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TITLE: Prostate Cancer Biorepository Network

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CONTRACTING ORGANIZATION: New York University School of Medicine
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6. AUTHOR(S)
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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

New York University School of Medicine
550 First Avenue
New York, NY 10016

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

The goal of this proposal is to contribute as a network site to the continued development of infrastructure and operations of the Prostate Cancer Biorepository Network (PCBN). The aim of the PCBN is to provide prostate researchers with high-quality, well-annotated biospecimens obtained in a systematic, reproducible fashion using optimized and standardized protocols. The PCBN is funded as a consortium of participating network sites that includes New York University, under the overall guidance of the coordinating center at Johns Hopkins. The NYU network site works collaboratively to contribute to the PCBN goals, through infrastructure development, biospecimen accrual and biospecimen specialized processing and disbursement to investigators. The NYU network site procures specimens from more than 3 facilities, from primary localized as well as metastatic and disproportionately affected prostate cancer patients and stores them to provide for high quality biospecimens. Additionally, clinical data including pathology and outcome data are annotated with the biospecimens. Specialized processing consists of tissue microarray design and construction. Biospecimens (mainly tissue microarrays) are disbursed to investigators approved through the PCBN. The combined efforts of the network site enables the PCBN consortium to successfully provide much sought after biospecimens for prostate cancer research.

15. SUBJECT TERMS

Prostate Cancer, Biorepository, tissue microarrays, tissue bank

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER *(include area code)*
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1. INTRODUCTION:

The goal of this proposal is to contribute to the continued development of infrastructure and operations of the Prostate Cancer Biorepository Network (PCBN). A prostate cancer biorepository fulfils an important need to enable prostate cancer research to be conducted by the wider research community through making readily available clinical biospecimens. Only few academic centers with high volume prostate cancer clinical services and an already developed banking infrastructure are well positioned to enable biospecimen collection. An external funding source as provided by the DOD enables support for the consortium of institutional biorepositories of the PCBN to provide to the wider research community.
The major goal of the PCBN is to develop a biorepository with high-quality, well-annotated biospecimens obtained in a systematic, reproducible fashion using optimized and standardized protocols. The PCBN is funded as a consortium of participating network sites that include: New York University, Johns Hopkins, University of Washington and Memorial Sloan Kettering, under the overall guidance of the coordinating center at Johns Hopkins. The goal of the NYU network site is to collaboratively contribute toward the PCBN goals, through participation in infrastructure development, biospecimen accrual and derivative product development for the purpose of disbursement to investigators to enhance prostate cancer research. The prior years' effort (2016-2017) toward these goals is detailed herein.

2. KEYWORDS:

Prostate cancer, biorepository, biomarkers, tissue microarrays, tissue bank, rapid autopsy, advanced cancer, ethnicity

3. ACCOMPLISHMENTS:

The 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.

Task 1. *Review of sources of patients and biospecimens at site that can be made available to the repository (Month 1): Completed in 1st quarter (October 2014)*
Task 2. *Data elements used to annotate demographic, clinical, pathology, and biospecimen life cycle will be provided to the Coordinating Center, and Network Site will participate in in the process of defining and harmonizing common data elements (CDEs): Completed in 1st quarter (October 2014)*
Task 3. *Submit SOPs to Coordinating Center (Month 1): Completed in 1st quarter (October 2014)*
Task 4. *Participate in development of draft SOPs, common consent formats, and MTA (Months 1-6): Completed in 1st quarter*
Task 5. Report on performance metrics: Ongoing (accrual reports are provided on quarterly basis)
Task 6. Continue offering existing biospecimens to the research community (Months 6-36): Ongoing – we continue to offer biospecimens at increasing demand to the research community (with substantial increase in application volume).
Task 7. Participate in SOP training (Month 9): New staff were trained in SOPs in first and second quarter (100%)
Task 8. Annotate, perform quality control for processing, storage & clinical data collection, and distribute specimens (Months 10-36): Quality control steps for data collection are performed ongoing basis. Specimens continue to be distributed.
Task 9. Report on performance metrics (Months 12, 18, 24, 30, 36): Month 24- 36 including quarter 32-36 reported herein (prior quarterly reports until month 32 previously submitted)

