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NRG Oncology Biospecimen Bank – San Francisco
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Dear Colleague:

We write to inform you about the ongoing NRG Oncology tissue banking efforts being made by the pathology community to enhance our abilities to successfully treat cancer patients. NRG Oncology is an NCI-funded national cooperative cancer study group, which explores through clinical trials alternative therapeutic options involving radiation therapy or surgery in combination with other modalities for cancer patient treatment. NRG Oncology's membership roster is comprised of over 1,900 member sites (including at your institution) including institutions on five continents. Our investigators represent all of the oncologic medical specialties and disciplines.

The NRG Oncology Biospecimen Bank is a tissue repository (Tissue Bank) for materials collected from patients consenting to enrollment into these trials. The NRG Oncology principal investigator and research associate at your institution has information about how enrolled patient tissue materials are to be collected and shipped to the NRG Oncology Biospecimen Bank, and how your institution is reimbursed for these efforts.

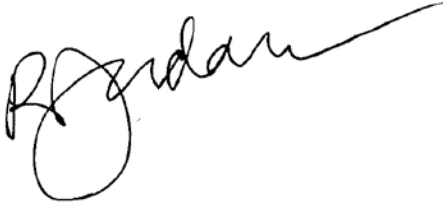
Being pathologists ourselves, we are aware of the extra effort needed from your department to provide these materials to NRG Oncology. If it is not possible to send the tumor block, your institution could instead submit 2 mm punch(es) from a tumor-containing region (or the NRG Oncology Bank can do this and return the block(s) to you). The NRG Oncology Biospecimen Bank provides a kit and instructions for this activity. Some protocols allow unstained slides to be submitted as acceptable alternative specimens. 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 patient enrollment reimbursement. We can provide that information if you are not sure who is the NRG Oncology PI at your institution.

We also understand that due to regulatory and compliance issues, you might be reluctant to release patient materials from your facility, especially if this is the diagnostic material of record in your files. For most protocols a duplicate cut stained H&E slide is acceptable, it does not have to be the diagnostic slide. **Please keep in mind that these patients enrolled in NRG Oncology clinical trials have explicitly consented to release of their materials to NRG Oncology.** The NRG Oncology Biospecimen Bank keeps these materials in a centralized location, and is capable of returning them to you whenever needed for clinical or legal reasons (usually within 24 hours).

I hope that you find the above information useful and that it encourages your help and participation in NRG Oncology efforts. Attached with this letter is additional information to answer other questions that you may have about the NRG Oncology Biospecimen Bank 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.

Sincerely,

A handwritten signature in black ink, appearing to read "R Jordan", with a long, sweeping horizontal line extending to the right.

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The NRG Oncology Biospecimen Bank pathologists are all anatomic pathologists practicing in a large tertiary care hospital. We are well aware of the concerns you might have over removal of blocks from your files because they are being removed from ours as well, but hopefully the following addresses your concerns:

1. *Patient Consent:* Each Patient, as part of enrollment into NRG Oncology studies, signs 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 case 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 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:* The tissue bank will permit the study of cases entered into NRG Oncology clinical trials by any qualified investigator (including pathologists) making an application regardless of affiliation; contact us 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. Applications are reviewed semiannually by either an NRG Oncology or Intergroup tissue banking committee who will decide whether tissue can be allocated for the proposed project. 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. Correlative studies are also funded as part of the clinical trial proposal. If you would like specific information about what has been discovered via previously supported projects, please contact us for a list of references.