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TITLE: Prostate Cancer Biospecimen Cohort Study

PRINCIPAL INVESTIGATOR: Bettina F. Drake, MPH, PhD

CONTRACTING ORGANIZATION: Washington University  
Saint Louis, MO 63130

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| 6. AUTHOR(S)<br>Bettina F. Drake, PhD, MPH<br>Associate Professor<br><br>E-Mail: drakeb@wustl.edu                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                 |                                  |                                                   | 5d. PROJECT NUMBER                             |                                               |
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| 13. SUPPLEMENTARY NOTES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                 |                                  |                                                   |                                                |                                               |
| 14. ABSTRACT<br>The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.                                                                                                                                                                                                                                                                                                                                                              |                                 |                                  |                                                   |                                                |                                               |
| 15. SUBJECT TERMS<br>Prostate cancer, disparities, biorepository, active surveillance, high risk                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                 |                                  |                                                   |                                                |                                               |
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| a. REPORT<br><br>Unclassified                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | b. ABSTRACT<br><br>Unclassified | c. THIS PAGE<br><br>Unclassified |                                                   |                                                | 19b. TELEPHONE NUMBER (include<br>area code)  |

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### **1. INTRODUCTION:**

The goal of the study is development of a Prostate Cancer Biorepository Network (PCBN) resource site with high quality and well-annotated urine, blood, and tissue specimens as part of a multi-institutional Department of Defense collaboration. De-identified data, tissue and other biospecimens will then be available through the sites to all prostate cancer investigators to conduct further research. This is a collaborative effort among the sites with no coordinating center and each site will be responsible for maintaining/storing their own data/samples.

### **2. KEYWORDS:**

Prostate cancer, biorepository, disparities, active surveillance, high risk

### **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, Month 3-4 – 100% complete
  - b. Complete and submit IRB forms for review – Year 1, Month 3-4 – 100% complete
  - c. Obtain approval for regulatory and IRB forms – Year 1, Month 4 – 100% complete
4. Recruitment – Ongoing in No Cost Extension
  - a. Active surveillance patients – Year 1, Month 5-12
  - b. High risk patients – Year 1, Month 5-12
  - c. African American patients – Year 1, Month 5-12
  - d. Recontact high risk patients from Prostate Cancer Prospective Cohort– Year 1, Month 6-12
5. PCBN-related travel
  - a. PCBN EAB meetings – Year 1, – 100% complete
  - b. 1-day meeting to present on progress at Integration Panel – Year 1, – 100% complete
6. Pathological review
  - a. Site visits by Dr. Humphrey (urological pathologist) – Year 1, Month 6 – 100% complete
  - b. Regular review by Dr. Sehn – Year 1, Month 6 – 100% complete

## What was accomplished under these goals?

1. Grant reviewed and parent study accessed for high-risk patients to recontact. Team meetings and meetings with TPC for study development.
2. Protocol developed and finalized for regulatory submission. Recruiter hired and trained along with data manager.
3. Protocol and application submitted to IRB, and approval letters obtained.
4. Recruitment

|                                                                               | Prostate Cancer<br>Prospective Cohort<br>Banked<br>Biospecimens | Biospecimen<br>Acquisition March<br>2016 – October 2017 | Total Banked<br>Specimens |
|-------------------------------------------------------------------------------|-----------------------------------------------------------------|---------------------------------------------------------|---------------------------|
| <b><u>Plasma/Serum/Cell<br/>Pellet***</u></b>                                 |                                                                 |                                                         |                           |
| Total High-risk                                                               | 320                                                             | 30                                                      | 350                       |
| African American                                                              | 38                                                              | 4                                                       | 42                        |
| Total Active<br>Surveillance                                                  | N/A                                                             | 20                                                      | 20                        |
| African American                                                              | N/A                                                             | 4                                                       | 4                         |
| Intermediate Risk                                                             | N/A                                                             | 11                                                      | 11                        |
| Low risk African<br>Americans (not on<br>Active Surveillance)                 | N/A                                                             | 4                                                       | 4                         |
| <b>Total<br/>Plasma/Serum/Cell</b>                                            | <b>320</b>                                                      | <b>65</b>                                               | <b>385</b>                |
| <b><u>Urine</u></b>                                                           |                                                                 |                                                         |                           |
| Total High-risk                                                               | N/A                                                             | 30                                                      | 30                        |
| African American                                                              | N/A                                                             | 4                                                       | 4                         |
| Total Active<br>Surveillance                                                  | N/A                                                             | 20                                                      | 20                        |
| African-American                                                              | N/A                                                             | 4                                                       | 4                         |
| Intermediate Risk                                                             | N/A                                                             | 11                                                      | 11                        |
| Low Risk African<br>Americans (not on<br>Active Surveillance)                 | N/A                                                             | 4                                                       | 4                         |
| <b>Total Urine</b>                                                            | <b>N/A</b>                                                      | <b>65</b>                                               | <b>65</b>                 |
| <b><u>Tissue</u></b>                                                          |                                                                 |                                                         |                           |
| Total High-risk                                                               | 243                                                             | 11                                                      | 254                       |
| African American                                                              | 26                                                              | 2                                                       | 28                        |
| Total Active<br>Surveillance                                                  | N/A                                                             | 0                                                       | 0                         |
| African-American                                                              | N/A                                                             | 0                                                       | 0                         |
| Intermediate Risk                                                             | N/A                                                             | 6                                                       | 6                         |
| Low Risk African<br>Americans (not on<br>Active Surveillance)                 | N/A                                                             | 2                                                       | 2                         |
| <b>Total Tissue</b>                                                           | <b>243</b>                                                      | <b>19</b>                                               | <b>262</b>                |
| <b>TOTAL SPECIMENS</b>                                                        | <b>563</b>                                                      | <b>149</b>                                              | <b>712</b>                |
| ***Only serum and cell pellet available on Prostate Cancer Prospective Cohort |                                                                 |                                                         |                           |

