**Standard Material Transfer Agreement For the Transfer of Human Tissues and Specimens**

**and Associated Data**

# Between Non-profit Organizations

The Provider and Recipient identified below hereby agree to be bound by the terms set forth in the attached Exhibit A, and Exhibit B if applicable, to govern the transfer of the Original Material described herein.

x If checked, this Agreement is also subject to additional terms and conditions set forth on the attached Exhibit B. In the event of a conflict between any specific terms or conditions in Exhibit A and Exhibit B, Exhibit B shall govern.

|  |  |
| --- | --- |
| **Provider** (the organization providing the Original Material)  | **Recipient** (the organization receiving the Original Material)  |
| Name:  |   | Name:  |
| Address:  |   | Address:  |
| **Provider Scientist**  | **Recipient Scientist**  |
| Name:  | Name:  |
| Title:  | Title:  |
|  |  |
| **Original Material** (description of the material being transferred)  | **Shipping Address**  |
|  | Name: Address:  |

**Provider Authorized Signatory Recipient Authorized Signatory**

Signature Signature

Print Name Print Name

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Title Title

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Date

**Exhibit A**

# Standard Terms

I. DEFINITIONS:

1. **Provider**: Organization providing the Original Material. The name and address of this party is specified on page 1 of this Agreement.

1. **Provider Scientist**: The name and address of this party is specified on page 1 of this Agreement.

1. **Recipient**: Organization receiving the Original Material. The name and address of this party is specified on page 1 of this Agreement.

1. **Recipient Scientist:** The name and address of this party is specified on page 1 of this Agreement.

1. **Original Material**: The description of the material being transferred is specified on page 1 of this Agreement.

1. **Material**: Original Material and Unmodified Derivatives. The Material shall not include: (a) Modifications, or (b) other substances created by the Recipient through the use of the Material which are not Modifications, or Unmodified Derivatives.

1. **Unmodified Derivatives**: Substances created by the Recipient which constitute an unmodified functional subunit of the Original Material. Some examples include: Original Material or unmodified portions thereof fixed as tissue sections or in arrays, and unmodified proteins, RNA, or DNA extracted from Original Material.

1. **Modifications**: Substances created by the Recipient which contain/incorporate the Material but which are not Unmodified Derivatives. Some examples include genetic modification or manipulation of cells extracted from the Original Material.

1. **Commercial Purposes**: The sale, lease, license, or other transfer of the Material or Modifications to a for-profit organization. Commercial Purposes shall also include uses of the Material or Modifications by any organization, including Recipient, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the Material or Modifications to a for-profit organization. However, industrially sponsored academic research shall not be considered a use of the Material or Modifications for Commercial Purposes per se, unless any of the above conditions of this definition are met.

1. **Nonprofit Organization(s)**: A university or other institution of higher education or a not-for-profit organization officially recognized or qualified under the laws of the country in which it is organized or located, or any nonprofit scientific or educational organization qualified under a federal, state or local jurisdiction’s nonprofit organization statute. As used herein, the term also includes national, state or local government agencies.

II. TERMS AND CONDITIONS OF THIS AGREEMENT:

1. The Provider retains ownership of the Material, including any Material contained or incorporated in Modifications.

1. The Recipient retains ownership of: (a) Modifications (except that, the Provider retains ownership rights to the Material included therein), and (b) those substances created through the use of the Material or Modifications, but which are not Unmodified Derivatives or Modifications (i.e., do not contain the Original Material or Unmodified Derivatives). If either 2 (a) or 2 (b) results from the collaborative efforts of the Provider and the Recipient, joint ownership may be negotiated.

1. The Recipient and the Recipient Scientist agree that the Material:

* 1. is to be used only for the purpose as specified in Exhibit C. If Recipient desires to use

Material for research other than that described, then Recipient must obtain written consent from Provider, before any such research is undertaken;

* 1. will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider;

* 1. is to be used only at the Recipient organization and only in the Recipient Scientist’s laboratory under the direction of the Recipient Scientist or others working under his/her direct supervision; and

* 1. will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.

1. The Recipient and the Recipient Scientist agree to refer to the Provider any request for the Material from anyone other than those persons working under the Recipient Scientist’s direct supervision. To the extent supplies are available, the Provider or the Provider Scientist agrees to make the Material available, under an agreement having terms consistent with the terms of this Agreement, to other scientists (at least those at Nonprofit Organization(s)) who wish to replicate the Recipient Scientist’s research; provided that such other scientists reimburse the Provider for any costs relating to the preparation and distribution of the Material.

