

LETTER TO PATHOLOGISTS ABOUT RETURN OF TISSUE SLIDES

Dear Colleague,

We have received a request from you concerning the return of block/slides on patients from your institution. Patients entered into NRG Oncology protocols have given specific consent that explicitly permits the use of their tissues for research. Several NRG Oncology translational research studies are either already underway or are planned using these tissue materials. **We therefore request that the blocks/slides remain in the NRG Oncology Biospecimen Bank unless you need them for immediate legal or direct patient care use.**

As a pathologist myself, I am well aware of the requirements for keeping patient blocks/slides available for important clinical reasons. All blocks/slides sent to the NRG Oncology Biospecimen Bank are maintained in appropriate storage conditions with a full time on-site steward that can promptly return them to you if there is an immediate clinical or legal need. Therefore, we hope that you will allow us to maintain these blocks/slides in the Biospecimen Bank so that we can carry out these important translational studies on the tissues that we have.

Translational research studies are only effective if the number of patients in the study is sufficient to answer the research questions being asked. The NRG Oncology Biospecimen Bank is part of the National Cancer Institute Tissue Resource and can be utilized by any investigators through a peer reviewed mechanism for research purposes. These tissue banks constitute a very important resource since clinical information and pathologic information are both available in a setting where patient stratification and treatment variables are standardized. These features make this bank an extremely valuable resource for successful cancer research, but it will only retain its value if submitted tissue materials are maintained within the bank itself. Thank you for your consideration and feel free to contact me if you have any questions regarding our activities.

Sincerely,

Richard Jordan, DDS PhD FRCPath Director NRG Oncology Biospecimen Bank – San Francisco

Jeffry Simko, MD PhD, Co-Director NRG Oncology Biospecimen Bank – San Francisco
Ken Aldape, MD, Co-Director NRG Oncology Biospecimen Bank – San Francisco

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. Since the tissue bank will reimburse pathologists for supplying blocks, funds will accrue at institutions that enroll the most patients, which they may elect to use to carry out projects on various tumor types. 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. Pooling funds from reimbursement of many tumors will likely result in significant funds being available. This is significantly more money for pathology projects than is usually available and represents a wonderful opportunity for pathologists submitting tissue to NRG Oncology.

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 we use

these resources 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. 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.