APPLICATION

DIRECTIONS

The Principal Investigator (PI) responsible for overseeing the project and controlling the laboratory and personnel who will receive, use and process the requested specimens should complete this application. A processing fee will be applied to each sample/aliquot to reimburse the CHTN for the processing and distribution of samples. Each PI is also responsible for all shipping costs.

Any transfer of samples, aliquots, derivatives or associated clinical data to collaborating personnel or laboratories that are not under the direct supervision of the indicated PI requires the following:

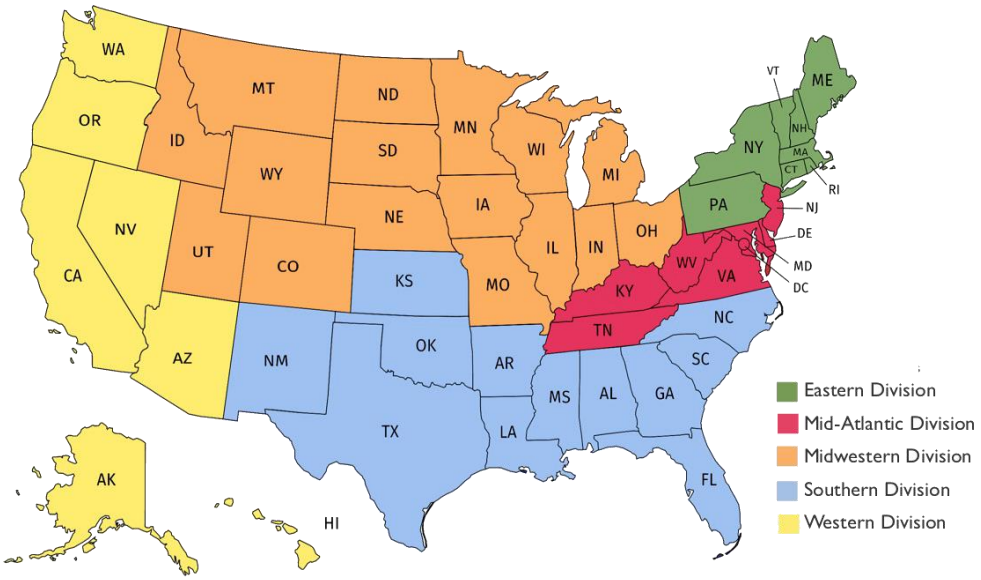
- A written justification of the need to transfer the materials and benefit to the applicant's research.
- Copies of the AGREEMENT FOR USE OF TISSUE and DATA USE AGREEMENT signed by the collaborator.
- Documentation of the collaborator's IRB approval or exemption unless the collaborator is covered under the IRB approval granted for the project proposed in this application.

The CHTN does not supply samples to specimen banks whose purpose is distribution to third-party researchers; those researchers should be encouraged to apply to the CHTN directly.

The information in these forms is necessary to document correctly your request for tissue and other services and to ensure that the CHTN operates within the guidelines of the National Cancer Institute. When submitting a written request for services:

1. Please print neatly or type.
2. If requesting specimens from more than one specific anatomic site or disease, please complete separate copies of the Request Information Form (biospecimen, donor and preparation details) as necessary. Please be specific about your requirements, including those for storing and handling tissue samples from the time the specimens are collected until they are delivered to your lab (i.e. transport media, refrigeration status, etc.).
3. Patient identity is confidential. Samples and accompanying clinical data will be identified by a code, which will not be released under any circumstances.
4. The PI is responsible for remission of processing fees to the originating CHTN division for each specimen provided, including fees for any additional services performed and any shipping costs not directly billed to the applicant's courier account. Please refer to our website for the current fee table.
5. PIs must obtain human subjects review from their institution to receive specimens from the CHTN. Full or expedited approval or an exemption for your project can be obtained from your Institutional Review Board (IRB) (Human Use Committee). **A copy of the Human Subjects approval or review documentation should be returned with this form**. Documentation of annual review of non-exempt protocols by the PI's institution must be forwarded to the CHTN to maintain eligibility to receive tissue. This is not necessary for exempt protocols. If your institution does not have internal review, contact your divisional coordinator. **NOTE:** Tissue microarrays are fully anonymized and do not require documentation of IRB approval or exemption.
6. Please provide a signed copy of the Agreement for Use of Tissue and Data Use Agreement (Agreements included below). **The language in the application and agreements are NOT to be altered.**
7. The CHTN is divided into five geographic regions as identified on the map below. PIs should submit their application to the appropriate primary division based on his/her geographic location. **PIs from any geographic area requesting pediatric specimens only** should forward their completed application directly to the Pediatric Division at The Research Institute at Nationwide Children's Hospital.
8. If you have any questions or need additional information, please contact your primary division based on your geographical location.

