1.0 PURPOSE

1.1 This standard operating procedure (SOP) and its associated work instructions describe the process to be followed by the BBRB-associated biospecimen source sites (BSS) for the collection of research tissues from surgical tissue donors, the preparation of experimental samples for variable formalin fixation or frozen preservation experimental protocols, and the preparation of frozen and formalin fixed control samples.

2.0 SCOPE

2.1 This procedure is applicable to all surgical tissue collection and preservation at all BSSs for Phase II of the BPV project.

2.2 This procedure is applicable to the collection of tissues from all consented subjects that are part of the BPV study. This procedure should be followed by all personnel performing the collection and processing of the tissues for the BPV project.

3.0 RESPONSIBILITY

3.1 It is the responsibility of the principal investigator (PI) at each BSS to ensure that this procedure is followed, the research tissue collection personnel have been trained in accordance with this SOP, associated work instructions, the Comprehensive Data Resource (CDR) database and/or appropriate case report forms (CRFs), and that the training is documented. Also, it is the responsibility of the PI to designate the staff for this project and assign their roles and responsibilities in regard to this project.

3.2 It is the responsibility of the project staff to ensure that all the required forms and documents in the CDR are completed (such as CRFs).

3.3 It is the responsibility of the research tissue collection personnel to ensure he/she has read, understood, and subsequently follows the SOP while collecting and preparing tissue biospecimens.

3.4 Any deviation or change from this SOP that is anticipated prior to a collection should be approved by the BSS technical project manager (TPM) [in conjunction with the pathology resource center (PRC) and project manager (PM)]and well documented by the site.

3.5 Any deviation or change that is unexpected or identified during or after a collection should be well documented by the site using either a Deviation Report or Nonconformance Report. Such reports should be submitted in a timely fashion to the BSS TPM along with a description of any proposed or implemented corrective action.

4.0 DEFINITIONS/ACRONYMS

4.1 Definitions

4.1.1 Case ID: identifies study subjects (BPV-XXXXX)

4.1.2 Experimental Key ID (Key ID): identifies the randomized configuration of experimental protocols by which research tissue will be processed. This ID is printed on the randomization key document provided by the CBR.

4.1.3 Experimental Samples: refers to the samples prepared from research tissue that are to be processed as "priority" according to unique formalin fixation or frozen preservation conditions (modules/experimental protocols).

4.1.4 Quality Control (QC) Sample: refers to the sample collected and prepared as a formalin-fixed paraffin-embedded (FFPE) block and hematoxylin and eosin (H&E)–stained slide that is used to confirm the histology of the collected experimental samples.

4.1.5 Research Tissue: refers to surplus surgical tissues released by the pathology department for research tissue collection after samples for patient diagnosis have been collected.

4.1.6 Specimen ID: a machine or human-readable combination of alpha-numeric characters that identifies the sample or case; used on all biospecimen containers (i.e., cryosettes, tissue cassettes, cryovials) and H&E-stained slides.

4.1.7 Experimental Protocol: refers to preservation or storage conditions by which each experimental sample will be processed (delay to fixation, time in fixative, method of frozen preservation, temperature of storage).

4.1.8 Resection/excision: the act of cutting out; the surgical removal of part or all of a structure or organ.

4.2 Acronyms

4.2.1 **BPV** Biospecimen Pre-Analytical Variables

4.2.2 **BSS** Biospecimen Source Site

4.2.3 **CBR** Comprehensive Biospecimen Resource

4.2.4 **CDR** BBRB Comprehensive Data Resource

4.2.5 **CRF** Case Report Form

4.2.6 **FFPE** Formalin-Fixed Paraffin-Embedded

4.2.7 **H&E** Hematoxylin and Eosin

4.2.8 **MSDS** Material Safety Data Sheet

4.2.9 **PI** Principal Investigator

4.2.10 **PM** Project Manager

4.2.11 **PPE** Personal Protective Equipment

4.2.12 **PRC** Pathology Resource Center

4.2.13 **QC** Quality Control

4.2.14 **SOP** Standard Operating Procedure

4.2.15 **TPM** Technical Project Manager

5.0 ENVIRONMENTAL HEALTH AND SAFETY

5.1 Comply with institutional policies regarding bloodborne pathogens and the use of personal protective equipment (PPE) at all times.

