Lahey Investigator will promptly report to Institution any improper use or disclosure (including any breach) of Patient Data.
- f. Compliance with Agreement. To the extent Lahey's obligations under this Agreement are fulfilled by Lahey Investigator, Lahey will ensure that Lahey Investigator complies with the requirements in this Agreement pertaining to such obligations, and Lahey Investigator acknowledges and agrees that he or she has read and understands these obligations. Lahey and Lahey Investigator will ensure that all employees and agents who assist in the conduct of the Study at Lahey comply with the terms and conditions of this Agreement.
- g. Compliance with Foreign Law. The Parties agree that, as a result of receiving and using Patient Data under this Agreement, Lahey is not subject to the laws of any state or nation outside the United States, including without limitation the EU Regulation 2016/679, the General Data Protection Regulation. The contracting parties are aware that this is exclusively anonymized data that is transmitted as part of this research and that the transmission of anonymized data is not subject to GDPR regulation.

4. INTELLECTUAL PROPERTY.

- a. Intellectual Property. Intellectual Property shall mean all rights in patents, patent applications, trademarks, trademark applications, inventions (whether patentable or not), know-how, data, results, information, concepts, discoveries, improvements, copyrights and industrial designs and all applications and rights to apply for any of the foregoing and all similar or equivalent rights or forms of protection in any part of the world. Inventorship of any Intellectual Property conceived, made, or reduced to practice will be determined as provided herein below, and ownership shall follow inventorship. The terms "conceived" and "reduced to practice" shall be construed in accordance with the United States patent law.
- b. Institution and Institution Investigator agree and acknowledge that Lahey shall own any and all right, title, and interest in and to Inventions. Institution will report to the Lahey, in writing, all inventions made during the Research Project ("Inventions") no later than thirty (30) days from the time the invention is disclosed to Institution by its Investigator. Reports will be written in sufficient detail and will be treated as confidential information of the Party that provided the reports. No Inventions that arise during the course of this Research Project shall confer to the title or ownership of the Institution under this Agreement.

5. TERM AND TERMINATION.

- a. Term. This Agreement shall be effective as of the Effective Date and shall continue in effect until the conclusion of the Research Project, unless terminated earlier in accordance with Sections 5.b or 5.c.
- b. Termination without Cause. Either Party may terminate this Agreement upon thirty (30) days prior written notice to the other Party.
- c. Termination with Cause. Either Party may terminate this Agreement upon written notice to the other Party in the event the other Party materially breaches this Agreement and fails to cure the breach within ten (10) days after receipt of written notice thereof. If breaching Party does not cure the breach within ten (10) days following breaching Party's receipt of written notice from non-breaching Party setting forth the details of such material breach, then non-breaching Party shall have the right, by further written notice to breaching Party, to terminate this Agreement. Notwithstanding the foregoing, if the material breach by Breaching Party is one that cannot be cured, non-breaching Party may, by written notice to breaching Party, immediately terminate this Agreement.
- d. Effect of Termination. Upon expiration or termination of this Agreement, Lahey shall return or destroy (as directed by Institution) all Patient Data received by Lahey; provided, however, that Lahey may retain a copy of the Patient Data to the extent, and for the amount of time, required by law to fulfill any applicable legal obligations, but may not use such Patient Data for any purpose other than to fulfill such legal obligations.

- 6. INDEMNIFICATION.** Each Party shall indemnify the other Party and its affiliates from and against any and all third party claims, causes of action, losses, damages, liabilities, costs and other expenses (including reasonable attorney's fees and court costs) arising out of the acts of the other Party or any subcontractor, agent, or person under the other Party's control in connection with the duties and obligations under this Agreement, including the other Party's or any such subcontractor's, agent's, or person's negligence or willful misconduct. The Parties' respective rights and obligations under this Section 6 shall survive expiration or termination of the Agreement for six (6) years after the date of expiration or termination.

7. MISCELLANEOUS.

- a. Publications. Lahey will include Institution investigator as a co-author (if appropriate under the International Committee of Medical Journal Editors guidelines) and/or acknowledge Institution as the source of the Patient Data in all presentations and publications resulting from any and all analyses of Patient Data. Institution may include its own Patient Data in any presentations or publications but will not have access to any aggregated or analyzed Patient Data. Lahey will not send any patient data to Institution.
- b. The Parties consent to the publication of the Agreement in the Public Register by the Institution in order to fulfill the obligations imposed by applicable and effective law and

regulations regarding the value provided herein below in Section 7(c). The Agreement shall not disclose any personal data of natural persons that is not already publicly available in public registers, Confidential Information pursuant to this Agreement, or trade secrets.