GEOGRAPHIC REGIONS/DIVISIONS & DIVISONAL CONTACTS



Pediatric Division serves pediatric requests throughout all of the U.S. & Canada.

Eastern Division	**Mid-Atlantic Division**	**Midwestern Division**
PI: Dr. Virginia LiVolsi Division Coordinator: Dee McGarvey dfitzsim@pennmedicine.upenn.edu 3400 Spruce St. 566 Dulles Hospital of the University of Pennsylvania Philadelphia, PA 19104 Tel: 215-662-4570 Fax: 215-614-0251	PI: Dr. Christopher Moskaluk Division Coordinator: Craig Rumpel chtn-midatl@hscmail.mcc.virginia.edu CHTN-Mid-Atlantic Division University of Virginia Dept. of Pathology Box 800904 Charlottesville, VA 22908 Tel: 434-924-9879 Fax:434-924-9438	PI: Dr. Anil Parwani Division Coordinator: Randy Mandt randy.mandt@osumc.edu CHTN Midwestern Division Innovation Centre 2001 Polaris Parkway Columbus, OH 43240 Tel: 614-293-5493 Fax: 614-293-7013
Pediatric Division	**Southern Division**	**Western Division**
PI: Dr. Nilsa Ramirez Division Coordinator: Tommy Liszkay Thomas.liszkay@nationwidechildrens.org The Research Institute at Nationwide Children's Hospital 700 Children's Drive Rm WA1340 Columbus, OH 43205 Tel: 614-355-3547 Fax: 614-722-2897	PI: Dr. Shannon McCall Division Coordinator: Aubrey Coulas Path-CHTN@duke.edu Duke University Department of Pathology DUMC 3712 Durham, NC 27710 Tel: 919-684-6928	PI: Dr. Kay Washington Division Coordinator: Kerry Wiles Kerry.wiles@vumc.org Vanderbilt University Medical Center 4918 TVC Building 22nd & Pierce Ave. Nashville, TN 37232-5310 Tel: 615-322-7486

PRINCIPAL INVESTIGATOR INFORMATION

First Name: Middle Name: Last Name:

Salutation: Degree: Title:

Institution Type: ☐ Academic/Non-Profit ☐ Government Lab ☐ Commercial

Mailing address:

Institution:

Department:

Address 1:

Address 2:

City: State: Zip code: Country:

Tel#: Alt. Tel#: Fax#:

Email:

LABORATORY CONTACT INFORMATION

First Name: Middle Initial: Last Name: Title:

Tel#: Alt. Tel#: Fax#:

Email:

First Name: Middle Initial: Last Name: Title:

Tel#: Alt. Tel#: Fax#:

Email:

SHIPPING INFORMATION

Preferred Shipping Courier: Courier Account# (required):

Shipping address same as mailing address: ☐

Attention:

Institution:

Department:

Address 1:

Address 2:

City: State: Zip Code: Country:

Tel#: Alt. Tel#: Fax#:

Email:

BILLING AND PAYMENT INFORMATION

Billing contact:

First Name: Middle Initial: Last Name: Title:

Tel#: Alt. Tel#: Fax#:

Email:

Billing address:

Same as mailing address: ☐

Attention:

Institution:

Address 1:

Address 2:

City: State: Zip code: Country:

Tel#: Alt. Tel#: Fax#:

Email:

Payment details: ☐ Purchase Order (PO#) ☐ Credit Card

Purchase Order (PO)#: PO Expiration Date: PO Amount:

Bill to Grant: Billing Ref#:

Copy of Bill to Investigator: ☐ Yes ☐ No

Is PO intended for: ☐ Use by any CHTN Division ☐ Use by only the primary CHTN Division

PROJECT INFORMATION

Project Title:

IRB Review Type (IRB documentation required to show IRB review decision):

☐ Full ☐ Expedited ☐ Exempt ☐ Not Human Subjects Research

☐ Human Use Agreement ☐ Not required (TMA's only)

IRB#: IRB Expiration Date: Exempt-no expiration ☐

Funding Information:

Tissues will be provided to investigators on a rotating basis in the following priority order:

1. Peer reviewed funded investigators (including Federal and National laboratories).
2. New investigators and academic investigators developing new research projects.
3. Other investigators.

To help determine your priority, please include your major research grant. Institutional and other funding sources may also be listed.