5.2 Dispose of all contaminated supplies in the appropriate biohazard and sharps containers.

5.3 Handle all chemicals appropriately according to their Material Safety Data Sheet (MSDS) and institutional policies.

6.0 MATERIALS/EQUIPMENT

6.1 Required materials

6.1.1 The Comprehensive Biospecimen Resource (CBR) will provide collection kits and kit materials. Refer to **OP-0014_BPV Kit Receipt Supplies and Shipping Procedure** and its associated work instructions for specific guidance.

6.1.2 The BSS will be responsible for any additional materials/equipment to be utilized during a case collection that are not provided by the CBR or Leidos Biomedical Research, Inc.

Materials the BSS Must Supply			
Item Number	**Description**	**Quantity per Subject**	**Vendor**
1	100 mL disposable plastic sterile specimen jars	As needed	May vary
2	Disposable scalpels (need not be sterile)	Minimum 2 (may vary)	May vary
3	10% neutral buffered formalin	800 mL (16 x 50 mL)	Fisher Diagnostics
4	Liquid nitrogen (for bench-top flask)	Approx. 300 mL	May vary
5	Biopsy sponges	As needed	May vary
6	Clean forceps	As needed	May vary
7	Disposable cutting board	As needed	May vary
8	Dry ice	As needed	May vary

6.2 **Equipment**

Item Number	Description
1	Liquid nitrogen vapor phase freezer
2	Liquid nitrogen Dewar
3	Leica tissue processor
4	Computer workstation
5	Imaging system/camera
6	Grossing station
7	Stainless steel beaker

7.0 PROCEDURE

7.1 Data entry into the required CRFs in BBRB's CDR database

7.1.1 Time frame for completing forms in the CDR:

7.1.1.1 The **PR-0006-F4 through F7_BPV (Primary Organ) Surgery-Anesthesia Form**. The applicable form is to be completed within 7 days post surgery.

7.1.1.2 **PR-0006-F2_BPV Tissue Gross Evaluation Form**. This form is to be completed within 3 days post collection.

7.1.1.3 **PR-0006-F8_BPV Tissue Receipt-Dissection Form**. This form is to be completed within 3 days post collection.

7.1.1.4 **PR-0006-F9_BPV Tissue Processing Worksheet**. This form is to be completed within 72 hours of tissue processing completion.

Note: Data for the above forms are to be captured at the time of sample handling/processing. The transfer of data to the CDR is to be completed according to the above time frames.

7.2 Prerequisites for research tissue collection

7.2.1 Research tissue samples should only be collected from patients having donated the minimum required pre-anesthesia blood samples, unless otherwise approved by TPM or designee (see **BPV Blood Collection and Processing, PR-0005**).

7.2.2 A surgical specimen identified as eligible for research sample collection may later be considered ineligible for any number of reasons, including too little specimen after clinical/diagnostic needs are met (no tissue for research), necrotic tissue, tissue of inadequate quality, etc. Reasons for failure to collect biospecimens should be recorded in the CDR database.

7.2.3 Pre-anesthesia blood samples collected from donors whose surgical specimens do not yield adequate quantities of surplus surgical tumor will still be provided to BBRB.

7.3 General research tissue collection guidelines

7.3.1 This study will include the collection of tissue from consented donors with renal cell carcinoma; lung adenocarcinoma or squamous cell carcinoma; colorectal adenocarcinoma; and carcinoma of the ovary, fallopian tube, or peritoneum (all types).

