

Data Use Agreement

For use by and amongst Members of the NIH Human BioMolecular Atlas Program (HuBMAP) for Internal Sharing of Data (“DUA”)

TERMS AND DEFINITIONS: The Human BioMolecular Atlas Program (HuBMAP) network (<https://commonfund.nih.gov/hubmap>) is a National Institutes of Health (NIH)-organized and -funded consortium of medical research institutions (“HuBMAP” or “HuBMAP Program” or “Program” or “Consortium”). The HuBMAP aims to facilitate research on single cells within tissues by supporting data generation and technology development to explore the relationship between cellular organization and function, as well as variability in normal tissue organization at the level of individual cells. Member institutions participating in the Consortium enable groups to effectively collaborate with each other to maximize the chances of overall success of the program. In addition to completing the research goals outlined in their applications, successful applicants will be expected to work collaboratively with all members of the Consortium to contribute to developing SOPs, data and metadata standards, and metrics for data generation; participate in cross-site studies; engage in cross-training; and guide development of data analysis and visualization tools that can be used by the broader scientific community. The program will generate 3D maps of the spatial organization of individual cells and relevant extracellular matrix in normal tissues through the integration of imaging and omics assays. The focus of the program is on fresh, fixed, or frozen normal human tissue using a combination of in situ and dissociative assays that can resolve individual cells. There will also be opportunistic incorporation and analysis of circulating cells, and of biomedical imaging techniques (MRI, CT, etc.) when appropriate and accessible. These maps will enable and encourage future studies and new insights into inter-individual variation and tissue changes across the lifespan and health/disease continuum. Detailed information on the HuBMAP network can be found at the HuBMAP website (<http://www.hubmapconsortium.org/>).

HuBMAP Program members (“HuBMAP Program Members” or “HuBMAP Members” or “Members”) include: sites funded through the various HuBMAP Program grant and other transaction mechanisms (can be found here, <https://commonfund.nih.gov/HuBMAP/fundedresearch>), the National Center for Biotechnology Information (NCBI), NIH, the NIH Common Fund, and other NIH Institutes. Members may be added or removed as the HuBMAP grows and changes with time.

Researchers with a wide range of expertise in single cell genomics, proteomics, metabolomics, bioinformatics, statistics, ethics, informatics, and clinical medicine employed by a HuBMAP Program Member participate in the HuBMAP network, including: Principal Investigators of the HuBMAP Tissue Mapping Centers, Transformative Technology Development Centers, the HIVE (HuBMAP Integration, Visualization, & Engagement), and Program Officials from the National Institutes of Health.

Data Sharing Guiding Principles: All data sharing will adhere to: 1) the terms of consent agreed to by research participants; 2) applicable laws and regulations; and 3) the principle that individual sites within the network have final authority regarding when their site’s data will be used or shared. These principles are intended to maximize sharing of all data generated by the HuBMAP Members among and between other Members as well as with the wider scientific community, and to do this without compromising data security or the confidentiality of information about individuals whose data and/or samples are used for research.

Data Sharing Responsibilities: Whereas data sharing with entities external to HuBMAP is governed by the External Data Sharing Policy, all HuBMAP Data, as defined below, can be provided to other Members with or without de-identification under the following provisions:

1. Nucleotide sequence level data, which can be considered identifying, can be freely shared with signatories of this DUA.
2. Data (e.g. images) with personal identifiers (e.g. names, dates of birth, medical record numbers, etc.) can be shared with signatories of this DUA but only for the purposes of stripping of these personal identifiers by Members with expertise in these tasks. Once de-identified, the Data can be freely shared with signatories of this DUA.

In the event that a HuBMAP Member becomes aware of a breach such that data, subject to HIPAA / not de-identified, has been inappropriately shared or subject re-identified, the providing member and the HuBMAP Network shall be immediately notified via email to all HuBMAP Member Principal Investigators. In order to accomplish the scientific goals of the HuBMAP Program, Principal Investigators of each HuBMAP award will, in compliance with this DUA, designate data that meet project requirements and share that data (the "HuBMAP Data") in one or more of the following ways: (1) distribution to others via dbGaP or similar secure NIH portal; (2) distribution to others via HuBMAP HIVE; (3) distribution directly among HuBMAP Program Members. In the spirit of protecting the privacy and confidentiality of the donor sources, the HuBMAP Data to be shared within HuBMAP prior to public release will be provided only to HuBMAP Program Members that have signed this DUA. In addition, all HuBMAP Program Members will adhere to NIH Genomic Data Sharing Policy.

