Data Use Agreement

This Data Use Agreement (“Agreement”) is entered into between **The Brigham and Women's Hospital, Inc.**, a not-for-profit Massachusetts corporation, having a principal place of business at 75 Francis Street, Boston, MA 02115 / **The General Hospital Corporation**, a not-for-profit Massachusetts corporation, d/b/a Massachusetts General Hospital, having principal place of business at 55 Fruit Street, Boston, MA / **The McLean Hospital Corporation**, a not-for-profit Massachusetts corporation d/b/a McLean Hospital, having a principal place of business at 115 Mill Street, Belmont, MA 02478 / **The Spaulding Rehabilitation Hospital Corporation**, a not-for-profit Massachusetts corporation, d/b/a Spaulding Rehabilitation Hospital – Boston, having a principal place of business at 300 First Avenue, Charlestown, MA 02129 / **Massachusetts Eye and Ear Infirmary**, a not-for-profit Massachusetts corporation, having a principal place of business at 243 Charles Street, Boston, MA 02114 / **Schepens Eye Research Institute**, a not-for-profit Massachusetts corporation, having a principal place of business at 20 Staniford Street, Boston, MA 02114 / **The MGH Institute of Health Professions, Inc.**, a not-for-profit Massachusetts corporation, having a principal place of business at 36 First Ave, Charlestown, MA 02129 (“Hospital”) and the individual listed in Appendix A section 1 (“Investigator”). Hospital and Investigator are individually referred to as a party (“Party”) or collectively referred to as the parties (“Parties”) of this Agreement.

# Introduction

* 1. As required by The Health Insurance Portability and Accountability Act of 1996, Pub.L. §§ 104–191, 110 Stat. 1936 (1996) (“HIPAA”), and in accordance with the Standards for Privacy of Individually Identifiable Health Information (“Privacy Rule”), codified at 45 CFR §§ 160–164 and its accompanying regulations, this Agreement will govern the transfer of all records, notes, data, images, and information which belong to the Hospital (“Hospital Data”) and that are transferred to Investigator.
	2. Incorporated to this Agreement is Appendix A, which describes the Investigator’s Study and Hospital Data being accessed. Both Parties certify that Hospital Data transferred between them represents the minimum amount necessary to achieve the research or public health purposes outlined by this Agreement (“Purpose”).
	3. Data provided under this Agreement is for the Site’s participation in a protocol titled “\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_” (“Study” or “Protocol”). Hospital will only provide the requested Hospital Data after such transfer is approved by Hospital’s Institutional Review Board (“IRB”).

# Data Protection Requirements

* 1. Hospital Data provided under this Agreement is solely for Investigator’s access only. No other person or entity may use or receive Hospital Data unless agreed to in writing by a duly authorized employee of Hospital.
	2. In accessing Hospital Data, Investigator will:
1. use and disclose Hospital Data only as permitted by this Agreement or as otherwise required by U.S. law, the IRB-approved Protocol, and the informed consent under which Hospital Data was originally collected;
2. use appropriate safeguards to prevent use or disclosure of Hospital Data other than as provided for by this Agreement or as required by U.S. law;
3. not use or further disclose Hospital Data in a manner that would violate HIPAA privacy laws, including, but not limited to the Privacy Rule;
4. ensure that Hospital Data will not be used or disclosed to any other person or entity;
5. report to Hospital within one (1) day any suspected or actual breach or unauthorized use or disclosure of Hospital Data not provided for by this Agreement of which it becomes aware; and
6. refrain from using Hospital Data to identify or to contact individuals.
	1. Each Party must be in compliance with all applicable U.S. federal, state, and local laws and regulations while handling or storing the Hospital Data.
	2. Within one (1) business day, Investigator will report to Hospital the suspected or actual unauthorized access to the any Hospital Data or information collected under this Agreement, or in the event of the suspected or actual loss of theft or an electronic device used to access or store the Hospital Data.
	3. Following the conclusion of this Agreement, Requestor agrees to contact the MGB Research Information Science and Computing office (“RISC”) and will cooperate with RISC to certify that all of devices which accessed Holder Information during this Agreement are sanitized and that all Hospital Data is destroyed in accordance with all applicable law.