a. Recruitment started in March of 2016 and there are currently 82 newly diagnosed patients consented.

i. Active surveillance patients: 22  
Active Surveillance African American patients: 5

ii. High risk patients: 34  
High risk African American patients: 5

b. An amendment to the IRB in recruitment has been submitted to cover patients considered to be “intermediate risk” (Gleason 3+4). This was changed because 65% of patients were being missed, that were considered “low risk” previously in our study, which went on to have treatment.

- i. Intermediate Risk: 9
    - ii. Intermediate Risk African American patients: 3
  - c. Recontacting patients from the Prostate Cancer Prospective Cohort study is in progress.
5. PCBN related travel
- a. PCBN EAB meeting on October 27, 2016
6. Pathological review
- b. Dr. Jennifer Sehn is the pathologist on the study and reviews all slides.
7. Sample Request: PI Wake Forest Baptist Medical Center
- a. 105 matched FFPE tissue slides (x4 slides each) and serum, along with clinical and socio-demographic variables.

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

Nothing to Report

**How were the results disseminated to communities of interest?**

Nothing to Report

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

Continue recruitment for active surveillance patients, high-risk, and African American patients. Recontact patients from the Prostate Cancer Prospective Cohort including recruitment for “intermediate risk” patients. We recently received approval for a 1-year no cost extension, therefore recruitment of participants and collection of specimens will continue. In addition, the protocol is being amended to include recruitment of all prostate cancer patients seen in clinic without prior treatment.

**4. IMPACT:**

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

Nothing to Report

**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 were missing a significant number of patients by selecting only high-risk and active surveillance prostate cancer patients. We expanding our recruitment to include intermediate risk patients and low-risk patients who do not choose active surveillance. However, priority remains on participants with high-risk disease or who choose active surveillance.

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

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**

**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):

- |                              |                                                   |
|------------------------------|---------------------------------------------------|
| Nearest person month worked: | 3.6                                               |
| Contribution to Project:     | Dr. Drake is the lead investigator on this study. |
| Funding Support:             | DoD Grant                                         |
2. Name: Shivani Thakkar, BS, MPH, CPH  
Project Role: Recruiter  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 12  
Contribution to Project: Ms. Thakkar is the recruiter on this study.  
Funding Support: DoD Grant
3. Name: Danielle Rancilio, MS, MPH  
Project Role: Data Manager  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 3  
Contribution to Project: Ms. Rancilio has worked on goals related to this study including data and study management.  
Funding Support: DoD Grant
4. Name: Alex Klim, RN, MHS, CCRC  
Project Role: Site Coordinator  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 1.2  
Contribution to Project: Mrs. Klim has worked on goals related to study and regulatory management.  
Funding Support: DoD Grant
5. Name: Jennifer Sehn, MD  
Project Role: Pathologist  
Researcher Identifier (e.g. ORCID ID):  
Nearest person month worked: 0.6  
Contribution to Project: Dr. Sehn serves as will serve as the study pathologist and leads the processing, annotation and storage of prostate biospecimens. In addition, Dr. Sehn works with consultant, Peter Humphrey, when a second opinion would be beneficial in reviewing the pathology.  
Funding Support: DoD Grant

**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?**

Nothing to Report

**8. SPECIAL REPORTING REQUIREMENTS**

**COLLABORATIVE AWARDS:**

N/A

**QUAD CHARTS:**

N/A

**9. APPENDICES:**

None