

AWARD NUMBER: W81XWH-18-2-0017

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

PRINCIPAL INVESTIGATOR: Colm Morrissey

CONTRACTING ORGANIZATION: University of Washington

REPORT DATE: OCTOBER 2021

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13. SUPPLEMENTARY NOTES					
14. ABSTRACT The purpose of the Prostate Cancer biorepository is to collect and distribute relevant biological specimens to prostate cancer investigators.					
15. SUBJECT TERMS Prostate Cancer Biospecimens					
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1. Accomplishments:

What were the major goals of the project?

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

Specific 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.

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

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

What was accomplished under these goals?

Database Management

Data abstraction and record updates continued at a regular pace with collections active again.

Prostatectomy Tissue Acquisition

During this year, we prepared frozen OCT embedded tissues from 36 prostatectomies. Eight were from high risk patients (Gleason 8 and above), 28 were from medium risk (Gleason 7) and 0 were low risk (Gleason 6).

Tissue Acquisition Necropsies (TAN)

We performed one prostate cancer TAN in the past year. The specimens are processed and read by a pathologist and the results entered into our database.

Tissue Microarrays (TMAs)

We constructed a new xenograft tissue microarray (TMA) in duplicate containing 40 patient derived xenograft lines. Our castration-resistant prostate cancer metastasis TMA is still in use, but we have constructed a new TMA, as prospective requests ensure we will exhaust the current metastasis TMA.

Longitudinal Sampling

Serum and Plasma Isolation

Sera were obtained from 35 prostatectomy patients and 45 metastatic patients. Plasma and buffy coats were obtained from 34 prostatectomy patients and 46 metastatic patients.

Patient Derived Xenografts (PDX)

We successfully grew a PDX implant from the rapid autopsy patient. We have passaged the PDX line in SCID mice (LuCaP 246.2). In addition, we developed four castrate-resistant lines from androgen sensitive lines.

Specimens Provided

This year we have provided to different groups:

1. Three PDX TMAs
2. Serum from 40 patients
3. A PDX TMA
4. A PDX TMA and a metastasis TMA
5. Two PDX TMAs
6. Serum from 40 patients
7. Twenty paraffin embedded bone metastasis
8. Frozen primary tumor and normal and buffy coat from 121 patients
9. Sixteen FFPE and sear from CRPC patients
10. Two PDX TMAs

Describe the Regulatory Protocol and Activity Status (if applicable).

Describe the Protocol and Activity Status for sections a-c, as applicable, using the format described for each section. If there is nothing significant to report during this reporting period, state "Nothing to Report."

TOTAL PROTOCOLS: 1

PROTOCOL (1 of 1 total):

Protocol [HRPO Assigned Number]: HRPO Log Number E00074.1a

Title: The Prostate Cancer Biorepository Network (PCBN)

Target required for clinical significance: NA

Target approved for clinical significance: NA

SUBMITTED TO AND APPROVED BY:

University of Washington IRB #2341

HRPO #_E00074.1a

STATUS:

- (i) Number of subjects recruited/original planned target: 85/150
Number of subjects screened/original planned target: 85/150
Number of patients enrolled/original planned target: 85/150
Number of patients completed/original planned target: 85/150

- (ii) Report amendments submitted to the IRB and USAMRMC HRPO for review: NA

- (iii) Adverse event/unanticipated problems involving risks to subjects or others and actions or plans for mitigation: NA

**(b) Use of Human Cadavers for Research Development Test & Evaluation (RDT&E),
Education or Training**

TOTAL ACTIVITIES: 1

ACTIVITES: *Prostate Cancer Rapid autopsy program*

- *The purpose of this activity is to collect metastatic and control tissue from patients within hours of death.*
- *The lead PI is Dr. Colm Morrissey, the lead Pathologist Dr. Lawrence True.*
- *The tissue was processed and frozen for molecular biology, embedded in paraffin for histology and fresh tissue used to implant into immune compromised animals to establish patient derived xenografts.*
- *No problems encountered in the procurement, inventory, use, storage, transfer, transportation and disposition of cadavers used for RDT&E.*

(c) Animal Use Regulatory Protocols

TOTAL PROTOCOL(S): 1

PROTOCOL (1 of 1 total):

Protocol [ACURO Assigned Number]: ACURO Log Number PC171113P3.e001

Title: *Title:* Prostate Cancer Biorepository Network (PCBN) - University of Washington Site

Target required for statistical significance: NA

Target approved for statistical significance: NA

SUBMITTED TO AND APPROVED BY:

University of Washington IACUC # 3202-01

ACURO # PC171113P3.e001

STATUS:

ONGOING

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

We will continue to fulfill requests for specimens made through the Prostate Cancer Biorepository Network where specimens are available from the Prostate Cancer Biorepository at the University of Washington.

