Biospecimen Kits

NRG Oncology Biospecimen Bank (NRG BB) biospecimen kits are protocol-specific and include supplies to help collect and ship biospecimens for certain protocols. To determine whether a kit is to be provided and for information about obtaining kits, check:

- Pre-activation/Activation Instructions
- Protocol
- Pathology/Correlative Instructions

These documents can be obtained from the CTSU website (https://www.ctsu.org) or the NRG Oncology website (https://www.nrgoncology.org/Clinical-Trials/Protocol-Table).

Note: Protocols can have very different biospecimen requirements. Check the protocol, instructions, or contact the biospecimen bank listed in the protocol to determine whether you may substitute one kit for another. *In most cases, kits cannot be substituted between protocols.*

Refer to the protocol-specific Pathology and Correlative Science Instructions for detailed instructions regarding ordering kits.

For Biospecimens Shipped to:

BB-Columbus

Order kits online via the Kit Management link: https://kits.bpc-apps.nchri.org.

Contact 614-722-2865 or BPCBank@nationwidechildrens.org for questions.

BB-Pittsburgh and -Baylor

Contact 412-697-6611 or <u>NRGbiobankPGH@NRGOncology.org</u> for questions regarding kits distributed from NRG BB-Pittsburgh.

Or Contact <u>tumor-bank@breastcenter.tmc.edu</u> or 713-798-1647 for questions regarding kits distributed from the Serum Bank at Baylor.

BB-San Francisco

When specified in the protocol order kits by sending an email to the bank at <u>NRGBB@UCSF.edu</u> or by filling out an online kit request form at <u>http://nrgbb.ucsf.edu/</u>.

All kit requests should include the following:

- Contact information and FedEx ship to address with room/suite number.
- Name of study for which the kit is needed, and confirmation of IRB approval for that study.

- Number of kits needed:
 - One kit per request until site has enrolled more than one case.
 - Requests for more than 3 kits must have been pre-approved by the bank.
- Date kits are needed:
 - Kits are shipped by FedEx Ground and should arrive within 5-10 business days.
 - Urgent kit requests require sites to provide a FedEx account to bill to or label.

Note: If kits are not used within 6 months, sites should return un-used kits to the bank.

Biospecimen Submissions

***BB locations will not accept biospecimens not listed in the protocol. ***

Formalin-Fixed, Paraffin-Embedded (FFPE) Blocks

Blocks are preferred and, in many cases, required per protocol. In some cases, the protocol or instructions may indicate that an alternative submission (e.g., cores, unstained slides) can be provided. Check the protocol requirements or contact the respective bank to determine whether an alternative submission is acceptable for the specific study.

Unstained Slides

If unstained slides are allowed by the protocol and will be submitted, the tissue sections should be the exact thickness (μ m) and on the exact slide type (charged, uncharged) specified in the protocol. All tissue sections should be cut sequentially from one block. Always check the protocol or pathology/correlative instructions - Often slides should not be baked. If slides for other study purposes (e.g., pathology review, integral biomarkers) that are shipped to other laboratories will be cut from the same block that will be submitted to the NRG BB, the institutional pathology department should cut those slides prior to submitting the block to the NRG BB.

Tissue biospecimens must be labeled with the pathology accession number and, if applicable, the block number.

- An example of an accession number and block number is S15-1111 and A2, respectively.
- The accession number frequently starts with the letter "S" and the year in which the tissue was collected (e.g., "15"), followed by the patient's pathology number (e.g., "1111").
- The block number denotes the individual block created from the patient's tissue when multiple blocks are generated. It may or may not be present.

Verify that you are submitting the correct tissue type (e.g., primary, metastatic, normal).

Blood Biospecimens

Always refer to the protocol for information on blood collection tubes, draw volumes, and processing instructions. In some cases, blood biospecimens are processed at the site prior to shipping. If applicable, the protocol document will also include information as to the type of blood collection tube that can be

used (e.g., brand, size, material), as well as shipping instructions. In some instances, sites are required to contact the receiving location prior to shipment.

The downstream use (e.g., testing) dictates collection and processing instructions. It is important to note that the same type of blood biospecimen (e.g., whole blood) may be collected differently in various protocols or even in the same protocol. Always refer to the specific protocol for details.

Other Biospecimens

Always refer to the protocol for information on collection materials and amounts, as well as processing and shipping instructions.

Biospecimen Labeling and Documentation

Labeling

Biospecimens to be used for central pathology ad biomarker testing may be labeled differently. Labeling requirements for biospecimens shipped to NRG BB locations may be different than requirements for biospecimens shipped to commercial laboratories. Refer to the specific protocol for details.