Institution shall publish the Agreement in the Register of Contracts and shall inform Lahey about the publication at [REDACTED].

- c. Remuneration. Lahey will provide remuneration to Institution in the amount of \$5,000 after receiving of the dataset requested according to the protocol. The Parties acknowledge and agree that any remuneration paid by Lahey to Institution for use of the Patient Data is a reasonable, cost-based fee to prepare and transmit the Patient Data pursuant to this Agreement. In order to receive payment, Institution shall complete a Lahey's vendor form and issue an invoice to Lahey. Payment from Lahey will be due within 45 days from the date of receipt of the invoice. The billing information is as follows: Fakultní nemocnice v Motole, [REDACTED].
- d. Use of Name. Except as permitted under Section 7.a., no press release, advertising, sales literature or other written statements or oral statements to the public in connection with or alluding to work performed under this Agreement or the relationship between the Parties created by it having or containing any reference to either Party or any of its affiliates or employees or any name, trademark, logo, trade name, or abbreviation of either Party shall be made by either Party without the prior written approval of the other Party.
- e. Governing Law. In the event of any dispute related hereto, the validity, construction and performance of the terms of this Agreement shall be governed by the law of the defending party, and any claims shall be submitted and subject to the determination of the courts of the defending party's domicile.
- f. Amendment. This Agreement may be modified or amended only in a writing signed by duly authorized representatives of both Parties. If any provisions of this Agreement are found to be invalid or unenforceable by a court of competent jurisdiction, the Parties intend that such invalidity shall not affect any other provision hereof.
- g. No Third-Party Beneficiaries. Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Lahey and Institution, and their respective successors and assigns, any rights, obligations, remedies, or liabilities.
- h. 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 as indicated below:

If to Lahey:

Lahey Clinic, Inc.
Attn: Director of Research Administration
41 Mall Rd.
Burlington, MA 01805



With a copy to:


41 Burlington Mall Road
Burlington, MA 01805
Attn: Office of General Counsel

If to Institution:

Department of Cardiology
Motol University Hospital
V Uvalu 84, Prague, Czech Republic

Documents for invoicing the study will be sent to the email address:

 All notifications to health service providers will be sent to FN Motol and marked Department of Clinical Studies, Department of the Deputy for LPP, V Úvalu 84, 150 06 Prague 5 or by contact email: 

- i. Order of Precedence. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof and supersedes any prior or contemporaneous oral or written understandings between the Parties with respect thereto.
- j. Waiver. Any waiver or failure of either Party to assert a right hereunder shall not constitute a waiver of or excuse a similar failure in any other circumstance.
- k. Headings. Headings in this Agreement are for convenience only and are not intended to be used to interpret or construe this Agreement.
- l. Interpretation. Except where expressly stated otherwise in this Agreement, the following rules of interpretation apply to this Agreement: (i) “include,” “includes,” and “including” are not limiting and mean include, includes, and including, without limitation; (ii) definitions contained in this Agreement are applicable to the singular as well as the plural forms of such terms; (iii) references to an agreement, statute, regulation, or instrument mean such agreement, statute, regulation, or instrument as from time to time amended, modified, or supplemented; (iv) references to a person are also to its permitted successors and assigns; (v) references to a “Section” or “Exhibit” refer to a Section of, or any Exhibit to, this Agreement unless otherwise indicated; (vi) the word “will” shall be construed to have the same meaning and effect as the word “shall”; (vii) the word “any” shall mean “any and all” unless otherwise indicated by context; and (viii) the word “day” shall mean calendar day, and days shall be counted by excluding the first and including the last day, provided that when the last day falls

on a Saturday, Sunday, or holiday, the last day shall be the next day which is not a Saturday, Sunday, or holiday.

[Signature page follows.]

IN WITNESS WHEREOF, Lahey and Institution have caused this Agreement to be executed as of the date first set forth above.

<p>LAHEY CLINIC, INC.</p> <p>Signature_____</p> <p>Name: Title: Date :</p>	<p>[INSTITUTION]</p> <p>Signature_____</p> <p>Name : XXXXXXXXXXXXXXXXXXXX Title: Deputy Director, acting on power of attorney Date:</p>
<p>READ, UNDERSTOOD AND AGREED TO BY THE LAHEY INVESTIGATOR:</p> <p>Signature_____</p> <p>Name: Date:</p>	<p>READ, UNDERSTOOD AND AGREED TO BY THE INSTITUTION INVESTIGATOR:</p> <p>Signature_____</p> <p>Name: XXXXXXXXXXXXXXXXXXXX Date:</p>

EXHIBIT A

Research Protocol and Patient Data Provided to Lahey

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

ethan.rowin@lahey.org

