

## AGREEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Cooperative Human Tissue Network (CHTN) will be used only for the purposes specified in this application. The recipient agrees not to attempt to obtain information identifying the individuals providing tissues to the CHTN. The recipient agrees that it shall not sell any portion of the tissues provided by the CHTN, or products directly extracted from these tissues (e.g. protein, mRNA or DNA). The recipient agrees that it shall not transfer tissue (or any portion thereof) supplied by the CHTN to third parties without the prior written permission of the CHTN.

The recipient understands that while the CHTN attempts to avoid providing tissues that are contaminated with highly infectious agents such as hepatitis and HIV, all tissues should be handled as if potentially infectious. The individuals who have supplied tissue to the CHTN have not agreed to have clinical tests performed on this tissue (e.g. for the presence of infective agents such as hepatitis), therefore, the recipient agrees not to perform such tests on the tissues supplied by the CHTN. The recipient acknowledges that the institution where the tissue will be used follows OSHA regulations for handling human specimens and will instruct their staff to abide by those rules. The recipient further agrees to assume all responsibility for informing and training personnel in the dangers and procedures for safe handling of human tissues.

Tissues are provided as a service to the research community without warranty of merchantability or fitness for a particular purpose or any other warranty, express or implied. The CHTN accepts no responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use.

The recipient agrees to acknowledge the contributions of the Cooperative Human Tissue Network in all publications resulting from the use of these tissues. Recommended wording to the methods or acknowledgement section is as follows: *"Tissue samples were provided by the Cooperative Human Tissue Network which is funded by the National Cancer Institute. Other investigators may have received specimens from the same subjects."*

**When tissue is to be used at State Institutions:** The institution agrees to be responsible for any claims, costs, damages, or expenses resulting from any injury (including death), damage or loss that may arise solely from the receipt, handling, storage and use of tissues received from the CHTN to the extent permitted under the laws of this State. The undersigned warrants that they have authority to execute this agreement on behalf of the recipient institution.

**When tissue is to be used at U.S. Government Agencies:** The US government assumes all risks and responsibilities in connection with the receipt, handling, storage and use of tissues received from the Cooperative Human Tissue Network. The United States assumes liability for any claims, damages, injury or expense arising from the use of the material or any derivative, but only to the extent provided under the Federal Tort Claims Act (28 U.S.C. Chap. 171).

**When tissue is to be used by all other institutions:** The institution agrees to assume all risks and responsibility in connection with the receipt, handling, storage and use of tissues from the Cooperative Human Tissue Network. It further agrees to indemnify and hold harmless the Cooperative Human Tissue Network and the United States Government from any claims costs, damages or expenses resulting from the use of the tissues provided by the CHTN. The undersigned warrant that they have authority to execute this agreement on behalf of the recipient institution.

### **BY MY SIGNATURE I AGREE TO THE TERMS SET FORTH IN THE ABOVE AGREEMENT**

Typed Name of PI Recipient \_\_\_\_\_ Agency \_\_\_\_\_

Typed Name of Official Authorized to Sign for the Agency \_\_\_\_\_

Signature of PI Recipient/Date \_\_\_\_\_ Division or Department \_\_\_\_\_

Authorized Signature of Agency Official/Date \_\_\_\_\_

**UPON RECEIPT OF THESE SIGNED UNDERSTANDINGS AND THE INFORMATION REQUESTED ABOVE, THE COOPERATIVE HUMAN TISSUE NETWORK WILL CONSIDER THIS REQUEST AND ALL FUTURE REQUESTS FOR TISSUE.** Specific questions about your application should be directed to your regional coordinator. Other questions may be directed to the NCI Program Director, Dr. Rodrigo Chuaqui at 301-496-7147.

**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 \_\_\_\_\_ day of \_\_\_\_\_, 20\_\_\_\_ by and between The Board of Trustees of the University of Alabama for the University of Alabama at Birmingham, 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, and the Columbus Children's Research Institute, ("Covered Entities"), 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 Covered Entities 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 Covered Entities 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 Covered Entities 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 Covered Entities 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 can be changed only by written modification signed by both parties.

**DATA RECIPIENT**

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

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