All HuBMAP Program Members may aggregate HuBMAP Data for different types of analysis from all Member sites. With documented Principal Investigator approval, the HuBMAP HIVE can submit said HuBMAP Data to dbGaP and/or other designated databases administered by the National Institutes of Health. Each HuBMAP Program Member may share its own data with external collaborators without approval of the other Members. HuBMAP Data may be shared by Members with their partner organizations (e.g., organizations that provide site-initiated subcontracted services and/or other services required for HuBMAP studies), provided that said partner organizations are held to an equivalent standard of confidentiality that applies to Program Members.

Statement of Confidentiality: By signing this Agreement, the authorized official representing a HuBMAP Program Member, certifies that s/he and the Principal Investigators, fellows, students, and research staff (collectively, "Program Member Representatives") working on HuBMAP-related projects on behalf of the HuBMAP Program Member and represented by such authorized official, are aware of the confidential nature of the research study participant data maintained by the Member, and of the necessity for maintaining that confidentiality.

The HuBMAP Member and their Program Member Representatives agree not to attempt to personally identify any HuBMAP participant or family members based on HuBMAP Data and agree not to attempt to contact any HuBMAP participant of a site other than their own. The Member agrees not to transfer or disclose any confidential data or any information about individual HuBMAP study participants, except as permitted by this Agreement or as required by law, either during or after the conclusion of the affiliation with HuBMAP. The Member agrees to provide appropriate security for the HuBMAP Data, including but not limited to administrative, technical, and physical safeguards intended to prevent unauthorized use or disclosure of such information. In addition, each Member agrees to report

in writing to any other Member any use or disclosure of any portion of that Member's data of which it becomes aware and that is not permitted by this Agreement, including disclosures that are required by law.

The HuBMAP Member agrees to ensure that they and their Program Member Representatives do not use, disclose or transfer any HuBMAP Data to non-HuBMAP members except as permitted by this Agreement or as required by law. Further, the Member agrees to return all HuBMAP Data that has not already been incorporated into analysis to the HuBMAP HIVE Infrastructure Component or delete/destroy all printed or electronic HuBMAP Data of other Members in its possession upon termination of its affiliation with the HuBMAP Program and to notify the HuBMAP HIVE Infrastructure Center when it has done so. A single copy of data may be kept for the limited purpose of compliance with record retention requirements under law and for research verification.

Limitations of Data Use: The HuBMAP Member agrees to ensure that Program Member Representatives will only use HuBMAP Data in a manner that is consistent with any limitations that have been specified for individual studies by the disclosing Member and agreed to by the HuBMAP Steering Committee and shall ensure compliance with all applicable state and federal laws and regulations governing the use of such data including the Health Insurance Portability and Accountability Act of 1996 (HIPAA), if applicable, including any and all future amendments.

Liabilities. Each Party shall be responsible for its negligent acts or omissions and the negligent acts or omissions of its employees, officers or directors, to the extent allowed by law; provided, however, that any Party that is an agency of the United States Government, may be liable only to the extent as provided under the Federal Tort Claims Act (28 U.S.C. Chapter 171). No indemnification for any loss, claim, damage, or liability is intended or provided by any Party under this Agreement.

Limitation. HuBMAP Data are shared between Members as a service to the research community and to accomplish the objectives of the HuBMAP network. They are supplied with no warranties, express or implied, including without limitation, any warranty of merchantability or fitness for a particular purpose or non-infringement. No warranty with respect to the HuBMAP infrastructure is provided, including without limitation, any uptime warranty. The Parties make no representations that the use of the Study Data will not infringe any patent or proprietary rights of third parties.

This Agreement supersedes and replaces all prior agreements made between HuBMAP Program Members regarding the sharing and confidentiality of HuBMAP Data. No modification or waiver of this Agreement shall be valid unless in writing and executed by Member's authorized official.

For active, central and accessible documentation, a copy of each HuBMAP Member's signatory page to this DUA, of which each is a Party upon signature, will be maintained for reference by the Infrastructure and Engagement Component (IEC) of the HuBMAP HIVE (HuBMAP Integration, Visualization and Engagement) provided by the Pittsburgh Supercomputing Center (PSC), Carnegie Mellon University and the University of Pittsburgh (Pitt) on behalf of the HuBMAP Consortium.

Signatory Page

DUA SIGNATURE PAGE

By the signature below of a representative or officer who is specifically authorized to execute documents of this type, the institution identified hereby agrees to the terms of this DUA for use by and amongst Members of the NIH Human BioMolecular Atlas Program (HuBMAP) for Internal Sharing of Data, Final Ver **02/03/2020** without modification.

Agreed to by:

HuBMAP Member Representative's Institution [Legal Name of Institution]

Address of Institution:

Authorized Signatory: _____

(Print Name)

Title: _____

Signature: _____ **Date:** _____

Read & Acknowledged by:

HuBMAP Member Scientific Representative: _____

(Print Name)

Title (Print): _____

Signature: _____ **Date:** _____