Note: When multiple tumor nodules are present, the BSS should first collect tissues from whichever tumor is largest. If feasible, all collections should be taken from a single tumor nodule. In the event that available tumor tissue from a single nodule is inadequate to allow for complete collection of all priorities, the BSS may collect from more than one region/nodule. Do not mix tissue specimens from multiple noncontiguous regions, however, to complete a single prioritized collection (i.e., DO NOT get half of Priority I from one nodule and the other half of Priority I from another distinct nodule). Tissue collection must always be done by trained individuals who are approved by the site project management team.

7.3.2 Appropriate universal precautions (safety precautions) must be taken to avoid infectious disease risks from blood- and tissue-borne pathogens.

7.3.3 To minimize risk and contamination of research biospecimens, the following key practices should be observed:

7.3.3.1 Always use clean disposable scalpels and forceps when cutting different types of tissue from the same patient or specimens from different patients. Do not use the same blade and forceps for handling tumor and normal tissue aliquots.

7.3.3.2 Never use previously soiled or bloody cutting surfaces.

7.3.3.3 Avoid contact of specimens with absorbent materials that may contaminate dissected research tissues or that, by capillary action, may draw fluid from the tissue sample.

7.3.4 Always ensure that biospecimen containers are appropriately labeled and organized, and segregate tissues from different anatomic sites as well as tumor and normal tissues to the extent possible.

7.3.5 Do not leave surgical specimens or resected tissues for research collection unattended. Handle all samples as quickly and safely as possible.

7.4 **Communicating cases planned for research tissue collection**

7.4.1 All consented surgical cases planned for BPV research tissue collection should be communicated to the appropriate surgical staff, pathology department staff (including gross pathology area), and research staff prior to, and again on the day of, collection.

7.5 **Collection of data in the surgical suite**

7.5.1 Designated operating room staff and/or research tissue staff should record all pertinent study details from the surgical procedure. This information should be recorded directly in the CDR database or on an applicable CRF (**PR-0006-F4 through F7_BPV [Primary Organ] Surgery-Anesthesia Form**) which contains a Case ID label. Documentation of specimen collection should be performed within the operating room setting and prior to transport of the resected surgical specimen.

7.6 **Transport of samples from surgery to gross pathology suite**

7.6.1 Research tissue collection staff should recover resected specimens directly from the operating room in order to expedite gross examination and research tissue sample collection.

7.6.2 In the event research tissue collection staff cannot recover resected specimens directly from the operating room, designated operating room staff should promptly notify research tissue collection staff of resected specimen availability.

7.6.3 After organ resection and upon release by the surgeon, designated operating room staff or research tissue collection staff should immediately transport the resected surgical specimen to the gross pathology suite.

7.6.4 Resected surgical specimens should optimally be transported from the operating room in a closed container (e.g., a sterile container or tray covered in plastic wrap) at ambient temperature. Do not use ice or wrap specimens in gauze.

7.7 **Receipt of surgical specimen in gross pathology suite**

7.7.1 Designated pathology staff or research tissue collection staff should acknowledge receipt of the resected surgical specimen from operating room staff in the gross pathology suite.

7.7.2 At the time of receipt, all pertinent details regarding specimen receipt in the gross pathology suite should be recorded in the CDR database or on applicable CRFs.

7.7.3 Resected surgical specimens must first undergo gross pathology evaluation and collection of appropriate samples for patient diagnosis. Complete the **PR-0006-F2_BPV Tissue Gross Evaluation Form** which contains a Case ID label. Once appropriate review and clinical sample collection has been completed, the residual surgical specimen may be released to research tissue collection staff.

7.7.4 After collection of research tissue from the resected surgical specimen, the remaining surgical specimen should be photographed by high resolution digital image on a clean disposable dissecting board. The captured digital image should include the BPV case ID to appropriately identify the specimen.

7.8 **Receipt of surgical specimen in tissue bank laboratory**

7.8.1 Record all pertinent details regarding the specimen in the CDR database or appropriate CRFs (**PR-0006-F9_BPV Tissue Processing Worksheet**).

