#### **GENERAL**

### What is the BRPC/CHTN?

The Duke BioRepository & Precision Pathology Center (BRPC) is an official shared resource of the School of Medicine, offering broad-consent biobanking as well as protocol-specific tissue procurement and research support services on behalf of the Department of Pathology & DUHS Clinical Laboratories. The BRPC also serves as the Southern Division of the National Cancer Institute's Cooperative Human Tissue Network (CHTN), and through this mechanism can meet the needs of internal and external investigators.

### I would like to investigate feasibility of obtaining a specific type of sample from the BRPC/CHTN. What should I do first?

Please send an inquiry to the BRPC shared email <a href="mailto:brpc@duke.edu">brpc@duke.edu</a> asking about the feasibility of your request. BRPC staff will answer your question or, if necessary, forward your question to a BRPC Pathologist who can answer.

## I would like to obtain frozen tissue/blood products/paraffin tissue from the general bank of samples. How do I proceed? What is the approval process? How much does it cost?

The preferred approach for new investigators is to request samples as a CHTN investigator. Please read more about CHTN here: <a href="https://www.chtn.org/">https://www.chtn.org/</a> This has several advantages. First, it is less expensive, as costs are somewhat offset by the CHTN grant funding mechanism. Second, your request can be met by a network of United States biobanks that can ship tissue directly to you in addition to BRPC. For specific requests, this may enable you to accrue samples more quickly.

Work with the CHTN Coordinator within BRPC to create your paperwork/<u>application</u> to register as a CHTN investigator (we will assist you with this). You will need to provide your fund code and your approved IRB protocol. Please provide as much information in the tissue processing section as possible. We will obtain necessary approvals and generate a budget for you. Once everyone agrees, processing and release of samples can begin.

For existing/older Duke investigators with open IRB protocols, please submit the BRPC's <u>Request for Samples form</u> to <u>brpc@duke.edu</u> and we will get back to you with a budget and any required next steps.

# I want to perform a research study utilizing BRPC and/or CHTN. Do I need to add all the BRPC staff as personnel on my IRB protocol?

No. BRPC activities (which often include access to Pathology-related PHI because of the nature of our work) are covered under our own IRB protocol Pro00035974. The language specifically states that the BRPC Shared Resource infrastructure will be "viewed as an extension of the specific study team's capabilities" and therefore each person in the BRPC does not need to be on every IRB protocol that we support.

#### **SAMPLES**

### What types of tissues/samples does the BRPC/CHTN collect and distribute?

We are flexible as to tissue types collected, as we meet the standard of 'fit for purpose' rather than any arbitrary sample type.

For example, we collect and distribute tissue "fresh" tissue (hydrated, maintained at 4C, for PDX creation, cell culture creation, immune profiling via flow cytometry).

We can also collect and distribute tissue frozen in OCT and held at -80C (in order to create a 'top slide' for histologic quality assurance).

We can also collect and distribute tissue as formalin-fixed, paraffin-embedded (FFPE) blocks or their derivatives.

If you are interested in a sample type not listed here, we can work with you to develop a protocol.

#### What is FFPE?

Formalin-fixed, paraffin-embedded (FFPE) blocks are the standard used to make clinical diagnoses. Tissue from biopsy or resection specimens is processed, fixed in formalin, then embedded in paraffin wax blocks. These blocks are thinly sectioned to make slides for diagnosis, and the tissue stored in these FFPE blocks can also be used for ancillary studies.

### I need snap-frozen tissue for my research. Do you have snap-frozen tissue?

BRPC has frozen samples of tumors, diseased organs, and normal organs. Most of our frozen samples have been embedded into water-soluble OCT medium prior to freezing.

For research using downstream nucleic acid analysis, we do not use snap frozen tissue without embedding material into OCT because we cannot evaluate it histologically. This is a CAP requirement – i.e., that all of our samples be qualified with % tumor nuclei and % necrosis.

However, research using downstream proteomics can be problematic using OCT-embedded samples. For this reason we have created an SOP by which we can snap freeze tissue without OCT/embedding medium if we take a 'mirror face' for FFPE block. This 'mirror face' allows us to quantitate % tumor nuclei and % necrosis.

Please contact us about specific tissue types required for your study.

### Can you screen for very specific cancer patients and provide fresh tissue?

Yes, we can provide this service prospectively for investigators.

### I need DNA from a cohort of patients with [XYZ] and controls. [XYZ] is really rare. What are the options?

For rare diseases, again, the preferred approach is to request samples as a CHTN investigator. The application is here: <a href="https://www.chtn.org/d/chtn-application.pdf">https://www.chtn.org/d/chtn-application.pdf</a>. This allows your request to be networked across the CHTN and gives you the greatest chance of success in addition to a slight financial advantage.

BRPC can also provide advice or assist with queries of the Duke Pathology Clinical Archival Specimen Warehouse, or the NCI's Specimen Resource Locator.

I need tissue samples that I'm unlikely to receive from surgery. Can BRPC/CHTN access organ tissues from autopsy patients for tissue types such as parathyroid, adrenal gland, testicle, coronary artery, etc.?

Yes. Please contact us about specific tissue types required. Again, new investigators should register with the CHTN to obtain these types of samples. More information is here: https://www.chtn.org/

### Can BRPC staff extract RNA from the samples I am requesting? What type of samples can you extract RNA from?

Yes. BRPC can extract RNA from fresh tissue, flash frozen tissue, tissue frozen in OCT, FFPE tissue, and whole blood buffy coat.

