1.0 PURPOSE

1.1 This procedure covers the requirements for study candidate screening, consenting, and enrollment for BPV studies.

1.2 The ethical conduct of research is based upon the voluntary consent of the candidate who was appropriately informed about a study's potential risks and benefits. It is the responsibility of the principal investigator (PI) to ensure that all federal, state, and local regulations are met through the language of the informed consent document, and that informed consent itself is properly obtained from the candidate or the candidate's legally authorized representative (LAR).

1.3 Documentation of the informed consent process is required to establish that the candidate is accurately and adequately informed and that no study-related procedures are initiated prior to obtaining informed consent.

2.0 SCOPE

2.1 This requirement document applies to the process of identifying, recruiting, consenting, and enrolling candidates in BPV studies. This requirement document includes steps for fulfilling the regulatory and ethical requirements for obtaining the candidate's informed consent. These required activities apply to all research candidates who are identified, recruited, consented, and enrolled in all BPV research studies.

3.0 RESPONSIBILITY

3.1 **Principal Investigator.** It is the responsibility of each PI at each biospecimen source site (BSS) to ensure that this procedure is followed and that all study candidates are appropriately recruited and consented. It is also the responsibility of the PI to develop and/or follow institutional standard operating procedures (SOPs), policies, and guidelines (that have been reviewed and approved by the study sponsor) that adhere to all federal, state, and local laws and regulations for the identification, recruitment, and consenting of candidates in the study.

3.2 **Consent Coordinator (also Consent Nurse or Research Analysts or similar role).** It is the responsibility of the consent coordinator to approach Candidates and to obtain and document informed consent from enrolled Candidates.

3.3 It is the responsibility of the project staff designated by the PI or BSS to ensure that all the required case report forms (CRFs) in the BBRB Comprehensive Data Resource (CDR) are completed and any time restrictions are adhered to.

3.4 Any deviation or change from this SOP, known prior to a collection, should be approved by the BSS technical project manager (TPM) 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. This deviation should be submitted to the BSS TPM along with a corrective action description for the documentation and comment.

4.0 DEFINITIONS AND ACRONYMS

4.1 Definitions

Case ID Identifies study participant for BBRB and BPV (BPV-XXXXX)

4.2 Acronyms

BBRB Biorepositories and Biospecimen Research Branch
BSS Biospecimen Source Site
CDR Comprehensive Data Resource
CRF Case Report Form
HHS Department of Health and Human Services
IRB Institutional Review Board
LAR Legally Authorized Representative
PI Principal Investigator
SOP Standard Operating Procedure
TPM Technical Project Manager

5.0 ENVIRONMENTAL HEALTH & SAFETY

None

6.0 MATERIALS/EQUIPMENT

None

7.0 PROCEDURE

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

7.1.1 Timeframe for completing the forms in the CDR: **ER-0007-F1_BPV Candidate Screening and ER-0007-F10_BPV Candidate Consent and Enrollment Form** are required to be completed within 12 hours of consent.

7.2 **Candidate Identification**

7.2.1 Candidates suitable for enrollment in particular studies are identified based on inclusion and exclusion criteria defined within the study protocols. Specifically:

7.2.1.1 Kidney Tissue Studies:

- Inclusion Criteria:
  - Scheduled for surgical treatment of kidney mass assumed to be primary renal cell carcinoma
  - Able to provide informed consent for pre-anesthesia blood (collected within 14 calendar days of surgery but prior to initiation of anesthesia), surgical tissue donation, and associated data
  - Meets age of majority for institution/state
  - Any sex (male or female)
- Exclusion Criteria:
  - Informed consent not provided
  - Tumor of experimental focus is a metastasis from another tissue or organ
  - Participant already received or is undergoing chemotherapy, radiation therapy, and/or immunotherapy for any previous or current cancer diagnosis
  - History of a transplanted kidney

7.2.1.2 Ovarian, Fallopian Tube, and Primary Peritoneal Carcinoma Tissue Studies:

- Inclusion Criteria:
  - Scheduled for surgical treatment for a mass of GYN origin assumed to be primary ovarian, primary fallopian tube, or primary peritoneal carcinoma (all subtypes, any stage and grade)

- Able to provide informed consent for pre-anesthesia blood (collected within 14 calendar days of surgery but prior to initiation of anesthesia), surgical tissue donation and associated data
- Meets age of majority for institution/state
- Sex: Female

