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CANCER DIAGNOSIS PROGRAM TISSUE MICROARRAY SLIDES

PART 2: SUPPLEMENTAL INFORMATION AND AGREEMENTS

***DO NOT SUBMIT UNTIL INSTRUCTED BY MID-ATLANTIC CHTN STAFF UPON SUCCESSFUL PRE-REVIEW.***

***THIS IS STEP 2 OF A TWO STEP PROCESS.***

# DIRECTIONS

Congratulations on the approval of your request for NCI Cancer Diagnosis Program (CDP) tissue microarrays (TMAs).

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 form. 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.
* A copy of the AGREEMENT FOR USE OF TISSUE MICROARRAY (TMA) SLIDES signed by the collaborator.

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 in order to document correctly your request for TMA slides and to ensure that the CHTN operates within the guidelines of the National Cancer Institute. When submitting:

1. Please print neatly or type.
2. Patient identity is confidential. Samples on the TMA slides have been fully anonymized, and no additional donor or clinical information is available beyond what is provided with the TMA slides or made publicly available through the CHTN TMA website.

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| *Mailing Address*:CHTN, Mid-Atlantic Division University of Virginia Dept. of Pathology Box 800904Charlottesville, VA 22908 | Mid-Atlantic DivisionTel: 434-924-9879 / Fax:434-924-9438CHTN-MidAtl@hscmail.mcc.virginia.eduDivision Coordinator: Rebecca BlackwellPI: Dr. Christopher Moskaluk |

1. Descriptions of currently available TMAs and fees are available at <http://chtn.sites.virginia.edu/>. **NOTE:** The CHTN does not provide or construct custom TMAs.
2. The PI is responsible for remission of processing fees to the Mid-Atlantic division for each TMA section provided, including fees for any additional services performed, and any shipping costs not directly billed to the applicant’s courier account.
3. Investigators requesting TMA slides from the CHTN should consult their local Institutional Review Board for policies and procedures for use of anonymous human tissue samples, such as are contained in the CHTN tissue microarrays. **NOTE:** The CHTN does not require documentation of IRB approval or exemption in order to request these materials.
4. Please provide signed copies of the QUALITY ASSURANCE ACKNOWLEDGEMENT FOR TISSUE MICROARRAY (TMA) SLIDES and AGREEMENT FOR USE OF TISSUE MICROARRAY (TMA) SLIDES (Included below). **The language in these agreements is NOT to be altered.**
5. Please mail, fax or e-mail this completed form and direct any questions to the Mid-Atlantic Division:

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| PRINCIPAL INVESTIGATOR INFORMATION |
|  First Name:       Middle Name:       Last Name:       Salutation:       Degree:       Title:        Institution Type: [ ]  Academic/Government [ ]  Commercial [ ]  Non-profit **Mailing address:** Institution:       Department:        Address 1:       Address 2:       City:       State:       Zip code:       Country:       Tel#:       Alt. Tel#:       Fax#:       Email:       |

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| 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:       |

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| 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:       |

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| 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#) Purchase Order (PO)#:       PO Expiration Date:       PO Amount:       [ ]  Credit Card (CHTN will call billing contact for account information at the time of each shipment) Bill to Grant:       Billing Ref#:       Copy of Bill to Investigator: [ ]  Yes [ ]  No  |

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| PROJECT INFORMATION |
| Project Title:     Funding Information:  Specimens are 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# and Title:       Grant Start Date:       Grant End Date:      **Funding Source #2:**       Grant# and Title:       Grant Start Date:       Grant End Date:       Currently unfunded: [ ]  Please explain:      **CHTN'S Research Resource Identifier (RRID): SCR\_004446** **If applicable, please enter your Open Researcher and Contributor ID (ORCID):**      If you do not have an ORCID but would like to obtain one, please click this [link](https://orcid.org/register) and you can follow the steps to apply. |