1. (a) The Recipient and/or the Recipient Scientist shall have the right, without restriction, to distribute substances created by the Recipient through the use of the Original Material only if those substances are not Unmodified Derivatives, or Modifications.

* 1. Under an agreement at least as protective of the Provider’s rights as this Agreement, the Recipient may distribute Modifications to Nonprofit Organization(s) for research and teaching purposes only.

* 1. Without written consent from the Provider, the Recipient and/or the Recipient Scientist may NOT provide Modifications for Commercial Purposes. It is recognized by the Recipient that such Commercial Purposes may require a commercial license from the Provider and the Provider has no obligation to grant a commercial license to its ownership interest in the Material incorporated in the Modifications. Nothing in this paragraph, however, shall prevent the Recipient from granting commercial licenses under the Recipient’s intellectual property rights claiming such Modifications, or methods of their manufacture or their use.

1. The Recipient acknowledges that the Material is or may be the subject of a patent application. Except as provided in this Agreement, no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of the Provider, including any altered forms of the Material made by the Provider. In particular, no express or implied licenses or other rights are provided to use the Material, Modifications, or any related patents of the Provider for Commercial Purposes.

1. If the Recipient desires to use or license the Material or Modifications for Commercial Purposes, the Recipient agrees, in advance of such use, to negotiate in good faith with the Provider to establish the terms of a commercial license. It is understood by the Recipient that the Provider shall have no obligation to grant such a license to the Recipient, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the Material to any third party(ies), subject to any pre-existing rights held by others.

1. The Recipient is free to file patent application(s) claiming inventions made by the Recipient through the use of the Material but agrees to notify the Provider upon filing a patent application claiming Modifications or method(s) of manufacture or use(s) of the Material.

1. Any Material delivered pursuant to this Agreement is understood to be experimental in nature and may have hazardous properties. THE PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.

1. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use, storage or disposal of the Material. 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, due to or arising from the use of the Material by the Recipient, except to the extent permitted by law when caused by the gross negligence or willful misconduct of the Provider.

1. This Agreement shall not be interpreted to prevent or delay publication of research findings resulting from the use of the Material or the Modifications. The Recipient Scientist agrees to provide appropriate acknowledgement of the source of the Material in all publications.

1. The Recipient agrees to use the Material in compliance with all applicable statutes and governmental regulations for the protection of human subjects. The Recipient represents that it has obtained Institutional Review Board approval, as appropriate, to use the Material.

1. Provider Scientist agrees to label, package, and transport the Original Material in accord with all applicable local, state and federal laws and regulations.

1. Provider ensures that the Original Material provided pursuant to this Agreement was collected or will be collected in accordance with the standard patient informed consent procedures of Provider in effect at the time of collection and subject to approval or an exemption determination by the Provider Institutional Review Board (“IRB”) or equivalent. Recipient may review the consent form used in collection of Original Material as well as any subsequent revisions thereof.,The Original Material provided to Recipient will not be accompanied by personally identifiable patient information and for Original Material subject to U.S. laws, will not be accompanied by “Protected Health Information” (“PHI”) as defined in 45 CFR 164.501 or personally identifiable information as described in 5 USC Section 522. However, if de-identified information (“Information”) is provided that nevertheless could be used to identify an individual at a later time, a Recipient in the U.S. hereby agrees to treat Information as PHI or personally identifiable information, as applicable. If Information is provided, it will be described in Exhibit C. In any circumstances, the Recipient agrees to use the Information only for the research purpose as set forth in Exhibit C and to the extent necessary for that specific research, and will not contact or make any effort to identify human subjects from whom the Original Material was obtained without specific written approval from the Provider. To the extent Provider is providing a Limited Data Set as defined under HIPAA data to the Recipient, the parties agree that additional data use terms will be set forth in a Data Use Agreement as set forth in Exhibit D.

1. The parties acknowledge that applicable state and federal laws relating to data security and privacy are rapidly evolving and that amendment of this Agreement may be required to provide for procedures to ensure compliance with such developments. The parties agree to take such action as is necessary to implement any amendments to the standards and requirements of such applicable laws or regulations relating to the security or confidentiality of patient information, including in the case of a U.S. Recipient, the Health Insurance Portability and Accountability Act (“HIPAA”) Privacy and Security Rules or the Privacy Act of 1974, and other applicable laws and regulations relating to the security or confidentiality of PHI or personally identifiable information. The parties further agree that if current or future applicable federal or state laws, rules, or regulations adversely impact a party’s performance under the Agreement, the parties will negotiate in good faith to amend the Agreement, as necessary, to be consistent with the requirements of such applicable laws, rules or regulations. If the parties are unable to modify the Agreement to fully comply with such applicable laws, rules and regulations, one or both parties may terminate this Agreement.

