

[PRINT ON MASS GENERAL BRIGHAM INSTITUTION LETTERHEAD]

*Template Instructions: Use this template for transfer of CODED tissue with CODED data or LIMITED DATA SET to an Academic Recipient. Mass General Brigham investigators must receive a signed agreement back before shipping samples. Mass General Brigham investigators must retain a copy of this signed document in their files. Mass General Brigham investigators and Recipient must fill in the text fields that describe the samples and proposed uses. Separate review of this agreement by CRSL and/or the IRB is NOT required if otherwise not altered. **Delete these instructions before printing.***

Date

Name of Recipient Scientist, and Title, if any
Institution
Address
Address
Address

Dear Recipient Scientist:

You have requested that **Mass General Brigham Institution/Name of Bank** (“Institution”) provide you with the following tissue samples **description of samples** in connection with the following not-for-profit project (*i.e.*, research or teaching) at your academic institution: **describe the research project, name institution and where the research project will take place** (“Project”). Because of the nature of your intended use at your institution, we can provide these samples if you agree to a few terms below. Please review and sign this letter below and return it to me, and I will promptly send the tissues you requested. If you later request additional samples of the same type in connection with the Project specified above, this letter also will apply to such requests.

1. You agree that you will use these samples only for the Project described above. You understand that **THESE SAMPLES ARE NOT INTENDED FOR USE IN, AND YOU AGREE THAT YOU WILL NOT USE THEM IN, HUMAN SUBJECTS.** You also agree that the samples will be used only by you and by individuals under your direct supervision on your Project team, and you agree not to transfer these samples to any other person, institution, or entity. You agree that you, and individuals under your direct supervision on your Project team, will use the samples in compliance with all applicable laws and regulations.
2. a) If you are requesting only coded information with the samples – that is, information linked by a code to identifiable information at our institution – then you agree that you, and your institution,

will not have or seek access to any identifiable information (such as the key to the code) under any circumstances. You agree to never use the samples or any material derived from the samples (e.g. DNA, RNA or the information provided with the samples) to attempt to ascertain the identity of the individual from whom they were obtained.

b) If you are requesting select information that falls within a “limited data set” – as explained in the attachment – then you agree to sign the attachment, which is a “Data Use Agreement” required under the HIPAA Privacy Rule.

3. You agree to review the details of the Project with your own institution and your institution’s IRB to determine whether they will require further institutional and/or IRB review. You also agree to acknowledge the source of the samples in any publications reporting use of them.
4. The samples are provided at no cost or with an optional transmittal fee solely to reimburse preparation and distribution costs. If a fee is requested, the amount will be indicated here: **insert fee or n/a.**
5. You accept these samples as-is. You understand that these samples may have hazardous properties and **may carry transmissible infectious agents.** I AND INSTITUTION MAKE NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED, INCLUDING 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. INSTITUTION, ITS PERSONNEL, AND I DISCLAIM ALL LIABILITY FOR ANY CLAIMS OF DAMAGES THAT MAY ARISE FROM YOU, YOUR INSTITUTION, OR THIRD PARTIES RELATING TO THE USE, STORAGE, OR DISPOSAL OF THE SAMPLES.

As stated above, once you sign and return this letter, along with the completed Data Use Agreement attached (if applicable), I will forward the samples you requested.

Sincerely,

Name of Institution Investigator/Bank Administrator Signing Above

Certification of Recipient Scientist: I have read and understood the terms outlined in this letter, and I agree to abide by them in the receipt and use of the samples described above.

Recipient Scientist

Date

DATA USE AGREEMENT: LIMITED DATA SET

As required by the Privacy Rule issued under the Health Insurance Portability and Accountability Act (HIPAA), as the Recipient Scientist receiving a Limited Data Set, you agree to the following terms of this Data Use Agreement.

I. You have requested the following data (“Limited Data Set”) for use with tissue samples in the Project described above, and you represent that such data are the minimum necessary to achieve the stated purpose:

- Dates (*e.g.*, admission date, birth date)
- Geographic information excluding street address (*e.g.*, city, zip code)
- Other information not excluded 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, full face photos and comparable images).

II. Only you, and individuals under your direct supervision on your Project team, will have access to the Limited Data Set.

III. In consideration of Institution sending the Limited Data Set to you, you agree:

- A. To use and disclose the Limited Data Set only for the purpose specified above, and to not use or further disclose such information in a manner that would violate the Privacy Rule if done by the Institution;
- B. To permit only yourself and the Project team to use or receive the Limited Data Set;
- C. To represent, warrant, and covenant that you (i) will not use or disclose the Limited Data Set other than as permitted by this Agreement or as otherwise required by law; (ii) will use appropriate safeguards to prevent use or disclosure of the information other than as provided for by this Agreement; (iii) will report promptly to Institution any use or disclosure not provided for by this Agreement of which you become aware; (iv) will ensure that any agents (allowed only with prior written approval), including a subcontractor, to whom you provide the Limited Data Set agrees to the same restrictions and conditions that apply to you as the Recipient Scientist with respect to such information; and (v) will not use this information to identify or to contact the individuals.

- D. To obtain institutional review board review and approval of research activities when required by law or regulation;
- E. To agree that in the event of a breach or violation of this Agreement, Institution 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.

Certification of Recipient Scientist: I have read and understood the terms outlined in this letter, and I agree to abide by them in the receipt and use of the samples described above.

Recipient Scientist

Date

Agreed to by:

Name: Name of Recipient Scientist

Title: Recipient Scientist's Title

Institution: Recipient Scientist's Institution

Phone number: Recipient Scientist's Phone Number

Email address: Recipient Scientist's Email Address

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