

BioRepository & Precision Pathology Center (BRPC) Protocol Support Review Form

Instructions:

Please fill out this form completely. Incomplete forms will be returned until all information is provided. Submit the following to the BRPC shared inbox (brpc@duke.edu):

- **Protocol Support Review Form (this form)**
- **Full IRB protocol**
- **Lab Manual**
 - If Lab Manual is amended, please inform BRPC with the updated version, ASAP so the SOP can be updated and implemented for any and all tissue collections.

Protocols are not considered approved for BRPC collaboration until an approval notice has been sent by BRPC.

NOTE: If your protocol requires archival tissue collection ONLY, this form is not needed. Please navigate to the BRPC website and fill out the appropriate clinical trial request form when you are ready to submit a request.

Duke IRB Protocol #:

Protocol Title (full):

Protocol Nickname / Short Name:

Duke PI:

CRU/Working Group:

Study Contact information

| Team Member Name | Email | Phone Number | Team Member Title |
|------------------|-------|--------------|-------------------|
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| | | | |
| | | | |

Funding Source Instructions:

A study fund code or a departmental HUB code must be submitted at the time of protocol support request. If a HUB code is provided in lieu of a study fund code, the code will not be kept on file and will only be used to charge for the protocol review fee. The study fund code will be required prior to opening enrollment in order to use BRPC services.

Funding Source (select one):

- Investigator Initiated
- Industry Initiated

Study Fund Code or HUB Code:

If protocol is canceled or not approved by the IRB within 3 months of submission of the Protocol Support Review Form, the study fund code or HUB code will be charged the "New Access-only Protocol Rev, Budget, SOW/SOP, Build Study in LV" fee

If the protocol is canceled or withdrawn after study team approval, the study fund code or hub code will be charged the "New Clinical Trial Protocol & Lab Manual Rev, Budget, SOW/SOP, Build Study in LV" fee

Consent

Will subjects be dually consented to BRPC and this proposed protocol by your study team?

- Yes
- No

If dual consent is needed, would your team like to be consent trained?

- Yes
- No

Please fill out table with team information below:

| Team Member Name | Email | Title |
|------------------|-------|-------|
| | | |
| | | |
| | | |

Collection

BRPC Requested Service Instructions: Please indicate all services you will be requiring from BRPC for this proposed protocol. If there are services that are not listed, please indicate them in the section marked "other". If there is something we need to know regarding the protocol that is not indicated in the protocol or lab manual, please indicate so in the summary portion below.

Please provide page numbers for all collection information in lab manual

Archival Tissue ____
Blood Processing ____
Fresh Tissue Biopsy ____
Surgical Tissue Collection ____

Anticipated number of subjects:

Anticipated protocol duration:

Archival Tissue

* From the clinical labs or standard of care diagnostic samples from previous cases*

Link: [Clinical Trials Form](#)

Receive Tissue from Outside Facility for cutting

Tissue Type:

Whole Slide Imaging (WSI)

Scanning entire standard of care/ diagnostic case

Cores

Size of punch:

How many?

FFPE Block

Slides

Unstained

How many and thickness (microns)?

Special slides needed (Super frost, Charged, Uncharged, etc):

Stained

How many and thickness (microns)?

Special stains needed (H&E, PAS, Trichrome, C4d, etc):

Labeling:

Tumor Requirements:

Storage Requirements:

Additional Information:

Blood Processing

Pertaining to fresh blood collection processing information

Will study team be drawing blood?

Yes

No, BRPC will facilitate blood collection

Will study team be handing off/dropping blood off for processing?

Yes

No

Will study team provide blood kit?

Yes

No

How many CCs/Aliquots:

Blood Separation:

Whole Blood

Serum

Plasma

Other:

Special Processing Instructions:

Blood Storage

Same day pick up (4°C storage)

-20°C

-80°C

Fresh Tissue Biopsy

Radiology/ Clinical procedures needing BRPC Assistance

BRPC needs at least 24 hour notice

Link: [Fresh Tissue Request Form](#)

Kit Provided

Surgical Tissue Collection

BRPC goes to OR to collect surgical resections

BRPC needs at least 24-hour notice

Link: [Fresh Tissue Request Form](#)

Kit Provided

Tissue Processing

Pertaining to fresh tissue biopsy/ surgical tissue collection processing information

Tissue Type:

Size needles:

How many cores/ Tissue dimension requirement:

Media Needed (10% NBF(FFPE), Ethanol, Flash Frozen/LN2, OCT, Specific Media (RNA Later, Saline, PBS, etc)):

Labeling Requirements:

Pathologist Review of sample needed?

Yes

If yes, will a study specific review form be needed?

Study Team Provided Review Form

BRPC Pathologist Review Form

No

Additional Information:

Ex: Transfer sample from 10% NBF to Ethanol

Tissue Storage

Same day pick up (4°C storage)

4°C

-20°C

-80°C

Other:

Ship to Sponsor/Collaborator

Shipping Kit Provided (Requisition form, shipping label, etc)

BRPC to complete requisition form

Shipping Address:

Additional Information (Days to ship, shipping notification, etc):

Additional Information (turnaround time needed, misc)