Funding Source #1:

Grant#:

Grant Start Date: Grant End Date:

Extramural peer-reviewed: ☐ Yes ☐ No

Funding Source #2:

Grant#:

Grant Start Date: Grant End Date:

Extramural peer-reviewed: ☐ Yes ☐ No

Currently unfunded: ☐ Please explain:

Please provide below a short research summary of the proposed research on the tissues you are requesting from the CHTN: (please click on the field to start typing)

How did you hear about the CHTN:

- AACR Annual Meeting
- AACR - Smaller Conference
- Colleague
- Previous CHTN Investigator
- NCI Specimen Resource Locator
- NCI Website
- Previous CHTN Investigator/Contact
- CHTN Presentation/Poster Session
- Google Search
- Publication
- Other (write in space below)

REQUEST INFORMATION FORM

If requesting specimens from more than one specific anatomic site or disease, please complete separate copies of this form, the Request Donor Details form and the accompanying Preparation Details form. Please be specific about your requirements, including those for storing and handling tissue samples from the time the specimens are collected until they are delivered to your lab (i.e. transport media, refrigeration status, etc.).

REQUEST INFORMATION: BIOSPECIMEN TYPE

Please check the appropriate tissue type below and complete the details for the biospecimen type requested. (***If submitting more than one request, complete a separate copy of this form for EACH request.***)

- ☐ Malignant Neoplasm
- ☐ Benign Neoplasm
- ☐ Normal Biospecimen
- ☐ Non-Neoplastic Disease
- ☐ Any Biospecimen

Primary Organ Site: Diagnosis Type(s):

Total number of donors requested:

If requesting **MALIGNANT**, **BENIGN** neoplasm, or **DISEASED** solid tissue please check all that apply:

- ☐ Primary Tumor (*if malignant*) or Diseased Tissue — ☐ Required or ☐ If available
- ☐ Metastatic Tumor (*applicable for malignant requests only*) — ☐ Required or ☐ If available
- ☐ Matching Grossly Uninvolved Tissue — ☐ Required or ☐ If available
- ☐ Matching Tissue Other Site (Site:) — ☐ Required or ☐ If available

If requesting **FLUID** biospecimens:

- ☐ Body Fluid (Type:) — ☐ Required or ☐ If available

If requesting **NORMAL** biospecimen, please check all that apply:

- Normal from healthy donors with no significant medical condition is acceptable: ☐ Yes ☐ No
- Normal or grossly uninvolved from donors with non-neoplastic disease is acceptable: ☐ Yes ☐ No
- Normal or grossly uninvolved from donors with cancer or a history of cancer is acceptable: ☐ Yes ☐ No

REQUEST INFORMATION: DONOR DETAILS

Donor Demographics:

Gender: ☐ Male ☐ Female ☐ Any Race: Any

Age Range 1: Minimum: Maximum:

Age Range 2: Minimum: Maximum:

Donor History:

Standard Information provided at no additional cost includes age, gender, race, and the final pathology diagnosis (typically a copy of the final pathology report) or CHTN QA assessment where applicable. Any requests for additional information, including prior therapy questions below, require prior CHTN approval and may incur an additional fee for chart review. Availability and completeness of clinical information is not guaranteed.

Additional Chart Review Required: ☐ Yes ☐ No

Review Information Requested:

Accept tissue from patients who have had prior chemotherapy:

☐ Yes ☐ No ☐ Unknown treatment status is acceptable

If YES, please check the following options:

☐ Yes, for different disease

☐ Yes, for prior presentation of this disease

☐ Yes, with neoadjuvant treatment for this procedure

Accept tissue from patients who have had prior radiation therapy:

☐ Yes ☐ No ☐ Unknown Treatment status is acceptable

If YES, please check the following options:

☐ Yes, for different disease

☐ Yes, for prior presentation of this disease

☐ Yes, with neoadjuvant treatment for this procedure

Procedure Type (check all that apply):

☐ Surgery – Post Excision Time:	☐ Time Not Applicable
☐ Autopsy – Post Mortem Time:	☐ Time Not Applicable
☐ Transplant – Post Transplant Time:	☐ Time Not Applicable
☐ Phlebotomy – Post Phlebotomy Time:	☐ Time Not Applicable

Please indicate the order of priority (1 being the highest priority) of the preparation type if you are requesting more than one preparation type for the same tissue specimen.

REQUEST INFORMATION: PREPARATION DETAILS

FRESH PREP TYPE

☐ Required ☐ If available Preparation priority (See above note):

Standard Fresh Preps: ☐ RPMI ☐ DMEM ☐ Dry ☐ PBS ☐ Saline ☐ RNALater

☐ Slides-Touch preps (#req'd) ☐ Other

☐ Investigator Supplied Media (Name of Media:) MSDS SHEET IS REQUIRED

☐ Additional Media Supplements (type and concentration)

☐ Antibiotics (100 μg/mL Penicillin and 100 μg/mL Streptomycin) ☐ Fetal Bovine Serum 10%

☐ Antimycotic Fungizone (2.5 μg/mL Amphotericin B)

Note: If other additives are requested, please contact your divisional coordinator.