2. Products: List any products resulting from the project during the reporting period. If there are no products to report for the current quarter, state "Nothing to report."

The products during the reporting period as described above were:

Prostatectomy Tissue Acquisition

During the year, we prepared frozen OCT embedded tissues from 36 prostatectomies. Eight were from high risk patients (Gleason 8 and above), 28 were from medium risk (Gleason 7) and 0 were low risk (Gleason 6).

Tissue Acquisition Necropsies (TAN)

We performed one TAN in the past year. Specimens were read by a pathologist and the results entered into our database.

Tissue Microarrays (TMAs)

TMAs were constructed to replace existing TMAs.

Longitudinal Sampling

Serum and Plasma Isolation

Sera were obtained from 35 prostatectomy patients and 45 metastatic patients. Plasma and buffy coats were obtained from 34 prostatectomy patients and 46 metastatic patients.

Patient Derived Xenografts (PDX)

We have successfully transplanted a new PDX line (LuCaP 246.2).

All specimens described have been entered into our Biorepository database. A summary of the specimens procured during the year are shown in the table (Inset).

Biospecimen Acquisition October 1 2020 – September 30 2021	Total Specimens Collected
Serum	
Pre-RRP	35
Metastatic	45
Total	80
Tissue	
Prostatectomy	36
Metastatic Sites Sampled	4
Normal Sites Sampled	4
Total	44

3. Participants & Other Collaborating Organizations

What individuals have worked on the project?

Provide the following information for: (1) Project Directors (PDs)/ PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort).

Name: Colm Morrissey

Project Role: PI

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 2

Contribution to Project: He supervised all biospecimen acquisition, processing, characterization, maintenance of the clinical database, interaction with the other sites when necessary, and the distribution of specimens.

Name: Lawrence True

Project Role: Co-director

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: As a surgical pathologist with expertise in GU cancers his input and participation has been in tissue acquisition and rapid autopsies.

Name: Eva Corey

Project Role: Co-director

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: Her primary responsibilities were to focus on the maintenance, development and processing of the LuCaP prostate cancer xenograft lines.

Name: Funda Vakar-Lopez

Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: As a surgical pathologist with expertise in GU cancers her input and participation has been in rapid autopsies.

Name: Hung-Ming Lam

Project Role: Co-Investigator

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: Managing members of rapid autopsy team and an active member of a rapid autopsy team.

Name: Conner Sessions

Project Role: Research Scientist

Researcher Identifier (e.g. ORCID ID):

Nearest person month worked: 1

Contribution to Project: Member of rapid autopsy team and implanting and maintaining LuCaP xenograft lines.

Name: Belinda Nghiem
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 2
Contribution to Project: Ms. Nghiem is our research study coordinator and phlebotomist. She spent 100% of her time in the Urology Oncology clinic helping to identify and consent patients for biospecimen donations. She draws blood on hundreds of patients per year and serves as the primary link between the research laboratory and clinic. She is also a member of the rapid autopsy team.

Name: Lori Kollath
Project Role: Biorepository Manager
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 4
Contribution to Project: Her primary responsibilities were to obtain human subjects approvals oversight of all biospecimen collections, processing, clinical chart abstractions, database entries and biospecimen distributions. She supervises the Biorepository team.

Name: Jordan Campbell
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 1
Contribution to Project: Member of rapid autopsy team and implanting and maintaining LuCaP xenograft lines.

Name: Andrew Ustach
Project Role: Research Scientist
Researcher Identifier (e.g. ORCID ID):
Nearest person month worked: 5
Contribution to Project: Mr. Ustach took over the role of Ms. Nghiem as our research study coordinator and phlebotomist. He spends 80% of his time in the Urology Oncology clinic helping to identify and consent patients for biospecimen donations. He draws blood on hundreds of patients per year and serves as the primary link between the research laboratory and clinic. He is also a member of the rapid autopsy team.

- 4. Changes/Problems:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency Grants Officer whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

a. Actual Problems or delays and actions to resolve them

Collections have been reduced due to a significant increase in telemedicine appointments due to COVID-19, limiting interactions with patients in the clinics and access to patient samples. Further, the rapid autopsy was suspended until approvals were obtained from the University to move forward with a new plan of action. We have only had two patients consented since the program was restarted. We have performed one rapid autopsy and have one pending.

b. Anticipated Problems/Issues

Provide a description of anticipated problems or issues that have a potential to impede performance or progress. Also provide course of actions planned to mitigate problems or to take should the problem materialize.

No problems or issues are anticipated moving forward.

5. Special Reporting Requirements:

Quad Charts: If applicable, the Quad Chart (available on <https://www.usamraa.army.mil>) should be updated and submitted with attachments.