

## DATA USE AGREEMENT BETWEEN COOPERATIVE HUMAN TISSUE NETWORK (CHTN) INSTITUTIONS PROVIDING A LIMITED DATA SET AND LIMITED DATA SET RECIPIENTS

This Data Use Agreement ("Agreement") is designed to permit the use of a Limited Data Set for research pursuant to the Standards for Privacy of Individually Identifiable Health Information, (Privacy Rule) 45 CFR Parts 160 and 164. All terms used in this agreement are as defined in the Privacy Rule.

This Agreement is made and entered into as of this \_\_\_\_\_ of \_\_\_\_\_, 20\_\_\_\_ by and between the Duke University, the University of Pennsylvania Health System and the University of Pennsylvania School of Medicine, The Rector and Visitors of the University of Virginia for the University of Virginia Medical Center, The Ohio State University, The Abigail Wexner Research Institute at Nationwide Children's Hospital and Vanderbilt University Medical Center, ("CHTN divisions"), which operate as various divisions of the Cooperative Human Tissue Network (CHTN) and \_\_\_\_\_ ("Data Recipient").

1. This Agreement sets forth the terms and conditions pursuant to which the CHTN divisions will disclose certain Protected Health Information (PHI) to the Data Recipient. PHI may include associated histopathologic, demographic, and clinical data that have been rendered a Limited Data set in compliance with 45 CFR 164.514(e) (1).
2. Except as otherwise specified herein, the Data Recipient may make Uses and Disclosures of the Limited Data Set consistent with the purpose of the research as described within their research application to the CHTN.
3. The individuals, or classes of individuals, who are permitted to use or receive the Limited Data Set include the Data Recipient and other researchers or individuals directly involved with the research project described within their research application to the CHTN.
4. The Data Recipient agrees to not Use or Disclose the Limited Data Set for any purpose other than the Research Project or as Required by Law.
5. The Data Recipient agrees to use appropriate safeguards to prevent Use or Disclosure of the Limited Data Set other than as provided for by this Agreement.
6. The Data Recipient agrees to report to the CHTN divisions any Use or Disclosure of the Limited Data Set not provided for by this Agreement, of which it becomes aware, including without limitation, any Disclosure of PHI to an unauthorized subcontractor.
7. The Data Recipient agrees to ensure that any agent, including a subcontractor, to whom it provides the Limited Data Set, agrees to the same restrictions and conditions that apply through this Agreement to the Data Recipient with respect to such information.
8. The Data Recipient agrees not to attempt to identify or contact the individual(s) to whom the Limited Data Set applies.
9. This agreement may be terminated by the CHTN divisions upon five (5) days written notice to the Data Recipient if the Data Recipient materially breaches any provision contained in this Agreement and such breach is not cured within the five (5) day period. The Data Recipient acknowledges that if efforts to cure the breach are unsuccessful, the CHTN Divisions may discontinue disclosure of Protected Health Information and report the problem to the Secretary of the Department of Health and Human Services.
10. The terms of this agreement cannot be changed.

### DATA RECIPIENT

Name and Title of Principal Investigator \_\_\_\_\_

Date \_\_\_\_\_

Authorized Signature \_\_\_\_\_

Date \_\_\_\_\_