Biospecimen size: Minimum Weight: Maximum Weight:

Minimum Dimensions: L H W

Minimum Volume (fluids): ☐ mL ☐ μL

FROZEN PREP TYPE

☐ Required ☐ If available Preparation priority (See above note):

Standard Freezing Methods: ☐ LN2 vapor phase ☐ Immersed in LN2 liquid ☐ OCT

Non-standard Freezing Methods: ☐ Frz -20 ☐ Frz -80 ☐ Frz in isopentane ☐ Dry Ice

☐ Scroll/Ribbon ☐ Macrodissection ☐ Other

Slides: ☐ H&E slides (#req'd) ☐ Frozen sections (#req'd)

☐ Touch prep slides (#req'd)

Biospecimen size: Minimum Weight: Maximum Weight:

Minimum Dimensions: L H W

Minimum Volume (fluids): ☐ mL ☐ μL

FIXED PREP TYPE

☐ Required ☐ If available Preparation priority (See above note):

Fixation Methods: ☐ Paraffin Block (Formalin 10%) ☐ Floating in Formalin ☐ Scroll/Ribbon

Slides: ☐ H&E slides (#req'd) ☐ Unstained slides (#req'd)

☐ Touch prep slides (#req'd) ☐ Other

Biospecimen size: Minimum Weight: Maximum Weight:

Minimum Dimensions: L H W

SHIPPING

Target # of Specimens in a shipment:

Saturday delivery: ☐ Yes ☐ No ☐ If notified

Shipping Instructions: Frozen: ☐ Dry ice ☐ Ice pack

Refrigerated: ☐ Wet ice ☐ Cold pack

Non-refrigerated: ☐ Ambient temperature

Shipping Choices: ☐ Ship day of procurement to arrive next day (standard for fresh shipments)

☐ Standard overnight shipment ☐ Investigator pickup same day as procured

AGREEMENT FOR USE OF TISSUE

The recipient/investigator agrees that the tissues provided by the Cooperative Human Tissue Network (CHTN) grantees (Duke University, The Ohio State University, University of Pennsylvania, University of Virginia, Vanderbilt University Medical Center and Nationwide Children's Hospital) will be used only in the laboratory of the recipient principal investigator for the research and/or educational purposes specified in this application and shall be used for no other purpose. 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 the principal investigator shall not transfer tissue (or any portion thereof) supplied by the CHTN to internal or external 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 purpose or any other warranty, express or implied. Neither the CHTN nor the grantees outlined above accepts any responsibility for any injury (including death) damages or loss that may arise either directly or indirectly from their use by recipient.

The recipient agrees to acknowledge the contributions of the CHTN in all publications resulting from the use of these tissues. Recommended wording for the methods or acknowledgement section is as follows: *"Tissue samples were provided by the Cooperative Human Tissue Network (CHTN), 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 about the receipt, handling, storage and use of tissues received from the CHTN. 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 about the receipt, handling, storage and use of tissues from the Cooperative Human Tissue Network. It further agrees to indemnify and hold harmless the CHTN, the grantees outlined above, 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

Name of PI Recipient_____

Acknowledgement of PI Recipient_____ Date_____

Name of Official Authorized to Sign for Agency_____

Signature of Agency Official_____ Date_____

Upon receipt of these signed understandings and the information requested above, the CHTN will consider this request and all future requests for tissue. Specific questions about your application should be directed to your regional coordinator. Any other questions should be directed to the NCI Program Director, Dr. Rodrigo Chuaqui at 240-276-5910.

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.

DATA RECIPIENT

Name and Title of Principal Investigator_____ Date_____

Authorized Signature _____ Date_____

CHTN Genomic Research Policy

CHTN investigators must identify the requirement for genomic DNA sequencing in this application so samples can be suitably screened for appropriate consent status. The human biospecimens collected from the CHTN come from a wide range of academic hospitals and allied health care entities. While all specimens are collected under local human subjects research institutional review board (IRB)-approved protocols that approve minimal-risk research to be performed on the collected specimens, not all specimens have received informed consent for genomic DNA sequencing or to be involved in studies of genetic inheritance. The CHTN does not re-contact subjects donating biospecimens for specific studies. Therefore, the CHTN will not give blanket assurance that tissue or biofluid specimens provided to our investigators can be used for genetic/genomic studies. All CHTN specimens are either fully anonymized or coded-linked but considered permanently de-identified to recipient investigators. CHTN investigators are responsible for the use of the specimens according to the requirements placed on their research by their local IRB and the requirements for publication of any genomic data generated by their studies.

☐ Yes, my studies involve genomic research and I need samples from appropriately consented patients.

☐ No, my studies do not involve genomic research.