1. This Agreement will terminate on the earliest of the following dates: (a) on completion of the Recipient’s current research with the Material, or (b) on thirty (30) days written notice by either party to the other, or (c) on the date specified in Exhibit B, provided that:

(i) if termination should occur under 16(a) or (c) above, the Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications;

and

(iii) in the event the Provider terminates this Agreement under 16(b) other than for breach of this Agreement or for cause such as an imminent health risk or patent infringement, the Provider will defer the effective date of termination for a period of up to one year, upon request from the Recipient, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, Recipient will discontinue its use of the Material and will, upon direction of the Provider, return or destroy any remaining Material. The Recipient, at its discretion, will also either destroy the Modifications or remain bound by the terms of this agreement as they apply to Modifications.

1. Paragraphs 6, 9, 10, and 14 shall survive termination.

**Exhibit B**

# Optional Terms

If checked, the following terms apply to this Agreement:

 This Agreement shall terminate on \_\_\_\_\_\_\_\_\_\_\_. Upon termination, the Recipient will either return or destroy any remaining Material to the Provider, as directed by the Provider.

 A transmittal fee shall be invoiced to and paid by Recipient to Provider, for preparation and distribution costs incurred.

 To the extent permitted by law, Recipient agrees to treat in confidence, for a period of three (3) years from the date of its disclosure, any of Provider’s written information about the Original Material that is stamped "Confidential" (“Confidential Information”). Any oral disclosures from Provider to Recipient shall be identified as being confidential by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Confidential Information does not include information that:

XX

1. has been published or is otherwise publicly available at the time of disclosure to the Recipient; was in the possession of or was readily available to the Recipient without being subject to a confidentiality obligation from another source prior to the disclosure;
2. has become publicly known, by publication or otherwise, not due to any unauthorized act of the Recipient;
3. Recipient can demonstrate it developed independently, or acquired without reference to or reliance upon Confidential Information; or
4. is required to be disclosed by law, regulation, or court order.

 Acknowledgment. “Access to patient samples was facilitated by the Massachusetts Consortium on Pathogen Readiness (MassCPR)” must be cited in all publications and presentations that arise from research conducted under this Agreement.

 Additional binding terms:

1. Confidentiality terms will apply indefinitely with respect to any individually identifiable health information disclosed by Provider to Recipient.
2. This Research (as defined in Exhibit C) is part of the Massachusetts Consortium on Pathogen Readiness (MassCPR). It is contemplated that results of the Research, if published, will be jointly published by Provider and Recipient; however, the Parties each separately reserve the right to publish information and data generated in the course of the Research; provided, however, that (as the Material has not yet been disclosed in a publication by Provider), Recipient shall not be entitled to solely publish its results generated using the Material within six (6) months of the completion of the Research without Provider’s express written consent.
3. In acknowledgment of the fact that all MassCPR research is related to COVID-19 and is in the service of combating the pandemic together, any data generated by Recipient using Materials received under this Agreement at the reasonable request of another MassCPR researcher must be reported back to MassCPR for sharing and collaborative discussion. In general, data generated by projects which receive Materials through MassCPR are expected to be shared as broadly as possible in a timely manner after publication, via deposition in publicly accessible data repositories consistent with applicable law, Institutional Review Board (“IRB) approval, and IRB-approved informed consent.
4. Notwithstanding and in spite of Section 8 in the Agreement, if Recipient intends to file a patent application for an invention and/or discovery which could not have been made but for the use of the Material, Recipient will contact Provider prior to filing to determine what interests, if any, Provider may have in such patent application and/or any potential commercial products derived from the subject Invention. Ownership of any such invention/discovery shall follow inventorship, as determined in accordance with U.S. patent laws.
5. No Assignment. Recipient may not assign this Agreement, in whole or in part, without the prior written consent of Provider.
6. No Third-Party Beneficiaries. Nothing express or implied in this Agreement is intended or shall be deemed to confer upon any person other than Provider and Recipient, and their respective successors and permitted assigns, any rights, obligations, remedies or liabilities.
7. Notices. Except as otherwise provided in this Agreement, all notices required or permitted under this Agreement to be in writing may be delivered personally, by electronic mail (with confirmation), or by registered or certified mail, postage prepaid, addressed as follows:

If to Recipient, to the name and address of Recipient indicated on page 1 of this Agreement.