- Exclusion Criteria:
  - Informed consent not provided
  - Tumor of experimental focus is a metastasis from another tissue or organ
  - Participant already received or is undergoing chemotherapy, radiation therapy and/or immunotherapy for any previous or current cancer diagnosis
  - Sex: Male

7.2.1.3 Lung Tissue Studies:

- Inclusion Criteria:
  - Scheduled for surgical treatment of lung mass assumed to be either primary lung adenocarcinoma or squamous cell carcinoma
  - Able to provide informed consent for pre-anesthesia blood (collected within 14 calendar days of surgery but prior to initiation of anesthesia), surgical tissue donation and associated data
  - Meets age of majority for institution/state
  - Any sex (male or female)
- Exclusion Criteria:
  - Informed consent not provided
  - Tumor of experimental focus is a metastasis from another tissue or organ
  - Participant already received or is undergoing chemotherapy, radiation therapy and/or immunotherapy for any previous or current cancer diagnosis

7.2.1.4 Colorectal Tissue Studies:

- Inclusion Criteria:
  - Diagnosed with colorectal adenocarcinoma and scheduled for surgical treatment
  - Scheduled for surgical treatment of colorectal mass assumed to be primary colorectal adenocarcinoma

- Able to provide informed consent for pre-anesthesia blood (collected within 14 calendar days of surgery but prior to initiation of anesthesia), surgical tissue donation and associated data
- Meets age of majority for institution/state
- Any sex (male or female)

- Exclusion Criteria:
  - Informed consent not provided
  - Tumor of experimental focus is a metastasis from another tissue or organ
  - Participant already received or is undergoing chemotherapy, radiation therapy and/or immunotherapy for any previous or current cancer diagnosis

7.2.2 Site consent coordinators and other site staff responsible for candidate selection and enrollment shall be trained and be knowledgeable of the inclusion/exclusion criteria outlined in the protocol as well as other protocol parameters outlined by the PI and site policies.

7.2.3 Candidates may be identified from the following sources among others:

- Clinic visit schedules
- Operating room schedules
- Participating physician and/or surgeon

7.3 Candidate Approach and Consent

7.3.1 General

7.3.1.1 Site staff will follow their local SOP for screening, approaching and consenting candidates for the study. This SOP should be on file at BBRB.

7.3.1.2 All staff approaching candidates to obtain informed consent will undergo appropriate institutional training. Documentation of current training for consenting must be provided to the BSS TPM.

7.3.1.3 All informed consent documentation, scripts, short forms, and other documents, including changes to these items, must be institutional review board (IRB)–reviewed and approved and must comply with Department of

Health and Human Services (HHS) regulatory requirements at 45 CFR Part 46 and all federal, state, and local laws, as applicable.

7.3.1.4 The informed consent process may take place anywhere from several weeks prior to biospecimen collection to immediately before pre-anesthesia blood donation and surgery.

7.3.1.5 Site staff must ensure that all materials used to consent and enroll candidates are currently IRB-approved and not expired.

7.3.1.6 The request for authorization for information from candidate's medical records and associated documents must adhere to the Health Insurance Portability and Accountability Act Privacy Rule and all federal, state, and local laws, as applicable.

7.3.2 The process for consenting English-speaking candidates must adhere to at least the following requirements:

7.3.2.1 The process for consenting must be administered in a location that provides privacy to the extent possible, and the consent coordinator must review the consent form with the potential candidate by discussing all elements as described in 45 CFR 46.116 and including the following:

- Overview and purpose of the study
- Procedures involved
- Potential risks and benefits
- Alternatives (not to participate)

7.3.2.2 Informed consent documentation must be read by the consent coordinator to each potential study candidate or to that candidate's LAR.

7.3.2.3 The consenting process must allow the candidate or LAR time to read the documents and ask questions. Input from family members and other care providers, if present and appropriate, must be encouraged.

7.3.2.4 On acceptance of participation in the study, the individual from whom consent is being obtained will sign and date the consent form.

7.3.2.5 The LAR may give consent on behalf of the candidate by signing and dating the consent form.

7.3.2.6 The individual obtaining informed consent from the candidate will also sign and date the consent form.

7.3.2.7 A signed copy of the informed consent will be provided to the candidate (or LAR) after it has been signed, or it can be mailed after the surgical procedure.

7.3.2.8 A hard copy or scanned electronic copy of the signed consent document will be securely filed in the appropriate study file or database at the BSS.

