STANDARD OPERATING PROCEDURE	**SOP No. 001** **Obtaining Informed Consent**
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1. PURPOSE

To describe the procedure for obtaining informed consents from patients for the procurement and storage of:

- Tissue, fresh-frozen and paraffin embedded
- Blood and blood products
- Demographic, clinical, pathological and/or epidemiological data as electronic and/or hard-copy files

Obtaining voluntary consent of participants who have been informed about all the relevant aspects of the biorepository is important for the ethical conduct of the Prostate Cancer Biorepository Network.

Participants consent to donate their surplus tissue (after scheduled surgical treatment) and/or biological material, allow access to their clinical records for future research, and acknowledge that they accept associated risks (if any).

NOTE: Informed patient consent is not obtained at the JHU Network site for participants donating tissue as procured tissue is considered surplus to clinical needs and diagnosis (deemed surplus by a Pathologist or delegate).

2. RESPONSIBILITIES

Authorized personnel must ensure that:

- all procedures are followed correctly
- privacy and confidentiality is maintained
- all documentation is completed, and accurate records maintained on all samples

3. EQUIPMENT AND MATERIALS

- Current Patient Information Sheets and Consent Form (PIS&CF)

4. PROCEDURES

- Identification of willing participants will be performed by the treating Urologist, Urological clinic staff or designate and referred to the Prostate Cancer Biorepository Network Site Coordinator or other authorized person.

- After receiving information about a potential participant, confirm that they have been briefed by the treating Urologist, Urological clinic staff or designate about the Prostate Cancer Biorepository Network and their willingness to be approached.
- Meet the potential participant in a space that offers a quiet and private environment.
- Extend an invitation for participation. Using the Informed Consent Form as a guide, give the patient information (in clear language) about the following:

- Objectives of the Prostate Cancer Biorepository Network (PCBN)
- Confidentiality issues. Reinforce that the discussion is confidential. Provide assurance that confidentiality of data and identity will be protected.
- Outline procedures the patient will have to undergo.
- Describe how the tissue sample, blood, other biological material, and data will be handled and stored.
- Discuss the potential risks of participation.
- Outline that there are no direct benefits to participating nor will the participant receive any compensation.
- Clarify that participation is voluntary. The decision to refuse participation or withdraw will not affect the standard of care the participant will receive.

- Provide the participant with a copy of the Patient Information Sheet and Consent Form (PIS&CF). Allow the participant adequate time to read. Encourage them to ask questions in return and answer the questions as honestly as possible.
- If the patient agrees to participate, request that they sign and date the PIS&CF. Ensure each page is initialed and dated.
- Provide the participant with a copy of the completed PIS&CF and retain the original copy for the biorepository records.

Consent using Legally Acceptable Representative

- If the patient is judged incapable of providing consent, the consent of a Legally Acceptable Representative can be obtained. Follow the procedures described above, but instead obtain the signature of the Legally Acceptable Representative.

Use of Interpreter

- If the patient or the legally acceptable witness does not speak the language of the PIS&CF, the consent discussion should take place in the patient's language using a qualified interpreter or family member if needed.

  NOTE: Indicate on the PIS&CF that the consent was discussed / read to the patient by the interpreter.