If to Provider, to the name and address of Provider indicated on page 1 of this Agreement.

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

 Limited Data Set Data Use Agreement attached as Exhibit D

XX

 Data sets that include dates of service or entire ZIP codes are considered limited data sets. As defined by HIPAA, limited data sets are data sets stripped of certain direct identifiers that are specified in the Privacy Rule. They are not de-identified information under the Privacy Rule. A limited data set is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

1. Names

2. Postal address information, other than town or city, State, and zip code

3. Telephone numbers

4. Fax numbers

5. E-mail addresses

6. Social security numbers

7. Medical record numbers

8. Health plan beneficiary numbers

9. Account numbers

10. Certificate/license plate numbers

11. Vehicle identifiers and serial numbers

12. Device identifiers and serial numbers

13. Web URLs

14. Internet Protocol (IP) address numbers

15. Biometric identifiers, including fingerprints and voiceprints

16. Full-face photographic images and any comparable images

Limited data sets may include the following: city, state and zipcodes; all elements of dates; and unique codes or identifiers not listed as direct identifiers

 De-identified Data Set Data Use Agreement attached as Exhibit D

XX

The HIPAA Privacy Rule (45 CFR, Parts 160 and 164(A) and (E)) specifies that patient data can be to de-identified by removing 18 elements that could be used to identify an individual or an individual’s relatives, employers, or household members; these elements are enumerated in the Privacy Rule. Investigators also must have no actual knowledge that the remaining information could be used alone or in combination with other information to identify the individual who is

the subject of the information. Under this method, the following identifiers must be removed:

1. Names

2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geographical codes, except for the initial three digits of a ZIP code if, according to the current publicly available data from the Census Bureau, a) the geographical unit formed by combining all ZIP Codes with the same three initial digits contains more than 20,000 people or b) the initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people are changed to 000.

3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such ages and elements may be aggregated into a single category of age 90 or older.

4. Telephone numbers

5. Facsimile numbers

6. Electronic mail addresses

7. Social security numbers

8. Medical record numbers

9. Health plan beneficiary numbers

10. Account numbers

11. Certificate/license numbers

12. Vehicle identifiers and serial numbers, including license plates

13. Device identifiers and serial numbers

14. Web universal resource locators (URLs)

15. Internet protocol (IP) address numbers

16. Biometric identifiers, including fingerprints and voiceprints

17. Full-face photographic images and any comparable images

18. Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

**Exhibit C**

# Research Purpose and Information

Research purpose:

Information (including data variables):

**Exhibit D**

**Limited Data Use Agreement**

As required by the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, including the Standards for Security for the Protection of Electronic Protected health Information (codified at 45 C.F.R. parts 160 and 164, Subpart C and implementing regulations, as may be amended from time to time, (hereinafter collectively referred to as “HIPAA”)), the undersigned parties agree to the following terms of this Data Use Agreement.

1. The Provider is the organization providing the information. The name and address of the Provider is specified on page 1 of the Standard Material Transfer Agreement For the Transfer Human Tissues and Specimens and Associated Data Agreement to which this Exhibit is appended (the “Agreement”). The Recipient is the organization receiving the information. The name and address of the Recipient is specified on page 1 of this Agreement.
2. Recipient requests the following information, to be accessed by the parties or individuals described herein, for the Research Purpose described in Exhibit C of the Agreement.
3. Recipient has requested the following “Limited Data Set” (as defined in 45 CFR 164.514(e)) for use with tissue samples in the Research, and Recipient represents that such data is the minimum necessary to achieve the Research Purpose:

[ ]  Dates (*e.g.*, admission date, birth date)

[ ]  Geographic information excluding street address (*e.g.*, city, zip code)

[ ]  Other information that the Rule does not exclude from a limited data set (the following information about an individual or the individual’s relatives, employers, or household members, is not permitted in a limited data set: name, street address, telephone/fax numbers, electronic mail address, social security number, medical record number, health plan beneficiary number, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate number, device identifiers and serial numbers, URLs and IP addresses, biometric identifiers, including finger and voice prints, and full face photos and any comparable images)

