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TITLE: Prostate Cancer Biorepository Network (PCBN) - Washington University Network Site

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CONTRACTING ORGANIZATION: Prostate Cancer Research Program

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14. ABSTRACT Washington University School of Medicine and the Alvin J. Siteman Cancer Center have a long standing tradition of supporting multi-institutional cancer trials, scientific collaborations, and coordinated biorepository operations with all of the expertise, resources, operational management and personnel required to be a successful Prostate Cancer Biorepository Network (PCBN) resource site. Our proposed PCBN site aims to contribute biospecimens from prostate cancer patients with high risk disease. Within these populations, the study team will target African-American prostate cancer patients. Increasing the number of African-American men present in our biorepository will strengthen the generalizability of results obtained from the use of biospecimens from our PCBN site. The added benefits of our long-term follow-up, comprehensive medical, and survey data on diet and social factors of the participant will allow researchers to explore the effects of genes and the environment on prostate cancer recurrence and mortality. The participants in our PCBN site may not directly benefit from participation in the biorepository; however, what we learn from analyses of their samples will greatly benefit the next generation by providing answers to why some men are diagnosed with more aggressive prostate cancer than other men and what clinicians and patients can do to reduce their risk of prostate cancer recurrence and mortality.					
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1. INTRODUCTION:

The Washington University team will expand the PCBN by collecting samples of tissue and body fluids (blood, urine). For participants receiving a prostatectomy, a sample of prostate tissue was sectioned and flash frozen. All participants complete a detailed questionnaire with including demographic, family history, health behaviors and dietary data. The study staff follow-up clinical data yearly. Previously collected samples have also been made available to the PCBN including 320 high risk samples and other samples as requested from the PI's Prostate Cancer Prospective Cohort at Washington University. This cohort consists of about 1900 participants with serum, fresh frozen tissue and detailed clinical, sociodemographic and dietary data.

2. KEYWORDS:

Prostate cancer; biorepository; minority; tissue; African-American; high-risk patients

3. ACCOMPLISHMENTS:

What were the major goals of the project?

Aim 1. Collect, process and store biospecimens annotated with clinical and pathology data from well-characterized populations of patients.

- Task1: Obtain HRPO and IRB approvals
 - Months 1-3 – 100% complete
- Task 2: Each pathology resource site contributes biospecimens from a minimum of 50 patients per year.
 - Months 1-36 (Ongoing) – 100% on target
- Task 3: Annotate, perform quality control for processing, storage and clinical data collection for prospective specimen accrual
 - Months 1-36 (Ongoing) – 100% on target

Aim 2. Maintain an informatics infrastructure for secure data storage and transfer, and a web-accessible portal for users to learn about and access specimens from the PCBN

- Task 1: Coordinating Site only
- Task 2: Data elements used to annotate demographic, clinical, pathology, and biospecimen life cycle will be provided to the Coordinating Center, and the Network Site will participate in the process of defining and harmonizing a set of common data elements (CDEs).
 - Months 1-6 – 100% complete
- Tasks 3-5: Coordinating Site only

Aim 3. Continue to develop harmonized SOPs for biospecimen acquisition, processing, storage and quality control to increase the fidelity of biospecimens provided to investigators.

- Task 1: This will encompass the initial work required to develop standard operating procedures (SOPs) incorporated into the PCBN infrastructure. These SOPs will govern how the prospective collection during this award at each Network Site will be annotated, undergo quality control, storage and made available for distribution to investigators. The harmonization of SOPs has been an ongoing PCBN effort, and this particular task will focus primarily of incorporating the SOPs from the new ICR Network Site into the network.
 - Months 1-6 – 100% complete
- Task 2: Finalize SOPs for all 5 Network operations described in Task 1.
 - Months 6-9 – 100% complete
- Task 3: Review of Network operation, use of SOPs, composition of repository.
 - Month 12 – 100% complete
- Task 4: Perform biospecimen science to continually improve upon best practices for biospecimen handling and storage.
 - Months 1-36 – in progress

Aim 4. Distribute biospecimens according to a prioritization plan to ensure maximal use by the prostate cancer community.