# Data Sharing Plan

* 1. Incorporated to this Agreement as Appendix B is the Data Sharing Plan (“Data Sharing Plan”). Under this Agreement, Investigator will have access to full Protected Health Information (“PHI”) as defined by HIPAA, of which a summary is incorporated within the Data Sharing Plan and within Appendix A (collectively referred to as “Hospital Data” throughout this Agreement).
	2. Prior to any activities conducted under this Agreement, Investigator must become familiar with the administrative, physical, and technical controls of data security described in Appendix B, and must review and separately execute the Data Sharing Plan.
	3. Investigator warrants compliance with all technical and administrative requirements outlined in the Data Sharing Plan and will adhere to the controls described therein for the duration of this Agreement. Any use or disclosure of Hospital Data in a manner inconsistent with the Data Sharing Plan, or any unauthorized modification or alterations of the controls described in the Data Sharing Plan may result in termination of this Agreement or individual sanctions, in accordance with applicable law.

# Other Requirements

* 1. This Agreement can be terminated by either Party with thirty (30) days prior notice to the other Party for any reason. Hospital may terminate this Agreement immediately if, in its sole discretion, Hospital suspects, or has discovered an actual breach or unauthorized access of any Hospital Data.
	2. At the sole discretion of the Hospital, Investigator will destroy all data or return data to the Hospital, at the conclusion of the Scope of Work. Investigator will provide evidence of data destruction as may be requested by the Hospital.
	3. All Hospital Data provided to Investigator by Hospital in performance of this Agreement will be owned and solely controlled by Hospital. Investigator grants to Hospital the right to use any data, reports, information, drawings, designs, analysis and written materials generated or created in the performance of this Agreement for educational and research purposes, which include the creation of derivative works.
	4. The Parties are encouraged to publish the results of their research. Subject to generally accepted academic standards, the Parties will make the decision regarding the authorship on research and other publications arising out of this Agreement together. All publications arising from this Agreement should acknowledge each Party’s respective contributions in an appropriate, accurate, and academically conventional way. In all cases, Hospital must be acknowledged as the source of Hospital Data.
	5. Investigator will provide Hospital at least thirty days advance notice of any drafts of manuscripts, presentations, or public disclosures of any information resulting from the use of Hospital Data under this Agreement. If any confidential, proprietary information is identified, Investigator will remove prior to its submission.

 *Remainder of page is intentionally left blank.*

*Signature of the Parties appear on the following page.*

IN WITNESS WHEREOF, authorized signing officials of the Parties have caused this Agreement to be fully executed as of the date of last signature.

|  |  |  |
| --- | --- | --- |
| Authorized Institutional Official  |  | Insert Investigator Name |
| Signature Date |  | Signature Date |

|  |
| --- |
| **Principal Investigator****(Insert Name)** |
|  |
| Signature Date |

Data Use Agreement

Appendix A

Data and Project Description

* 1. **Investigator**: the departing individual receiving the data.

Investigator Name:

Investigator Leave Date:

Investigator New Location:

* 1. **Principle Investigator (“PI”)**: the MGB Principal Investigator of the project

PI Name:

PI Department:

* 1. **Statement of Work**: Describe how the Investigator will use the Data (for example, data analysis, manuscript preparation, secondary analysis)
	2. **Purpose**: Select a purpose for receiving the data

[ ]  Research: Provide Protocol name and IRB number

[ ]  Public Health: describe

# Description of Hospital Data: Describe the data that will be shared with the Investigator (how it was collected, if data is subject to another DUA, what elements it includes, how many subjects are included, etc).

 Check any HIPAA Identifiers that will be included in this data set:

[ ]  Names, including initials

[ ]  All geographic subdivisions, including non-US ones, smaller than a state or its foreign equivalent, including street address, city, county, precinct, ZIP Code and equivalent geographical codes, etc.

[ ]  All elements of data (except year) for dates related directly to the individual, including, but not limited to, dates of birth, death, admission, discharge, or any service

[ ]  All ages over 89 and all elements of dates (including year) indicative of such age

[ ]  Telephone numbers

[ ]  Fax numbers

[ ]  Email 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

[ ]  Full face photographic images and any comparable images

[ ]  Any other unique identifying number, characteristic, or code, including, but not limited to, globally unique identifier (GUID) and universally unique identifier (UUID), or equivalent

# Funding: Please describe any funding associated with project or used to collect this data (grant, contract, sponsored research agreement).