1. Only Recipient Scientist and individuals under Recipient Scientist’s direct supervision will have access to the Limited Data Set.
2. The Original Material provided to Recipient is accompanied by Protected Health Information (“PHI”) as defined under HIPAA constituting a “Limited Data Set” and the following binding terms (the “Data Use Terms”) apply:
3. Any ambiguity in these Data Use Terms relating to the use and disclosure of the Limited Data Set by Recipient shall be resolved in favor of a meaning that further protects the privacy and security of the information, and the definitions in the HIPAA shall govern in the event of any conflict between these Data Use Terms, on the one hand, and HIPAA, on the other.
4. Obligations of Provider. In connection with this Agreement, Provider agrees to share with Recipient the Limited Data Set. The Limited Data Set shall not contain any of the following identifiers of the individual(s) who is(are) the subject(s) of the PHI, 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.
5. Material Breach, Enforcement and Termination.
6. Termination. Upon any of the following events, Provider reserves the right to terminate this Agreement, notwithstanding anything to the contrary in this Agreement:
7. immediately if Recipient is named as a defendant in a criminal proceeding for a violation of HIPAA;
8. immediately if a finding or stipulation that Recipient has violated any standard or requirement of HIPAA, or any other security or privacy laws is made in any administrative or civil proceeding in which Recipient has been joined;
9. immediately if Provider determines that Recipient has breached or violated a material term of these Data Use Terms;
10. immediately if it is in the best interest of Provider, as deemed by Provider in its sole discretion to do so; and
11. upon ten (10) days’ written notice in the event that Recipient does not promptly enter into an amendment of these Data Use Terms that Provider, in its sole discretion, deems necessary to ensure that Provider will be able to comply with applicable state and federal laws and regulations relating to the privacy, security, and confidentiality of PHI or the Limited Data Set.
12. Disposition of Records. Upon termination of this Agreement for any reason, Recipient agrees to return or destroy, at Provider’s direction, the Limited Data Set, including copies and derivative versions, immediately. If Recipient is instructed to destroy the Limited Data Set, Recipient shall destroy the Limited Data Set within thirty (30) days of receiving such instruction and shall, within such 30-day period, provide Provider with written certification of such destruction. Recipient shall extend the protections of this Data Use Agreement to any Limited Data Set information that it does not destroy or return to Provider and limit further uses and disclosures of such Limited Data Set for so long as Recipient and its agents and contractors retain Limited Data Set information.
13. EXCEPT AS PROVIDED BELOW OR PROHIBITED BY LAW, ANY DATA DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE PROVIDED “AS IS.” PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Notwithstanding, Provider, to the best of its knowledge and belief, has the right and authority to provide the Limited Data Set to Recipient for use in the Research.
14. Recipient shall be liable for damages, losses, claims, and demands which may arise from its use, storage, disclosure, or disposal of the Limited Data Set except to the extent (a) prohibited by law and/or (b) caused by the negligence, willful misconduct, or violation of applicable privacy or security laws and regulations by the Provider. No indemnification for any damage, loss, claim, demand, or liability is intended or provided by either Party under this Agreement.
15. Survival. All of Recipient’s confidentiality obligations in these Data Use Terms shall survive the expiration or termination of this Agreement indefinitely.
16. Obligations of Recipient.

A. To use and disclose the Limited Data Set only for the Research Purpose, and to not use or further disclose such information in a manner that would violate the Privacy Rule.

B. To permit only the Recipient Scientist and individuals under Recipient Scientist’s direct supervision to use or receive the Limited Data Set. Recipient shall not disclose the Limited Data Set to any non-employee agent, or subcontractor of Recipient, except with the express prior written consent of Provider. Recipient shall ensure that any agents (including employees, non-employee agents, and subcontractors) to whom it provides the Limited Data Set are bound by the same restrictions and conditions that apply to Recipient with respect to the Limited Data Set.

C. To agree that (i) it will not use or disclose the limited data set other than as permitted by this Agreement or as otherwise required by law; (ii) it will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) it will report to Provider within five (5) days any use or disclosure not provided for by this Agreement of which it becomes aware; and (iv) it will not use this information to identify or to contact the individuals. To the extent that Recipient creates, receives, stores, or transmits the Limited Data Set in electronic form (“Electronic PHI”), Recipient shall also implement administrative, physical and technical safeguards that reasonably and appropriately protect the confidentiality, integrity and availability of any Electronic PHI that may be transmitted in conformity with the requirements of the HIPAA, the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009) (full-text), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq.) ( “HITECH Act”), or any other applicable Federal or state laws.