### Can you collect materials for study of the microbiome?

Yes, if they are tissue-based. BRPC does not collect or process stool or saliva specimens. For microbiome collections, the protocol will depend on types of tissue samples you want to collect and if there is any added value from histologic QC. For example, if you are taking tissue samples of 'normal' colon it might be appropriate just to snap freeze these without histologic confirmation. However, if we are taking tissue samples of tumor, we may considering freezing a "mirror face" in OCT for histologic evaluation, if, for example, you want to know whether the organisms came from a region of viable tumor or necrosis.

## I just need some fresh normal (\_\_organ\_\_) tissue for pilot testing. What's the easiest way for me to proceed?

The simplest approach for a one-time request is via anonymous tissue release. This means that the tissue is deidentified and all links to additional patient information are broken. BRPC can anonymize the tissue from up to 10 patients and release as fee-for-service under our own IRB protocol, with no need for additional IRB approval.

## I would like to start regularly receiving fresh (\_\_organ\_\_) tissue for my research. How should I proceed?

Again, the preferred approach for new investigators is to request samples as a CHTN investigator. Please read more about CHTN here: <a href="https://www.chtn.org/">https://www.chtn.org/</a> This has several advantages. First, it is less expensive, as costs are somewhat offset by the CHTN grant funding mechanism. Second, your request can be met by a network of United States biobanks that can ship tissue directly to you in addition to BRPC. For specific requests, this may enable you to accrue samples more quickly.

Work with the CHTN Coordinator within BRPC to create your paperwork/<u>application</u> to register as a CHTN investigator (we will assist you with this). You will need to provide your fund code and your approved IRB protocol. Please provide as much information in the tissue processing section as possible. We will obtain necessary approvals and generate a budget for you. Once everyone agrees, processing and release of samples can begin.

## Why do I need an IRB protocol just to receive anonymized or de-identified/coded samples? I'm a academic basic science researcher, how do I begin?

Within the Duke system, you'll need to be up-to-date on your CITI training. Google Duke IRB CITI training to find out more about this requirement. Then, submit a new protocol request to the Duke IRB using their website <a href="here">here</a> indicating that you wish to receive either (1) anonymized leftover clinical samples and/or (2) leftover clinical samples labelled with BRPC ID only where the patient has signed BRPC broad consent for tissue donation. These protocols should be "exempt" from further IRB oversight and should turn around rather quickly. For assistance, please consult your departmental research coordinator. Submit your approved IRB protocol to BRPC along with your request.

#### **CLINICAL TRIAL SUPPORT**

## I would like BRPC to provide tissue processing support services for my upcoming clinical trial. What is the procedure for this?

BRPC provides support for clinical trials taking place within Duke. Please submit your approved IRB protocol, lab manual (as soon as available from sponsor), and the following protocol request form, and send to <a href="mailto:brpc@duke.edu">brpc@duke.edu</a>. Please provide as much information in the tissue processing section as possible. For most studies, an IRB protocol should also be submitted. BRPC will review the documents, and send back a scope of work and budget. Once everyone is in agreeance, BRPC will create internal Standard Operating Procedures, and your study will be considered approved. There are one time fees associated with protocol start up, which are covered in "Are there one-time project start-up fees? What do these cover? Additional details on pricing and budget are given below."

## The clinical trial I want to open requests original diagnostic slides/entire archival paraffin blocks. Why won't Duke Pathology and Clinical Laboratories release these? What other options do I have?

The United States Federal Government enforces CLIA law requiring pathology labs to maintain original diagnostic material. Duke strictly follows CLIA regulations as enforced through our CAP inspection process. That said, Duke offers a flexible array of options for the above.

For original diagnostic slides, alternative options are:

- -Whole Slide Images (WSI)
- -recut sections from archival paraffin blocks

For archival paraffin blocks, we are extremely flexible with options short of sending an entire diagnostic block:

- core tumor from the archival block and re-embed it into a new paraffin block for release
- prepare scrolls of tissue from archival paraffin blocks
- prepare multiple unstained sections from archival blocks

-special exemption from the Directors of Surgical Pathology and Duke Clinical Laboratories – this exemption is required in less than 3% of clinical trials.

#### CONSENTING PATIENTS TO BIOBANKING

I would like my research staff trained to consent patients to BRPC protocol so that their leftover clinical samples can more easily be biobanked. What should I do?

The BRPC conducts training sessions for a fee on consenting to the BRPC protocol. Please contact the BRPC shared inbox: <a href="mailto:brpc@duke.edu">brpc@duke.edu</a> to submit a consent training request for your staff members.

I would like to recommend that the Duke BRPC consent a patient for biobanking or an existing tissue distribution project. I have already spoken with the patient. What should I do?

Please contact the BRPC shared inbox at <a href="mailto:brpc@duke.edu">brpc@duke.edu</a> with the following information: patient name, patient MRN, date of clinic visit if known, date of surgery if known, type of consent request (excess tissue for resections or additional tissue for biopsy procedures), and confirmation whether the patient has been introduced to biobanking research or not.

### Why doesn't BRPC consent everyone for biobanking?

The Duke BioRepository & Precision Pathology Center (BRPC) is an official shared resource of the School of Medicine and the Duke Cancer Institute (DCI). As such, our primary responsibility is to support research groups and efforts of the SoM and DCI. The consent process is time-consuming and requires dedicated and trained personnel. The BRPC works closely with disease groups, and in addition to BRPC staff, different disease working group staff members are trained to serve as consenters to the BRPC protocol. While we all work together to ensure that many patients (over 6,000 to date) can be consented, the logistics and time involved preclude us from consenting every patient who is seen at Duke.

#### **CORE FACILITIES + SERVICES**

- BioRepository & Precision Pathology Center ▼
- Precision Cancer Medicine Initiative (PCMI)
- Research Animal Pathology Service
- Research Electron Microscopy Service ▼
- Research Immunohistology Lab
- PhotoPath