- Task 1: Continue offering biospecimens from all 5 Network Sites to the research community using prioritization plan outlined in our Tissue and Data Access Policy that is already developed and available to all investigators/detailed and posted online on our website.
 - Months 1-36 - ongoing
- Task 2: Review specimen requests, distribute specimens to approved investigators.
 - Months 1-36 - ongoing
- Task 3: Review of sources of patients and biospecimens at each site that can be made available to the repository. Discussion every six months on what derivatives might be useful to the group. New TMAs, RNA, DNA, new methods to collect cfDNA etc.
 - Discussion every 6 months – ongoing

Other Tasks

- Meet with the EAB twice a year (once by teleconference and once in a face-to-face meeting) for scientific review and to evaluate progress.
 - Months 1-36 – 100% for year 1 and ongoing
- Begin developing proposals for continued funding of the Network.
 - Months 24-36 – 0%
- Marketing of the PCBN at annual meetings (via fliers/pamphlets as well as poster presentations on biospecimen science studies), via email, via social media, etc. We will use our new Network site in the UK to increase marketing internationally.
 - Months 1-36 – 100% for year 1 and ongoing

What was accomplished under these goals?

1. Major activities:

	Current Year	Total
Patients Consented	26	308
Patients in consent process	18	259
Total	105	540

	Total Since September 2020
Plasma/Serum/Cell Pellet***	
Total High-risk	17
African American	1
Total Plasma/Serum/Cell	26
Urine	
Total High-risk	13
African American	1
Total Urine	20
Tissue	
Total High-risk	17
African American	0
Total Tissue	17
TOTAL SPECIMENS	63

The Washington University PCBN site recruited patients from the Washington University urology clinics. Our site collects blood and urine at the time of diagnosis and consent to participate. For participants receiving a prostatectomy, a sample of prostate tissue was sectioned and flash frozen. All participants complete a detailed questionnaire with including demographic, family history, health behaviors and dietary data. The study staff follow-up clinical data yearly. This cohort also consists of about 1900 participants with previously collected serum, fresh frozen tissue and detailed clinical, sociodemographic and dietary data. In the past year (September 2020 to October 2021) we have consented 26 participants and collected 63 specimens. Many of the specimens shared through samples request come from the previously banked 1900 participants.

2. Specific objectives: Recruitment, data collection and follow-up of prostate cancer patients including serum, urine and prostate tissue at time of diagnosis.

3. Significant results or key outcomes:

Sample Requests

The Washington University PCBN site has fulfilled 3 specimen requests for the 456 Case Race Disparity TMA Set in the past year, and 1 specimen request for Frozen DNA Pellets.

Amount Collected Per Participant (depending on blood collected)

Plasma: 3- 1 mL aliquots

Serum: 3- 1 mL aliquots

Cell pellet: 3

Urine: 5- 1.8 mL aliquots

4. Other achievements:

N/A

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

The availability of specimens from all of the PCBN sites were presented online through the PCBN website. To advertise the local prostate cancer researchers for the Washington University site, Dr. Drake presents the PCBN annually at the prostate cancer urology conferences at Washington University.

What do you plan to do during the next reporting period to accomplish the goals?

We have added e-consent as an option for participants in response to limited staff being allowed in the clinic and more appointments being virtual.

4. **IMPACT:**

What was the impact on the development of the principal discipline(s) of the project?

Biorepositories hold great promise for the future of medicine, since they provide a way to significantly improve the effectiveness and efficiency of clinical trials through an improved understanding of the disease process. Our PCBN site contributes prostate cancer patient samples and clinical, sociodemographic and dietary data at baseline and follow-up which will provide the necessary biospecimens for researchers' use to address the Prostate Cancer Research Program Overarching Challenges of (1) distinguishing aggressive from indolent disease in men with newly diagnosed prostate cancer; and (2) addressing mechanisms of resistance for men with high risk or metastatic prostate cancer.

