

Standard Material Transfer Agreement

**For the Transfer of De-identified Human Tissues and Specimens
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, to govern the transfer of the Material/Original Material described herein. **Each party hereby represents that it has made no changes to the attached Exhibit A or Exhibit B as published by the Association of University Technology Managers and available on its website, except as modified by the checked boxes in Exhibit B.**

For clarity, this Agreement is also subject to all additional terms and conditions set forth on the attached Exhibit B that are marked, as applicable. In the event of a conflict between any specific terms or conditions in Exhibit A and Exhibit B, Exhibit B shall govern.

Provider (Institution)	Vanderbilt University Medical Center	Recipient (Institution)	National Cancer Institute
Provider Scientist	Xaio-Ou Shu	Recipient Scientist	Demetrius Albanes
Provider Scientist email	xiao-ou.shu@vumc.org	Recipient Scientist email	albanesd@mail.nih.gov

Recipient Shipping Address	
Fed Ex/Courier	

Material Information	
Material/Original Material	human serum or fluid
Descriptive name of material for referencing	Human plasma
Quantity to be shipped	One tube of 150 ul plasma from 130 SWHS/SMHS participants
If a genetically modified organism, a description of the gene/allele mutation making it unique	NA

Provider Authorized Signatory

Signed electronically by: Alan Bentley
Signature

Alan Bentley
Print Name

Assistant Vice Chancellor
Title

Date - this date shall serve as the Effective Date
of this Standard Material Transfer Agreement

Recipient Authorized Signatory

Signature

Lisa D. Finkelstein, PhD
Print Name

Supervisory Technology Transfer Manager
Title

7/30/2019
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.
2. **Provider Scientist:** The name and address of this party is specified on page 1 of this Agreement.
3. **Recipient:** Organization receiving the Original Material. The name and address of this party is specified on page 1 of this Agreement.
4. **Recipient Scientist:** The name and address of this party is specified on page 1 of this Agreement.
5. **Original Material:** The description of the material being transferred is specified on page 1 of this Agreement.
6. **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.
7. **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.
8. **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.
9. **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.
10. **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.
2. 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.
3. The Recipient and the Recipient Scientist agree that the Material:

- (a) 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;
 - (b) will not be used in human subjects, in clinical trials, or for diagnostic purposes involving human subjects without the written consent of the Provider;
 - (c) 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
 - (d) will not be transferred to anyone else within the Recipient organization without the prior written consent of the Provider.
4. 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.
5. (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.
- (b) 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.
- (c) 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.
6. 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.
7. 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.
8. 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.
9. 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.

10. 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.
11. 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.
12. 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.
13. Provider Scientist agrees to label, package, and transport the Original Material in accord with all applicable local, state and federal laws and regulations.
14. 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.
15. 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.
16. 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
 - (ii) 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.

17. 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 5 years from the Effective Date. Upon termination, the Recipient will either destroy any remaining Material or return it to the Provider, as directed by the Provider.
- ☐ A transmittal fee of \$0 shall be paid by Recipient to Provider, for preparation and distribution costs.
- ☒ 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 Material that is stamped "Confidential" ("Confidential Information"). Any oral disclosures from Provider to Recipient shall be identified as being Confidential Information by notice delivered to Recipient within ten (10) days after the date of the oral disclosure. Confidential Information does not include information that:
 - a. has been published or is otherwise publicly available at the time of disclosure to the Recipient;
 - b. 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;
 - c. has become publicly known, by publication or otherwise, not due to any unauthorized act of the Recipient;
 - d. Recipient can demonstrate it developed independently, or acquired without reference to or reliance upon Confidential Information; or
 - e. is required to be disclosed by law, regulation, or court order.

- ☒ Additional binding terms:
 Non-Identification. Recipient and Recipient Scientist agree not to disclose or publish any individual human subject Material Data, as defined below, obtained from the Original Material. Recipient and Recipient Scientist agree that neither Original Materials nor Material Data will be used: (i) either alone or in conjunction with any other information, in any effort to contact or determine the individual identities of any of the human subjects from whom the Original Materials were obtained or derived; (ii) for or with health insurance companies and group health plans for making decisions regarding the eligibility or premiums of a human subject from whom the Original Material and/or Material Data was obtained; and (iii) for determining the ability to gain or maintain employment of a human subject from whom the Original Materials and/or Material Data was obtained.

Notwithstanding Section II, Terms and Conditions, Article 3(c) and 3(d), it is understood that the Material will be further transferred to Metabolon, Inc. for pooled analysis of ~900 metabolites identified by the Metabolon HD4 global LC-MS/MS platform (at Metabolon, Inc., under contract to NCI).

Recipient agrees that if genomic, transcriptomic, proteomic, metabolomics, phenomic and/or other data concerning properties of the Materials are generated from the Materials ("Material Data") that such Material Data is owned by the Provider. Recipient will promptly provide a data file containing such Material Data to Provider ("Results") and Provider may use the Results for academic research purposes. Recipient may not use Material Data with or provide Material Data to for-profit entities. Recipient has the right to publish aggregated Material Data subject to the Non-Identification section above. For example, the sequence of DNA extracted from the Material is Material Data and the data file containing the sequence is Results; in this instance the Recipient does not own the Material Data but does

own the Results and as such can use this Results for any purpose subject to this Agreement. Except to the extent prohibited by law, the Recipient assumes all liability for damages which may arise from its use of the Results.

The Material being transferred under this Agreement is subject to Subsection 301(d) of the Public Health Service Act and any applicable notices of changes to NIH policy for issuing certificates of confidentiality, including Notice Number NOT-OD-17-109, as described in <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>. In receiving the Material, Recipient acknowledges that it is subject to and shall comply with all guidelines and requirements of Subsection 301(d) of the Public Health Service Act, including Notice Number NOT-OD-17-109.

Exhibit C
Research Purpose and Clinical Information

Research purpose (if applicable):

Plasma samples will be measured for metabolites using metabolomics technology. Metabolites and glioma association will be investigated.

Clinical information (if applicable):

age, sex, disease status (glioma) and other factors that are associated with glioma risk and metabolites.