7.9 **Overview of research tissue biospecimen requirements and experimental protocols**

7.9.1 Research tissue biospecimen requirements:

The minimum tissue requirement for a complete case is the collection of the Priority I experimental module with size as noted in the following table and as described in associated work instructions.

If there is tumor tissue available from the case beyond what is needed for one module (Priority I), additional tissue may be collected either for another experimental module or additional tumor tissue. “Priority” indicates the size of the tissue being collected, how it should be dissected, whether the tissue is normal or tumor tissue, and the method of processing that will be designated for it. The BSS will receive instructions as to which experimental module shall be invoked for processing the prioritized tissue collections, as the requested experimental modules will change over time and additional modules may be added. Details regarding the current experimental modules, including sample dissection, processing, and storage are to be found within the appropriate work instruction.

Note: A case should be stopped if it is apparent during gross assessment that the tissue provided is <50% tumor or >20% necrotic.

Priority I and II collections will be of tumor tissue divided to yield experimental blocks as described within work instructions.

Additional tissue blocks are being collected that are not considered experimental and are solely being collected to provide additional tissue to the research community as a

part of this study. These collections shall consist of up to six blocks, at least 200mg each (approximately 0.5 cm x 0.5cm x 1.0 cm, and not to exceed the size accommodated by the tissue cassette/cryosette), of normal adjacent tissue to be frozen or formalin-fixed and paraffin-embedded (three each), and up to six additional blocks, at least 200 mg each (approximately 0.5 cm x 0.5 cm x 1.0 cm, and not to exceed the size accommodated by the tissue cassette/cryosette) of additional tumor tissue for comparable processing.

Note: For these extra tissue collections, please distribute the tissue blocks to collect roughly equal aliquots to be frozen and formalin-fixed from the available tissue.

These extra tissue blocks (normal adjacent and additional tumor tissue) should be collected and processed within 90 minutes of excision.

7.9.2 Summary of minimum samples collected from each case:

The following table summarizes the types of tumor and normal adjacent tissue (when available) biospecimens that should be collected from each surgical case, including optimal sample sizes and tissue containers to be used.

Tissue collection minimum requirements
(L = length, W = width, D = depth)

Summary of required and optional surgical tissue samples for Phase II

TISSUE COLLECTION					
Collection Priority	**Biospecimen Type**	**Sample Name**	**Prepared As (Container)**	**Expected Sample Size (LXWXD)**	
Delay to Fixation and Time in Fixative (Modules I and II)					
Priority 1 or 2	Tumor Tissue	"Experimental" Samples 1-4	4 FFPE "Experimental" Samples (Tissue Cassettes)	Each Sample (4): Kidney: 0.33 cm x 0.5 cm x 1.0 cm Colon/Ovary/Lung: 0.33 cm x 0.5 cm x 0.5 cm	
	Tumor Tissue	"FFPE QC"	1 FFPE Sample for QC (Tissue Cassette)	Kidney: 0.33 cm x 0.5 cm x 1.0 cm Colon/Ovary/Lung: 0.33 cm x 0.5 cm x 0.5 cm	
	Tumor Tissue	"Frozen control"	1 Frozen Sample (Cryosette)	Kidney: 0.33 cm x 0.5 cm x 1.0 cm Colon/Ovary/Lung: 0.33 cm x 0.5 cm x 0.5 cm	