Incomplete or improper biospecimen labeling may delay biospecimen receipt and, in some instances, may even render the biospecimen unusable.

Pathology Reports for Tissue Biospecimens

Pathology Reports are often required for the submission of tissue, regardless of use (i.e., central review, biomarker testing).

Depending on the use and disease site, pathology reports may be submitted to the BB or Data Management Center (SDMC). Each protocol can have different pathology report requirements. Check the protocol and instructions to determine where pathology reports should be sent to and if the pathology reports need to have PHI redacted.

In some instances, a Pathology Verification Form will be accepted in lieu of a pathology report for tissue biospecimen used for biomarker testing. The specific protocol will state whether this option is available.

Biospecimen Transmittal Forms

All biospecimens must be shipped with a completed copy of the corresponding biospecimen transmittal form. Form name and content may vary by use, protocol, disease site, or shipping location. Some forms are generic (i.e., used across all protocols) and others are study-specific. Always check the protocol for details.

Depending on the protocol, forms may be completed online or by hand. Regardless of the method for completion, incomplete forms may delay the processing of biospecimens. IN some instances, incomplete forms may result in a query from the Statistics and Data Management Center (SDMC).

For Biospecimens Shipped to:

> NRG BB-Columbus

Refer to the protocol for labeling instructions. Depending on whether the biospecimen is submitted for screening or research purposes, labeling will differ.

A copy of the corresponding pathology report must accompany all tissue biospecimens shipped to the BB-Columbus. In some instances, a Pathology Verification Form will be accepted in lieu of a pathology report.

An electronically completed copy of the corresponding biospecimen transmittal form (e.g., SP or TR) must accompany each biospecimen shipped to BB-Columbus.

BB-Pittsburgh and -Baylor

Frozen tissue should be labeled with Pre-Entry Number or Study Number.

Refer to protocol-specific Pathology Instructions for details regarding blood labeling.

Refer to protocol-specific instructions for details on where to send pathology reports to BB-Pittsburgh.

BB-San Francisco

H&E slides must be submitted and must correspond to and accompany blocks/punches/unstained slides.

Specimen Submission Forms and Pathology Reports must be included with all submissions.

PHI information must be redacted from the pathology reports except for accession and block numbers and date of procedure.

Biospecimen Handling

Always use Universal Precautions when handling biospecimens.

Most institutions provide annual training on work practices to help prevent the spread of blood borne pathogens.

Please refer to your institutional guidelines for more information on Universal Precautions and the handling of biospecimens.



Shipping Regulations

Shipments to the NRG BB must conform to **International Air Transport Association (IATA)** guidelines, if shipped by air.

For more information regarding IATA regulations, please visit their web site: http://iata.org.

National and international regulations require Safe Shipping training for those who handle Dangerous Goods (e.g., dry ice).

Training is available through institutions or:

- International Air Transport Association (IATA) offers training.
- Saf-T-Pak offers current compliance training and a competency exam.

Proper training and compliant shipping can greatly reduce the risk of incurring very high fines and civil suits with no upper limit.

Contact your institution's Environmental Health and Safety or Shipping and Receiving Department for training related to shipping biospecimens.

General Shipping Information

Read the NRG and CTSU Weekly Mailings for holiday closure notices and instructions.

- Whenever possible, wait to ship **frozen biospecimens** until after major holidays including Memorial Day, July 4th, Labor Day, Thanksgiving, Christmas, and New Year's Day.
- Christmas is a **busy shipping season** and packages routinely get delayed by a day or more. Make sure to include plenty of dry ice. Check protocols for shipping instructions.
- Ship frozen biospecimens Monday through Wednesday; avoid Thursday shipments.

Check FedEx and UPS websites for weather delay alerts. Bad weather in one area will affect overnight shipments to ALL states, not just the part of the country with the bad weather.

Record the tracking information associated with the shipment. Follow up with the courier to ensure that the package arrives at its destination.

Make sure you ship to correct the NRG BB!

Occasionally a protocol may have special shipping instructions as a result of the testing to be done. Refer to the protocol documentation for protocol-specific shipping instructions.

Glass slides will break when shipped if not packaged tightly in hard sided containers. Rule of thumb: If you hear slides shaking, they will be breaking!

When shipping **blocks or unstained slides** the wax will melt in warm weather. Use cold packs and ship next day. Never wrap blocks in bubble wrap or gauze as the material can become embedded in the warm wax and can permanently damage the tumor tissue in the block.