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| **TISSUE MICROARRAY REQUEST INFORMATION** |
| **Currently available CDP TMA designs are listed below. Based on the pre-review approval notification you received, please indicate the number of slide sets of each design to be provided.** Slides provided will be serial unstained histologic sections at 4 microns thick, on charged glass slides unless by prior arrangement.[ ]  **CDP Breast Cancer Stage I Prognostic** **TMA** # of slide sets requested:      [ ]  **CDP Breast Cancer Stage II Prognostic** **TMA** # of slide sets requested:      [ ]  **CDP Breast Cancer Stage IIII Prognostic** **TMA** # of slide sets requested:      [ ]  **CDP Melanoma Progression TMA** # of slide sets requested:      **Please indicate your shipping preference**[ ]  **Ship immediately (next available date)**[ ]  **Delay shipment until a specific date.\*** Date requested:      [ ]  **Do not ship until notification received from PI.\*** Anticipated date:       Reason/Comment:     **\*Note that CDP TMA sections are not reserved and are a finite resource. The CHTN cannot guarantee that sufficient sections will be available to fulfill your request at a later date.**For additional information, please contact the Mid-Atlantic Division at (434) 924-9879 or email your query to the CHTN Mid-Atlantic Division (CHTN-MidAtl@hscmail.mcc.virginia.edu).  |

**QUALITY ASSURANCE ACKNOWLEDGEMENT FOR TISSUE MICROARRAY (TMA) SLIDES**

The TMA sections that you are receiving have been inspected by the Cooperative Human Tissue Network prior to shipment and judged to be of acceptable quality.

Please note that it is typical for some spots on the TMA to be missing or not to contain the intended target tissue. These difficulties are inherent to the TMA construction process and are not unique to CDP TMAs. Our quality control studies have indicated that missing or incorrect target tissue may occur with a frequency as high as approximately 25-30%, depending on the depth at which the sections were cut from the TMA block.

You may also observe some distortion of the sections and some rolling or folding of certain tissue spots, particularly for the larger tissue spots. These effects are not uncommon when making TMAs in a consortium setting such as the CDP TMAs, when tissue fixation and embedding can vary widely among the donating archival tissue sources. It is our experience that these distortions generally do not significantly limit the ability to obtain reliable assay readings.

Additional spot loss or displacement may occur during the assay procedure, with the rate of loss dependent on the assay conditions. It is recommended that investigators optimize their assay using relevant human tissues prior to using CDP TMA sections.

The CDP TMAs have been designed with the above issues in mind, and the number of cases represented on the TMAs has been increased to account for the expected rate of unusable cores. It is recommended that the TMA sections should be stored in the dark at 4 °C upon receipt and that TMA sections intended for immunohistochemistry be stained within one week of receipt unless you have prior experience that your particular antigen is more stable.

The CHTN cannot accept returns of unused TMA sections.

The receipt of this signed and dated form is required before the Cooperative Human Tissue Network will provide any approved tissue microarray sections.

**BY MY SIGNATURE, I FULLY UNDERSTAND AND ACKNOWLEDGE THE ABOVE INFORMATION**

Typed Name of PI Recipient

Signature of PI Recipient/Date

**AGREEMENT FOR USE OF TISSUE MICROARRAY (TMA) SLIDES**

The recipient/investigator agrees that the TMA slides 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 the tissue samples contained on the TMA slides are anonymized and no further clinical information is available other than the data that accompany the arrays or made publicly available through the CHTN website.

The investigator agrees to contact his/her Institutional Review Board regarding local policies and procedures for the use of anonymous human tissue samples, such as are contained in CHTN tissue microarrays.

The tissue microarray slides 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 TMA slides. Recommended wording for the methods or acknowledgement section is as follows: *“Tissue samples were provided by the Cooperative Human Tissue Network (CHTN) and the Cancer Diagnosis Program which are 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 certifies 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 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 certifies 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 the Agency

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 TMA SLIDES.** Specific questions about your application should be directed to the Mid-Atlantic Division Coordinator. Other questions may be directed to the NCI Program Director, Dr. Rodrigo Chuaqui at 301-496-7147.