What was the impact on other disciplines?

Nothing to report

What was the impact on technology transfer?

Nothing to report

What was the impact on society beyond science and technology?

Nothing to report

5. **CHANGES/PROBLEMS:**

Changes in approach and reasons for change

We have added e-consent as an option for participants in response to limited staff being allowed in the clinic and more appointments being virtual.

Actual or anticipated problems or delays and actions or plans to resolve them

Nothing to report

Changes that had a significant impact on expenditures

Nothing to report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents

Nothing to report

Significant changes in use or care of human subjects

Nothing to report

Significant changes in use or care of vertebrate animals.

Nothing to report

Significant changes in use of biohazards and/or select agents

Nothing to report

6. PRODUCTS:

Publications, conference papers, and presentations

▪ **Journal publications.**

Nothing to report

▪ **Books or other non-periodical, one-time publications.**

Nothing to report

▪ **Other publications, conference papers, and presentations.**

Nothing to report

○ **Website(s) or other Internet site(s)**

Nothing to report

○ **Technologies or techniques**

Nothing to report

○ **Inventions, patent applications, and/or licenses**

Nothing to report

○ **Other Products**

Biospecimen collection and creation of a TMA from prostate cancer tissue is described above.

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

1. Name: Bettina F. Drake, PhD, MPH
Project Role: Principal Investigator
Researcher Identifier (e.g. ORCID ID): <https://orcid.org/0000-0001-9340-5848>
Nearest person month worked: 6
Contribution to Project: Dr. Drake is the lead investigator on this study.
Funding Support: DoD Grant

2. Name: Dengfeng Cao, MD
Project Role: Urologic Pathologist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 3
Contribution to Project: Dr. Cao serves as the urologic pathologist and provides consultation, review and analysis of specimens.

Funding Support: DoD Grant

3. Name: Aleksandra Klim, RN, CCRC, MHS
Project Role: Resource Site Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.2
Contribution to Project: Mrs. Klim will work with the Coordinating Center Network Manager on Network-wide functions in addition to site-specific functions. The site-specific functions will include expediting protocols through the approval process and maintaining regulatory approvals and compliance. Mrs. Klim will oversee the review, evaluation, selection and specimen distribution. In addition, she will coordinate training and management of personnel including the Data Manager, and the Research Technician/recruiter.

Funding Support: DoD Grant

4. Name: Ariana Ahmed
Project Role: Recruiter
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 12
Contribution to Project: Ms. Ahmed meets with the urologists to explain the biorepository, including when and how she will approach potential participants. Using our patient scheduling system ClinDesk and AllScripts, she will identify potential participants, consent and enroll them into the biorepository. Ms. Ahmed works with Ms. Klim (Resource Site Coordinator) to ensure samples are transported to the TPC for processing and storage. Ms. Ahmed monitors surgery schedules to ensure tissue extraction is provided for all consented participants. Ms. Ahmed meets with Dr. Drake and Ms. Klim (Resource Site Coordinator) weekly and also attends the monthly study team meetings.

Funding Support: DoD Grant

5. Name: Mark Watson, MD, PhD
Project Role: collaborator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0
Contribution to Project: As director of the Tissue Procurement Core at Siteman Cancer Center, Dr. Watson works with the team to ensure appropriate biospecimen collection, processing, storage and shipment when necessary.

Funding Support: Siteman Cancer Center

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

What other organizations were involved as partners?

This grant is part of the Prostate Cancer Biorepository Network

8. SPECIAL REPORTING REQUIREMENTS

○ **COLLABORATIVE AWARDS:**

This grant is part of the Prostate Cancer Biorepository Network

○ **QUAD CHARTS:**

Nothing to report

9. APPENDICES:

Nothing to report