Method of Freezing and Frozen Storage (Modules III and IV)					
Priority 1 or 2	Tumor Tissue	"Experimental" Samples	6 "Experimental" Samples (Cryosettes)	Each Sample (6): 0.33 cm x 0.3 cm 1.0 cm	
	Tumor Tissue	"FFPE QC"	1 FFPE Sample for QC (Tissue Cassette)	0.2 cm x 1.0 cm x 1.0 cm	
	Tumor Tissue	"Frozen control"	1 Frozen Sample (Cryosette)	0.2 cm x 1.0 cm x 1.0 cm	
Method of Freezing and Frozen Storage (Module V)					
Priority 1 or 2	Tumor Tissue	"Experimental" Samples	4 "Experimental" Samples (Cryosettes)	Each Sample (4): 0.33 cm x 0.5 cm x 1.0 cm	
	Tumor Tissue	"FFPE QC"	1 FFPE Sample for QC (Tissue Cassette)	0.33 cm x 0.5 cm x 1.0 cm	
	Tumor Tissue	"Frozen control"	1 Frozen Sample (Cryosette)	0.33 cm x 0.5 cm x 1.0 cm	
Normal Adjacent Tissue and Additional Tumor Tissue					**Sample Size**
	Normal Adjacent Tissue (if resected specimen permits)	Normal Samples	Up to 3 FFPE Samples (Tissue Cassettes)	0.5 cm x 0.5 cm x 1.0 cm	200 mg, Any Dimension
	Normal Adjacent Tissue (if resected specimen permits)	Normal Samples	Up to 3 Frozen Samples (Cryosettes)	0.5 cm x 0.5 cm x 1.0 cm	200 mg, Any Dimension
	Additional Tumor Tissue	Tumor Samples	Up to 3 Frozen Samples (Cryosette)	0.5 cm x 0.5 cm x 1.0 cm	200 mg Any Dimension
	Additional Tumor Tissue	Tumor Samples	Up to 3 FFPE Samples (Tissue Cassettes)	0.5 cm x 0.5 cm x 1.0 cm	200 mg Any Dimension

7.9.3 Summary of biospecimen preparation grid:

Each BSS will utilize a laminated grid (provided) to assist with the organization and preparation of tissue aliquots. Each of the experimental samples will be placed in a tissue cassette/cryosette containing a biopsy sponge (as applicable) and temporarily placed in one square of a laminated biospecimen preparation grid (examples provided within applicable work instructions).

7.9.4 Summary of sample randomization key (experimental key):

The experimental key guides the random assignment of experimental samples from the biospecimen preparation grid to different downstream experimental protocols. A sample randomization key that correlates with the biospecimen preparation grid

should be used to assign each of the tumor sub-samples to one of the defined experimental conditions. Each letter in the key represents a specific experimental protocol and is used by the BSS staff to determine which experimental sample receives which experimental protocol. Each experimental sample should then be processed according to the specific processing parameters to which it was randomly assigned.

The BSS should scan the barcode of the key ID and the barcode of each pre-labeled tissue cassette used into the CDR database to capture the assignment of each tissue aliquot to an experimental protocol letter. In addition, a PDF of the randomization key(s) used for the case is to be uploaded into the CDR by the BSS.

An example of a sample randomization key and the experimental designs for delay to fixation and time in fixative are shown below.

BBRB BPV Project Phase II Randomization Key **Randomization Key: KE023459-BPV**	
Experimental Protocol	**Grid Location**
Module I	
A	**3**
B	**1**
C	**2**
D	**4**
If Module II Collected:	
E	**2**
F	**1**
G	**4**
H	**3**

7.10 **Preparation of workspace and supplies for research tissue collection**

7.10.1 Advanced preparation of study supplies and safe, fast, and efficient handling of samples is essential to keep with the Experimental Protocols and timing.

7.10.2 Research tissue collection staff should ensure the availability and readiness of biospecimen collection supplies prior to tissue collection. This includes the appropriate number of items, a clean workspace of adequate size, and a computer workstation running the CDR database or paper forms.

7.10.3 At a minimum, the research tissue collection workspace should have the following materials available:

- Sample preparation grid
- Sample randomization key (“experimental key”)
- Labeled tissue cassettes for tissue sample fixation
- Labeled cryosettes for collection and freezing the frozen samples
- Clean disposable cutting boards
- Disposable scalpels (need not be sterile)
- Clean forceps
- 100 mL formalin jars
- Gauze pads
- Biopsy sponges
- Sterile deionized water
- Cryosette storage box
- Crushed dry ice/pellets of dry ice
- Dry ice pan (or Styrofoam container) with cover
- Bench top Dewar flask(s) with liquid nitrogen and suspended stainless steel beaker
- Computer workstation with internet access for the CDR database application (or appropriate system of CRF)

7.10.4 Prior to the start of tumor tissue dissection, ensure a sample randomization key ("experimental key") and labeled tissue cassettes (for FFPE samples) and cryosettes (frozen specimens) are ready.