1. To obtain institutional review board review and approval of research activities when required by law or regulation.
2. To agree that in the event of a breach or violation of this Agreement, Provider has the right to report the problem to the Secretary of Health and Human Services and to take other appropriate action, including but not limited to terminating this Agreement.
3. Mitigation of Security Incident or Breach. Recipient shall mitigate promptly, to the extent practicable, any harmful effect that is known to Recipient caused by a security incident regarding Electronic PHI or breach of unsecured Electronic PHI by Recipient in violation of these Data Use Terms, the HITECH Act, or other applicable Federal or state laws.
4. In the event of a breach or violation of this Agreement, Recipient shall report the breach, incident, or unauthorized use or disclosure within twenty-four hours from the time it is discovered by contacting, in writing the Provider Scientist and the Provider Authorized Signatory provided that such notification shall not be deemed an admission of any wrongdoing or breach of this Agreement, nor shall such notification or other such communication be admitted – as an admission of wrongdoing or breach - against the notifying party in any action, proceeding, claim or controversy. The report must include all known information regarding the breach, such as the nature of the incident, the type of information involved, as well as a description of plans for further investigation and immediate remediation.

**Exhibit D**

**De-identified Data Use Agreement**

As required by the Privacy Rule issued under the Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, including the Standards for Security for the Protection of Electronic Protected health Information (codified at 45 C.F.R. parts 160 and 164, Subpart C and implementing regulations, as may be amended from time to time, (hereinafter collectively referred to as “HIPAA”)), the undersigned parties agree to the following terms of this Data Use Agreement.

1. The Provider is the organization providing the information. The name and address of the Provider is specified on page 1 of the Standard Material Transfer Agreement For the Transfer Human Tissues and Specimens and Associated Data Agreement to which this Exhibit is appended (the “Agreement”). The Recipient is the organization receiving the information. The name and address of the Recipient is specified on page 1 of this Agreement.
2. Recipient requests the following information, to be accessed by the parties or individuals described herein, for the indicated purpose:

[x] Research: as described in Exhibit C

[ ]  Health Care Operations: type:

[ ]  Public Health: activity:

1. Recipient has requested the following data (“De-identified Data Set”) for use with tissue samples in the Research and Recipient represents that such data is the minimum necessary to achieve the purpose:

[ ]  Age (89 and under)

[ ]  Duration between sample collection and index date (e.g., number of days between sample date and subsequent PCR test date))

[ ]  Other information that HIPAA does not exclude from a de-identified set (the following information about an individual or the individual’s relatives, employers, or household members, is not permitted in a de-identified data set: name, street address, telephone/fax numbers, electronic mail address, social security number, medical record number, health plan beneficiary number, account numbers, certificate/license numbers, vehicle identifiers and serial numbers, including license plate number, device identifiers and serial numbers, URLs and IP addresses, biometric identifiers, including finger and voice prints, and full face photos and any comparable images, dates, geographic location)

1. Obligations of Recipient:
	1. To use and disclose the De-identified Data Set only furtherance of the Agreement and specifically for the purpose(s) specified above, and to not use or further disclose such information in a manner that would violate the Privacy Rule;
	2. To permit only the Recipient Scientist and individuals under Recipient Scientist’s direct supervision to use or receive the de-identified data set;
	3. If the De-identified Data Set is necessary for research, to obtain institutional review board review and approval of research activities when required by law or regulation.
	4. To agree that in the event of a breach or violation of this Agreement, Provider has the right to report the problem to the Secretary of Health and Human Services and to take other appropriate action, including but not limited to terminating this Agreement.
	5. Only Recipient Scientist and individuals under Recipient Scientist’s direct supervision will have access to the De-identified Data Set.
2. Mitigation of Security Incident or Breach. Recipient shall mitigate promptly, to the extent practicable, any harmful effect that is known to Recipient caused by a security incident regarding Electronic PHI or breach of unsecured Electronic PHI by Recipient in violation of these Data Use Terms, the Health Information Technology for Economic and Clinical Health (HITECH) Act (Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226 (Feb. 17, 2009) (full-text), codified at 42 U.S.C. §§300jj et seq.; §§17901 et seq.), or other applicable Federal or state laws.
3. In the event of a breach or violation of this Agreement, Recipient shall report the breach, incident, or unauthorized use or disclosure within twenty-four hours from the time it is discovered by contacting, in writing the Provider Scientist and the Provider Authorized Signatory provided that such notification shall not be deemed an admission of any wrongdoing or breach of this Agreement, nor shall such notification or other such communication be admitted – as an admission of wrongdoing or breach - against the notifying party in any action, proceeding, claim or controversy. The report must include all known information regarding the breach, such as the nature of the incident, the type of information involved, as well as a description of plans for further investigation and immediate remediation.