NRG Oncology Biospecimen Bank
Letter to Pathologists regarding tissue submissions

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Pittsburgh: NRGbiobankPGH@NRGOncology.org

Dear Colleague:

We write to provide you important information about ongoing NRG Oncology's efforts to enhance the successful treatment of patients with cancer and the role community pathologists play in these efforts.

NRG Oncology is an NCI-funded national clinical trials network (NCTN) that studies the use of new radiation, chemotherapy, or surgery in combination with other modalities such as immunotherapies for cancer patient treatment. NRG Oncology's membership roster is comprised of over 1,900 member sites (including your institution) on five continents. Our investigators represent all the oncologic specialties and disciplines, including pathologists.

The NRG Oncology Biospecimen Bank (NRG-BB) is a biospecimen repository (also known as a tissue bank) for biospecimens collected from patients consenting to participate in NRG Oncology trials. The NRG Oncology principal investigator (PI) and research associate at your institution have information about how enrolled patient tissue materials are to be collected, possibly processed and ultimately shipped to the NRG-BB, and how your institution will be reimbursed for these efforts.

Being pathologists ourselves, we understand the extra effort needed from your department to provide these materials to NRG Oncology. The protocols typically request a paraffin block but if this is a problem you could instead submit 2- or 3-mm dermatologic punch biopsies from a tumor-containing region (if this is listed as an alternative in the protocol). The NRG-BB provides a kit and instructions for this alternative, or we can do the punch biopsies for you and return the block(s) to you. For studies involving biopsy specimens (e.g. GU Trials) punch biopsies may not be an option because the punch biopsy might deplete these blocks. Unless included in the protocol, unstained slides are generally no longer an acceptable alternative for NCTN trials as they are often not useful for downstream analyses.

When an institution enrolls patients onto an NCTN clinical trial they are reimbursed for the submission of biospecimens. You should submit your request for reimbursement to the Principal Investigator of the NRG Oncology grant at your specific institution as pathology reimbursement is now included in the global patient reimbursement for trial participation. We can provide their contact information if you are not sure who is the local NRG Oncology PI at your institution.

We also understand that due to regulatory and compliance issues, you might be hesitant to release patient materials from your facility, especially if this is the diagnostic material of record in your files. **Please keep in mind that patients enrolled in NRG Oncology clinical trials have explicitly given informed consent to the release of their materials to NRG Oncology.** For most protocols, a duplicate H&E stained section is an acceptable alternative. The NRG-BB keeps these materials in a centralized location and can return them to you whenever needed for clinical or legal reasons (usually within 24-72 hours).

I hope that you find the above information useful and that it will encourage your participation in NRG Oncology efforts. Attached with this letter is additional information to answer other questions that you may have about the NRG-BB and its activities. We look forward to working with you and we are here to help answer any other questions you might have about these efforts, as we all work together to improve the lives of cancer patients on our way to discovering new cures.

Sincerely,

Jeff Simko, MD PhD, Nilsa Ramirez, MD, Tanner Freeman, MD PhD, Richard Jordan, DDS PhD FRCPath.
Directors of the NRG Oncology Biospecimen Banks - San Francisco, Columbus, and Pittsburgh

NRG Oncology Biospecimen Banks

The NRG Oncology Biospecimen Bank pathologists are all anatomic pathologists practicing in a large tertiary care hospital. We are aware of the concerns you might have over removal of tissue blocks from your files because we too send blocks to the NRG-BB and other clinical trial biobanks. We hope that the following will address your concerns:

1. *Patient Consent:* Each Patient, as part of enrollment into NRG Oncology studies, undergoes informed consent procedures a may elect to sign a study-specific consent form explicitly stating permission to use their tissues for research purposes. Tissues used for research are only labeled by NRG Oncology patient ID number in a HIPAA-compliant manner, and no patient identifying information can be obtained by researchers. These are population-based studies, which look at population characteristics rather than individual patient related issues. We know from our previous experience that patients want these studies to be done, and they have only rarely declined participation in tissue bank studies.

2. *Access of Institution to Tissue Blocks and Requirement for 10 years of Storage to Satisfy Regulations (CAP):* The tissue blocks are stored in a cool, dry place by accession number. The location of blocks and material disposition is available on a database that is readily available. Institutions needing their blocks returned because of patient, physician or legal requirements can have their blocks returned overnight by faxing or e-mailing a request to the NRG Oncology Biospecimen Bank (contact numbers are above).

3. *Ability of Pathologists in the Institution to Perform Scientific Studies:* The storage of these tissues centrally does not preclude investigation using this material by anyone. Any scientist with a scientifically valid proposal, and the funds and methods to investigate it can use the tissue bank, and such access is a requirement of NIH (U.S.A. Federal) funding of tissue bank activities. The bank makes it possible to study larger numbers of patients on which treatment is standardized and follow up is available. By sharing our resources, we are much more likely to answer important scientific questions related to cancer. Enrollment in clinical trials rarely involves more than 5% of patients of a particular tumor type and thus does not compromise the group of patients available for local studies in most cases.

4. *Gaining Access to these materials:* NCI will permit the study of patients registered on NRG Oncology clinical trials by any qualified investigator (including pathologists) making an application regardless of affiliation. Information on the application process can be found at https://www.nrgoncology.org/Scientific-Program/Biospecimen-Access and you may contact us directly about this application process. This tissue resource will allow correlative studies to be performed on clinically homogeneous patient populations, which will give us important information about prognostic factors, treatment selection factors and biologic behavior, if the resources are used wisely. All applications must be reviewed by NCI's CTEP program for final approval. The investigator must have funds and facilities available to carry out the proposed research project. If you would like specific information about what has been discovered via previously supported projects, please contact us for a list of references.