7.10.5 Prior to the start of sample collection and dissection for each case, prepare and label the necessary number of 100 mL disposable plastic specimen jars based upon planned processing as per applicable work instructions. Ensure a jar designated for the additional tissue collections has been filled with 50 mL of formalin.

7.10.6 It is the responsibility of staff to manage these biospecimens such that each experimental sample is able to be processed in a manner consistent with the experimental design.

7.10.7 Use only the tissue cassettes and cryosettes provided for this study.

7.10.8 Prior to the start of research tissue sample dissection, arrange the pre-labeled tissue cassettes and other project-specific supplies within the workspace.

7.10.9 Use biopsy sponges, as appropriate, to maintain orientation of tissue in cassettes during processing.

7.11 **Procedure for preparation of experimental samples**

7.11.1 Use the **associated work instructions as specified by the TPM** to dissect and prepare experimental and control specimens.

7.11.2 If the Delay to Fixation and Time in Fixative modules are to be studied, follow the guidance within PR-0006-W1 for processing.

7.11.3 If the Method of Freezing and Frozen Storage modules are to be studied, follow the guidance within PR-0006-W3 (Module V) for processing.

7.12 **Procedure for collection of additional (non-experimental) samples**

7.12.1 General guidance on additional tissue samples

7.12.1.1 If collected, cut normal adjacent and additional tumor tissue into at least 200 mg blocks (any dimension) for additional FFPE and frozen collections. Aliquots should not exceed dimensions readily accomodated by specimen cassettes/cryosettes.

7.12.1.2 The normal tissue is to be collected from a grossly normal appearing region of tissue that is as remote as feasible from apparent tumor tissue.

7.12.1.3 Tissue samples to be frozen should be weighed prior to freezing.

7.12.1.4 For the additional (non-experimental) tissue collections, distribute the tissue in a way to collect roughly equal aliquots for frozen and FFPE from the available tissue.

7.12.1.4.1 If only a single 200 mg portion of tissue is available for normal adjacent tissue collection, this tissue is to be designated for FFPE and processed according to the handling of the QC block from Priority I.

7.12.1.4.2 If only a single 200 mg portion of tissue is available for additional tumor tissue collection, this tissue is to be designated for frozen preservation.

7.12.1.5 Record the sample weight, date and time of freezing, and all other relevant details associated with frozen tissue biospecimens in the CDR database or on the CRF form.

7.12.1.6 Additional tissue specimens should be collected and processed within 90 minutes of excision.

7.12.2 Frozen normal adjacent samples

7.12.2.1 Collect up to three normal adjacent tissue samples at 200 mg in weight and of any dimension (tissue cryosette must readily accomodate) available from the surgical specimen. Weigh the samples and record the weight in the CDR form (**PR-0006-F9_BPV Tissue Processing Worksheet**).

Note: in ovarian cases in which the ovary is entirely replaced by tumor and no grossly apparent normal tissue is available for submission, concurrently resected uninvolved tissue from another site (such as uterus or fallopian tube) may be submitted.

7.12.2.2 Place normal tissue samples for freezing in labeled, pre-chilled cryosettes, close lids, and freeze tissue by placing cryosette in liquid nitrogen vapor. Record the date and exact time of freezing into the CDR database or on an appropriate form if using paper forms. The freezing should be performed by placing the cryosette into a stainless steel beaker suspended inside a bench top Dewar flask pre-filled with liquid nitrogen. The beaker should not be filled with liquid nitrogen but should be suspended in the liquid nitrogen.

7.12.2.3 After freezing for at least three to five minutes, transfer the cryosette containing the frozen tissue to a properly labeled cryosette storage box and store in liquid nitrogen vapor.