For Biospecimens Shipped to:

BB-Columbus

Frozen biospecimens can be shipped to the bank on Monday through Wednesday for Tuesday through Thursday delivery.

Ambient whole blood biospecimens can be shipped to the bank on Monday through Friday for Tuesday through Saturday delivery.

Blocks and unstained slides should never be shipped for Saturday delivery.

Do not ship any biospecimens the day before a holiday. Watch the Weekly Mailing for holiday closure notices and instructions.

BB- Pittsburgh and -Baylor

Refer to the protocol-specific Pathology Instructions for details on the timing of shipping **frozen** biospecimens.

Blood biospecimens typically cannot be received on Saturday. Please refer to the Pathology Instructions for details on the timing and location of blood shipments.

Do not ship biospecimens the day before a holiday. Watch the Weekly Mailing for holiday closure notices and instructions.

> NRG BB-San Francisco

Batch shipping is encouraged.

Frozen biospecimens can be shipped to the bank on Monday through Wednesday for Tuesday through Thursday delivery. Do not ship on Thursday or Friday as the building is not open for deliveries on Saturdays. A one-day delay due to weather (or for no reason at all) can cause samples to be delivered thawed on Monday.

Do not ship biospecimens two days prior to UCSF and National holidays and, if possible, do not ship at all during holiday weeks. Watch the Weekly Mailing for holiday closure notices and instructions.

Please Remember to Always . . .

Check a specific protocol for details

e.g., specimen types, collection times, shipping instructions, etc.

Obtain consent from the patient; register the patient

This should be done *before* biospecimens are shipped.

Label biospecimens and accompanying documentation

e.g., protocol number, Bank ID, etc., as specified in the protocol

Complete required documentation

Submit to the appropriate location (BB, SDMC) as specified in protocol.

Include completed documentation with biospecimen shipments

e.g., transmittal forms, pathology reports, as specified in protocol

Additional Contact Information

> GY Protocols: BB-Columbus

For questions about biospecimen collection, processing, kits, or shipments:

NRG Bank Team <u>BPCBank@nationwidechildrens.org</u>

614-722-2865

For technical problems with completing banking forms, consent, Rave, etc.:

Support@NRGOncology.org

716-845-5702

➤ BR and GI-Colorectal Protocols: BB- Pittsburgh and -Baylor

For questions about biospecimen preparation, shipping, or kit procurement:

NRG Bank Team NRGbiobankPGH@NRGOncology.org

412-697-6611

For questions about biospecimen collection, timing, and associated clinical aspects:

Clinical Coordinating Division ccdPGH@NRGOncology.org

800-477-7227

For questions about **blood collection or blood kit procurement**:

BB-Baylor <u>tumor-bank@breastcenter.tmc.edu</u>

713-798-1647

For technical problems with completing banking forms, consent, Rave, etc.:

Support@NRGOncology.org

716-845-5702

> BN, GI (Non-Colorectal), GU, HN, and LU Protocols: BB-San Francisco

For questions about submission requirements, central reviews, integral and integrated biomarker studies, inventory, problems with pathology or other submissions, or new protocols:

Sandy DeVries, MA NRGBB.Manager@UCSF.edu

NRG BB-SF Bank Manager 415-476-5268

For general questions about biospecimen preparation, shipping, and kit procurement:

NRG BB-San Francisco NRGBB@UCSF.edu

415-476-7864

For questions about **patient enrollment, collection timing, clinical issues, or consent**, please contact the following disease site data managers at SDMC-Philadelphia West:

Brain

Liz Wise <u>wisem@nrgoncology.org</u> Sherrell Carter <u>carters@nrgoncology.org</u>

GI (Non-Colorectal)

Wendy Bergantz, RN BergantzW@NRGoncology.org

<u>GU</u>

Margaret Kennishkennishm@nrgoncology.orgLaura Hallhall@nrgoncology.org

Head and Neck

Holly LaPerriere <u>laperriereh@nrgoncology.org</u>
Jessi Leichtnam <u>leichtnamj@nrgoncology.org</u>

Lung

Tammy Bausinger bausingert@nrgoncology.org

NCORP Trials

Tiffany Simpson-Small SmallT@nrgoncology.org
Neelima Dobbala dobbalan@nrgoncology.org

➤ For questions about translational research projects and access to biospecimens from the NRG Biospecimen Banks:

Biospecimen Access <u>biospecimenaccess@nrgoncology.org</u>

Additional information can be found on the NRG Biospecimen Access (https://www.nrgoncology.org/Scientific-Program/Biospecimen-Access) and NCTN Navigator (https://navigator.ctsu.org/navigator/login) websites.

