

AWARD NUMBER: W81XWH-18-2-0019

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

PRINCIPAL INVESTIGATOR: Bettina F. Drake, PhD, MPH

CONTRACTING ORGANIZATION: WASHINGTON UNIVERSITY
ONE BROOKINGS DR
SAINT LOUIS MO 63130-4862

REPORT DATE: October 2022

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.
PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.

1. REPORT DATE OCTOBER 2022			2. REPORT TYPE Annual			3. DATES COVERED 30SEPT2021 - 29SEPT2022			
4. TITLE AND SUBTITLE: Prostate Cancer Biorepository Network (PCBN) - Washington University Network Site						5a. CONTRACT NUMBER W81XWH-18-2-0019			
						5b. GRANT NUMBER			
						5c. PROGRAM ELEMENT NUMBER			
6. AUTHOR(S) Bettina F. Drake, PhD, MPH E-Mail: drakeb@wustl.edu						5d. PROJECT NUMBER 0011150667-0001			
						5e. TASK NUMBER			
						5f. WORK UNIT NUMBER			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) WASHINGTON UNIVERSITY, THE ONE BROOKINGS DR SAINT LOUIS MO 63130-4862						8. PERFORMING ORGANIZATION REPORT NUMBER			
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Development Command Fort Detrick, Maryland 21702-5012						10. SPONSOR/MONITOR'S ACRONYM(S)			
						11. SPONSOR/MONITOR'S REPORT NUMBER(S)			
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited									
13. SUPPLEMENTARY NOTES									
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.									
15. SUBJECT TERMS Prostate cancer; biorepository; minority; tissue; African-American; High-Risk patients									
16. SECURITY CLASSIFICATION OF:						17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 10	19a. NAME OF RESPONSIBLE PERSON USAMRDC	
a. REPORT	b. ABSTRACT	c. THIS PAGE	19b. TELEPHONE NUMBER (include area code)						
U	U	U							

TABLE OF CONTENTS

	<u>Page</u>
1. Introduction	4
2. Keywords	4
3. Accomplishments	4-6
4. Impact	6
5. Changes/Problems	6-7
6. Products	7
7. Participants & Other Collaborating Organizations	7-8
8. Special Reporting Requirements	8-9
9. Appendices	9

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, tissue, serum, high-risk patients

3. ACCOMPLISHMENTS:

What were the major goals of the project?

1. Team meeting
 - a. Review grant and progress of recruitment in parent study – Year 1, Month 1 – 100% complete
 - b. Team meetings will occur monthly throughout the award – Year 1-2, Monthly – 100% complete
 - c. Meetings with Tissue Procurement Core – Year 1-2, Monthly – 100% complete
2. Protocol development
 - a. Meet with Tissue Procurement Core and the Resource Site Coordinator to finalize protocol – Year 1, Month 3 – 100% complete
 - b. Train Recruiter and Data Manager on protocol to use for recruitment and data entry – Year 1, Month 3-4 – 100% complete
3. Regulatory review and Institutional Review Board (IRB)
 - a. Complete and submit forms for regulatory review – Year 1, Months 3-4 – 100% complete
 - b. Complete and submit IRB forms for review – Year 1, Months 3-4 – 100% complete
 - c. Obtain approval for regulatory and IRB forms – Year 1, Month 4 – 100% complete
4. Recruitment
 - a. Active surveillance patients – Year 1-2 – 100% complete
 - b. High risk patients – Year 1-2 – 100% complete
 - c. Recontact high-risk patients from Prostate Cancer Prospective Cohort –Recontact of participants went slower than expected. We have contacted half of the initially identified high-risk participants for recontact, but we have run into issues with patients who have moved or experienced recurrence with follow-up treatment. We have recently stopped recruitment of additional participants and are now primarily focused on follow-up of consented participants.
5. PCBN-related travel
 - a. PCBN EAB meetings – Year 1-2 – 100% complete
 - b. 1-day meeting to present on progress – Year 1 – 100% complete
6. Pathological review
 - a. Site visits by Dr. Humphrey (urological pathologist) – Year 1-2 – 100% complete
 - b. Regular review by Dr. Pfeifer – Years 1-2 – 100% complete
7. Scientific presentations – Year 2 – 100% complete

What was accomplished under these goals?

1. Major activities:

The Washington University PCBN site recruited patients from the Washington University urology clinics. The award period began in October 2015 and recruitment and collection of specimens began January 2016. Our site collected 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. 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. To date we have consented 309 participants and collected 1019 specimens as seen in Table 1 and Table 2.

Table 1: Number of patients consented during current quarter and overall since 2016.

	Current Quarter	Total
Patients Consented	2	309
Patients being followed for consent	0	96
Ineligible/No Response	0	464
Total	2	869

Table 2: Number of specimen banked previously and current overall total since 2016.

	Prostate Cancer Prospective Cohort Previously Banked Biospecimens	Total Since Jan. 2016	Overall Totals
<u>Plasma/Serum/Cell Pellet***</u>			
Total High-risk	320	171	491
African American	38	20	58
Total Plasma/Serum/Cell	320	191	549
<u>Urine</u>			
Total High-risk	N/A	111	111
African American	N/A	7	7
Total Urine	N/A	118	118

<u>Tissue</u>			
Total High-risk	243	76	319
African American	26	7	33
Total Tissue	243	83	352
TOTAL SPECIMENS	563	392	1019
***Only serum and cell pellet available on Prostate Cancer Prospective Cohort			

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 12 specimen requests for tissue and serum. One request was uniquely filled by our site given our long-term follow-up and our detailed dietary data, because of the need to stratify specimens by specific dietary data.

Specimens Collected

Plasma: 560

Serum: 484

Cell pellet: 408

Urine: 1075

Frozen Tissue: 198

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:

We have finalized a race-matched, 1:2 of African-American to White participants, tissue microarray (TMA). The TMA includes 525 prostate cancer cases with an average of 3 years of follow-up.

These biospecimens will have matched blood, urine and tissue from the time of diagnosis, prior to treatment. All participants are monitored yearly for PSA levels and indications for PCa recurrence.

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. In addition, the PCBN was shared at scientific conferences attended by prostate cancer researchers such as the Prostate Cancer Foundation retreat and the DOD Impact conference. To advertise the local prostate cancer researchers for the Washington University site, Dr. Drake presented 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?

Nothing to Report

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

Nothing to report

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

One of the aims was to recontact high-risk prostate cancer patients who have not recurred to provide a repeat serum sample. Recontact of these participants went slower than expected due to COVID and other factors. We have contacted half of the identified high-risk participants for recontact but have run into issues with patients who have moved or experienced recurrence with follow-up treatment. We have recently stopped recruitment of additional participants and are now primarily focused on follow-up of consented participants.

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 since it is the aim of the study.

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: 2.6
Contribution to Project: Dr. Drake is the lead investigator on this study.
Funding Support: DoD Grant

2. Name: Aleksandra Klim, RN, CCRC, MHS
Project Role: Resource Site Coordinator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1.7
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

3. Name: Ariana Ahmed

Project Role: Recruiter
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 6
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 EPIC, 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 and that all data elements and consent forms are entered. 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.
Funding Support: DoD Grant

4. Name: Thomas Walsh
Project Role: collaborator
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 0.5
Contribution to Project: Mr. Walsh facilitates shipment of tissue samples and coordination of the development and sharing of the race-matched TMA.
Funding Support: DOD Grant

5.

6. 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