PCBN POLICY	**Policy No. 001** **Tissue & Data Access Policy**
UNAUTHORIZED COPYING PROHIBITED	**Version Number: 4.0 (February 2021)** Number of Pages: 4
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PCBN welcomes requests from academic and private industry scientists. Receipt of materials requires IRB approval from the host institution in order to safeguard patient rights.

PCBN materials are categorized into three levels of priority, according to rarity or research value.

PRIORITY 1 SPECIMENS: these are specimens that are readily available, and have little or no linked clinical data. These specimens will be made available for early stage research, e.g. to demonstrate that a particular biomarker is differentially expressed in normal vs. tumor tissue. *Little or no preliminary data regarding differential expression of the biomarker will be required to justify the request*; ***however, the applicant must still provide evidence that the proposed assay performs well in human prostate samples (including analytical validation of antibodies for IHC assays)***. An *expedited review* procedure will be used to review applications for Priority 1 specimens.

PRIORITY 2 SPECIMENS: these are specimens that have greater research value, either due to their relative abundance or the richness of linked data or other linked specimen types. *Access to these specimens would* ***require preliminary data showing that the biomarker assay performed well (including analytical validation of antibodies for IHC assays)*** *and that the biomarker was differentially expressed in cancer*.

PRIORITY 3 SPECIMENS: these are rare and/or data-rich specimens. Requests for these specimens would *require more mature preliminary data, e.g. demonstration that the biomarker was correlated with a measure of aggressiveness to justify request for matched recurrent vs. non-recurrent cases*. ***Access to these specimens would also require preliminary data showing that the biomarker assay performed well (including analytical validation of antibodies for IHC assays).***

All requests will undergo peer review procedure (PCBN.SOP11.Specimen Request Review Process) by the *PCBN Specimen Request Review Committee* (expedited or full) using the following criteria:

Table 1: Review Criteria by Priority, and Specimen Types Included at each Priority Level

PRIORITY 1 SPECIMENS	PRIORITY 2 SPECIMENS	PRIORITY 3 SPECIMENS
Review Criteria:	**Review Criteria:**	**Review Criteria:**
1. Scientifically valid objective	1. Scientifically valid objective	1. Scientifically valid objective
2. PI and institution have suitable resources to conduct the study	2. PI and institution have suitable resources to conduct the study	2. PI and institution have suitable resources to conduct the study
3. Methods and sample amount/number of specimens appear appropriate	3. Methods and sample amount/number of specimens appear appropriate	3. Methods and sample amount/number of specimens appear appropriate
	4. Biomarker(s) of interest have been shown to be differently expressed in prostate cancer vs. non-tumor	4. Biomarker(s) of interest have been shown to be associated with other prostate cancer prognostic factors

Specimens with Priority 1	Specimens with Priority 2	Specimens with Priority 3
TMA: 8 Case Test	**TMA**: 80 Case Grade/Stage	**TMA**: 235 Case Natural History of Prostate Cancer*
TMA: 10 Case Test PSA Progression	**TMA**: 200 Case Grade/Stage	**TMA**: 726 Case PSA Progression*
TMA: 40 Case Screening	**TMA**: 125 Case Hormone Sensitivity	**TMA**: 217 Case Biochemical Recurrence
TMA: Fixation	**TMA**: 343 Case Family History	**TMA**: 150 Case Race Disparity*
TMA: Ischemia/Fixation Delay	**TMA**: 119 Case HGPIN	**TMA**: 114 Case Race Disparity
TMA: 50 Case BPH	**TMA:** 135 Case Grade/Stage	**TMA**: 180 Case Race Disparity*
TMA: 38 LuCaP PDX Models*	**TMA:** 319 Case Enrichment*	**TMA**: 456 Case Race Disparity
Frozen Tissue (<10 samples), no clinical data	Frozen Tissue, with clinical data but not recurrence or outcomes data	**TMA**: 27 Case Lymph Node Mets*
FFPE Tissue (<20 samples), no clinical data	FFPE Tissue, with clinical data but not recurrence or outcomes data	**TMA**: 52 Case Lymph Node Mets*
DNA (<20 samples), no clinical data	DNA/RNA/protein, with clinical data but not recurrence or outcomes data	**TMA**: 45 Case Bone and Visceral Metastasis from Rapid Autopsy*
RNA (<20 samples), no clinical data	Blood Components (serum, plasma, buffy coat), with clinical data but not recurrence or outcomes data	**TMA**: 20 Case Bone and Visceral Metastasis from Rapid Autopsy*
Protein (<20 samples), no clinical data	Prostatic / Seminal Vesicle Fluids, with clinical data but not recurrence or outcomes data	**TMA**: 15 Case Metastasis from Rapid Autopsy*
Blood Components (serum, plasma, buffy coat) (<20 samples), no clinical data		Frozen Tissue, large sample size (>25 samples) and/or linked to recurrence or outcomes data
Prostatic / Seminal Vesicle Fluids (<20 samples), no clinical data		FFPE Tissue, large sample size (>100 samples) and/or linked to recurrence or outcomes data
		DNA/RNA/protein, large sample size (>50 samples) and/or linked to recurrence or outcomes data
		Blood Components (serum, plasma, buffy coat), large sample size (>100 samples) and/or linked to recurrence or outcomes data
		Prostatic/Seminal Vesicle Fluids, large sample size (>100 samples) and/or linked to recurrence or outcomes data

*These TMAs were developed by other investigators prior to the establishment of the PCBN, and using funds from sources other than the PCBN. Because of this substantial investment of investigator time and resources, use of these TMAs may require some collaboration between the applicant requesting the TMA and the originator of the TMA. Whether a collaboration is required will be determined after discussion with the applicant for the TMA, the PCBN Director, and the originator of the TMA. No intellectual property of the applicant (e.g. study hypothesis, biomarker of interest) will be revealed to the originator of the TMA without the permission of the applicant. The nature of the collaboration (if collaboration is required) may range from acknowledgement in a manuscript or conference presentation, co-authorship of a manuscript, or input on study design or analysis, and will be determined by agreement among the involved parties. This policy will have minimal impact on the speed with which the applicant can receive the samples, and can potentially provide the applicant with the benefit of the originator's research experience with the particular TMA.

Responsibilities of Investigators accessing PCBN material

The Principal Investigator(s) of the project must agree:

1. To sign the Material Transfer Agreement and not to distribute the material or data to investigators or institutions who are not named in the approved application.
2. To include any investigators as co-authors as agreed upon before sample distribution for samples that may require collaboration as indicated in Table 1. Otherwise, the Prostate Cancer Biorepository Network (PCBN) should be acknowledged in the **acknowledgements or funding information** section of manuscripts resulting from use of PCBN specimens as per the following statement: **This work is supported by the Department of Defense Prostate Cancer Research Program, DOD Award No W81XWH-18-2-0013, W81XWH-18-2-0015, W81XWH-18-2-0016, W81XWH-18-2-0017, W81XWH-18-2-0018, and W81XWH-18-2-0019 PCRP Prostate Cancer Biorepository Network (PCBN).**This is required as an outcome measure of the network's productivity.
3. To notify the PCBN of project completion and, once the results have been approved for publication, to deposit individual biomarker results in the PCBN database. This will allow the data value of each specimen to increase dynamically as research results on the same patient specimens cumulate over time, which will benefit the applicant, PCBN and the prostate cancer research community.
4. To return unused materials to maintain the longevity of the repository.