7.3.3 Consenting of Candidates Who Cannot Read and Speak Fluent English

7.3.3.1 The consenting of non-English speaking candidates will be done at the discretion of each BSS under the guidelines and approval of their local IRB. The procedure for consenting non-English speaking candidates or a LAR must be implemented in the candidate's (or LAR's) primary language using an institutionally approved interpreter and must comply with HHS regulatory requirements for the protection of human research candidates at 45 CFR 46.

7.3.3.2 In addition, the consenting of non-English speaking candidates must follow the same procedure as described above for English language consent.

7.4 Tracking Candidate Participation

7.4.1 A record of all candidates identified for recruitment will be maintained and entered into the **ER-0007-F1_BPV Candidate Screening Form** in the CDR database.

7.4.2 The site protocol number and name of person performing screening is recorded on the form.

7.4.3 If the patient meets all eligibility criteria, select Yes. If No, select No, and a pop-up window will automatically appear and a selection must be made. If Other is selected, please provide a reason in the space provided.

7.4.4 Record whether consent was obtained and the name of the person obtaining consent.

7.4.5 Note expected date of surgery for patients who have consented in the comments section on the screening form.

7.4.6 The comment section will also be used to record reasons for screen failures.

7.4.7 In the event that a candidate is eligible and approached, but declines participation, use **BPV Candidate Screening Form, ER-0007-F1** to record the reason the candidate declined participation in the comment section.

7.5 Tracking and Communicating with Enrolled Candidates

7.5.1 Record all relevant information regarding candidate consent in the CDR database and on the appropriate forms.

7.5.2 The individual obtaining consent will notify the research tissue recovery team of the enrolled candidate and anticipated surgery details (procedure, tumor type, surgery date, etc.).

7.5.3 Candidates are considered enrolled in the study once they have given informed consent and have signed and dated the consent form.

7.5.4 The signed and dated consent form must be kept on file in a secured and limited access location as part of the study record available for audit.

7.5.5 At the time of enrollment, the candidate will be assigned a BPV Case ID.

7.5.6 Each BSS should maintain a study enrollment log that appropriately identifies each study candidate by their name, their hospital medical record or pathology number, and their BPV Case ID. This link of the candidate identity to the BPV Case ID must be securely stored, and access must be limited to approved staff only.

7.5.7 All consented candidates should be reported to the PI and other appropriate research staff so that necessary specimen and data collections can be coordinated.

7.5.8 At no time should candidate names or any other directly identifiable information be disclosed to the study sponsor or entered into sponsor-provided databases. Study

candidates should be referenced exclusively by their BPV Case ID to maintain the privacy and confidentiality of the candidate.

7.5.9 For paper forms, a BPV Case ID label should be applied to every page of the candidate informed consent form. A BPV Case ID label should also be used on all other paper documentation associated with the case, including CRFs, to ensure appropriate linkage of paper and database records. A BPV Case ID label should be applied to every page of every paper document.

7.5.10 Candidates' names, social security numbers, addresses, telephone numbers, and other directly identifiable information are ***never*** to be recorded in any documentation that will be available to people outside of the BSS.

7.6 Withdrawal of Consent

7.6.1 Each enrolled candidate has the right to withdraw their consent for specimens and data collected on behalf of the study. During the consent process, candidates are to be made aware that they may withdraw consent at any time after enrollment and shall be given the name and contact information to do so at any time requested.

7.6.2 It is the responsibility of the PI at each BSS to appropriately initiate the process of withdrawing consent. A withdrawal of consent may be reported by the candidate's physician, by the candidate, or by the LAR to the source site.

7.6.3 The PI must ensure that withdrawn candidates are immediately recorded as such within study documentation and databases. Their associated biospecimens and derivatives (if available) and related data should be processed in accordance with local site policy or SOP.

7.6.4 In the event that specimens have been forwarded to the study sponsor prior to withdrawal of consent, the PI should report the withdrawal event to the study sponsor so that appropriate action may be taken. When reporting to the study sponsor, only the BPV Case ID may be used for identification of the specimens and data. Do not use any personally identifiable information.

7.6.5 Study withdrawals should be reported to the local IRB by the PI and include in the report: study name, the IRB number, study PI, reason for withdrawal, method of

revocation (written or oral), and confirmation of the disposition of unused samples (i.e., destruction or return if required).

7.6.6 Please note that for samples that have been processed or forwarded to research entities or end users for use in approved studies, samples will not be retrieved and existing data not deleted.

8.0 ATTACHMENTS

- BPV Candidate Consent and Enrollment Form, ER-0007-F1
- BPV Candidate Screening Form, ER-0007-F3