7.12.3 Frozen additional tumor samples

7.12.3.1 Collect up to three additional tumor samples at 200 mg in weight and of any dimension (tissue cryosette must readily accomodate) from any remaining portion of tumor. Weigh the samples and record the weight in the comments field in the CDR form (**PR-0006-F9_BPV Tissue Processing Worksheet**).

7.12.3.2 Place tumor tissue samples for freezing in labeled, pre-chilled cryosettes and close the lid. Record the date and exact time of freezing into the CDR database by scanning the barcode of each cryosette into the appropriate row. Freeze the tissue by placing cryosette in liquid nitrogen vapor. The freezing should be performed by placing the cryosette into a stainless steel beaker suspended inside a bench top Dewar flask pre-filled with liquid nitrogen. The beaker should not be filled with liquid nitrogen but should be suspended in the liquid nitrogen.

7.12.3.3 After freezing for at least two to five minutes, transfer the cryosette (with frozen tissue) to a properly labeled cryosette storage box and store in liquid nitrogen vapor.

7.12.4 FFPE Normal adjacent tissue samples

7.12.4.1 Collect up to three samples of normal adjacent tissue for fixation at 200 mg minimum weight of any dimension (tissue cassette must readily accomodate).

7.12.4.2 These normal tissue samples for FFPE should be placed into a tissue cassette and scanned into the CDR database in the Tissue Processing Worksheet. They may then be placed immediately into a formalin jar designated for additional tissue specimens. These samples shall be processed with the QC FFPE samples from collected modules. It is important to note that these additional three fixed normal tissues are not included as part of the experimental samples.

7.12.4.3 Record the date and exact time of placement into fixative in the CDR database by scanning the barcode of each cassette into the appropriate row.

7.12.5 FFPE additional tumor samples

7.12.5.1 Collect up to three samples of additional tumor tissue for fixation at 200 mg minimum weight of any dimension (tissue cassette must readily accomodate).

7.12.5.2 These tumor tissue samples for FFPE should be placed into a tissue cassette and scanned into the CDR database in the Tissue Processing Worksheet. They may then be placed immediately into a formalin jar designated for additional tissue collection specimens. These samples shall be processed with the QC FFPE samples from collected modules. It is important to note that these additional three fixed tumor samples are not included as part of the experimental samples.

7.12.5.3 Record the date and exact time of placement into fixative in the CDR database by scanning the barcode of each cassette into the appropriate row.

7.13 **Completion of tissue collection**

7.13.1 After research tissue collection, the operator should clear the work area, spray it with disinfectant, and wipe it down.

7.13.2 Dispose of all used collection supplies in a manner compliant with appropriate biosafety and waste disposal requirements.

7.13.3 All specimens are to be shipped in accordance with **OP-0014_BPV Kit Receipt Supplies and Shipping Procedure**. All specimens that have undergone collection, processing, and pathology review are to be shipped to the CBR for storage, unless otherwise directed by the TPM and or PM.

8.0 REFERENCES

8.1 Factorial Design for Tissue Fixation Variables — Dr. Gail, BRN Scientific Steering Committee (2011)

9.0 ATTACHMENTS

9.1 BPV Tissue Gross Evaluation Form, PR-0006-F2
9.2 BPV Kidney Surgery-Anesthesia Form, PR-0006-F4
9.3 BPV Ovary Surgery-Anesthesia Form, PR-0006-F5
9.4 BPV Lung Surgery-Anesthesia Form, PR-0006-F6
9.5 BPV Colon Surgery-Anesthesia Form, PR-0006-F7
9.6 BPV Tissue Receipt-Dissection Form, PR-0006-F8
9.7 BPV Tissue Processing Worksheet, PR-0006-F9
9.8 BPV Program Work Instruction for Processing of Specimens for Delay to Fixation and Time in Fixative Modules (MI and MII), PR-0006-W1
9.9 BPV Program Work Instruction for Processing of Specimens for Module V, PR-0006-W3