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Major activities:
The major activities of the NYU network site are detailed under the following areas
A) Regulatory approval
B) Biospecimen accrual
C) Specimen characterization and data annotation
D) Specialized processing of biospecimens
E) Biospecimen disbursement

A. Regulatory Approval:

NYU Medical Center

Regulatory approval: The NYU site includes several hospital facilities, each of which requires its own approval for conduct of activities. NYU has access to three hospitals: NYU Langone Medical Center, Bellevue (an HHC hospital) and the New York Harbor VA hospital and active case recruitment is performed at all sites, each with its own regulatory oversight.

The NYU PCBN maintains compliance with IRB issues at NYU Langone Medical center and Bellevue Hospital in accordance with the NYU IRB. Details of these activities over the last year are summarized below (table 1)

Table 1a: Regulatory Approval NYU/BH 10/1/2016 - 9/30/17	Date Submitted	Date Approved
NYU IRB Continuing Review	1/17/17	1/24/17
Bellevue Hospital IRB Annual Review	2/21/17	2/21/17
HRPO (A-18319.a)	1/31/17	2/1/17
Modification 49 – addition of NYU Lutheran Medical Center	12/15/16	12/27/16
Modification 50 – removal of discontinued research personnel	11/8/16	1/6/17
Modification 51 – edit to protocol (H+H expansion, BRANY)	6/21/17	6/28/17
Modification 52 – addition of personnel (Dr. David Wise)	7/26/17	7/28/17

NY VA

The NYU PCBN maintains compliance with IRB issues at the Manhattan and Brooklyn VA Hospitals in accordance with the New York Harbor VA IRB. Details of these activities over the last year are summarized below (table 1b)

Table 1b:Regulatory Approval at VA over last year	Date Submitted	Date Approved
VA IRB Continuing Review	8/2/17	8/21/17
VA Subcommittee for Human Studies Annual Review	8/10/17	9/12/17
HRPO (A-18319.b)	9/6/17	9/7/17

NY State

NYU PCBN renewed its official tissue bank license with the NY State Department of Health on August 19, 2016 (current expiration set for September 1, 2018). Annual activity report for 2016 was submitted on 9/21/17

Regulatory Approval: Other collaborating sites

The NYU PCBN obtained IRB approval to add other sites as collaborating institutions (for access to archival material):

Access to NYC H+H Hospitals*: IRB approval by Biomedical Research Alliance of New York (BRANY) on 7/17/17

*Coney Island Hospital, Elmhurst Hospital, Harlem Hospital, Jacobi Medical Center, Kings County Hospital, Lincoln Medical and Mental Health Center, Metropolitan Hospital Center

Table 2a. Accrual for past 3 years for NYU PCBN:

NYU PCBN Accrual	2015	2016	2017	Total Accrual
Patients Consented	218	264	259	741
Surgery Performed	175	184	164	523
Frozen Tissue	165	168	160	493
Serum	172	298	236	706
Plasma	15	90	63	168
Buffy Coat	15	10	6	31
Urine	92	153	104	349
Prostatic Fluid	119	154	135	408
Seminal Vesicle Fluid	86	121	111	318
Metastatic cases (RP LN) cases	11	12	33	56
Rapid autopsy cases consented	9	5	4	10*
*Currently have 10 patients alive and consented that are agreeable to participate				

The prospective accrual according to hospital site is detailed below: Table 2b. Accrual 2016-2017 by site:

Accrual by Hospital Site	NYUU Total	BH Total	VA Total	Total
Patients Consented	581	87	73	741
Surgery Performed	482	27	14	523
Frozen Tissue	462	22	8	493
Serum	546	87	73	706
Plasma	112	7	49	168
Buffy Coat	18	7	6	31
Urine	199	81	69	349
Prostatic Fluid	391	17	0	408
Seminal Vesicle Fluid	314	4	0	318

Table 3a-d. The accrual per quarter is shown below:

Table 3a: Biospecimen Acquisition Oct 1 2016 – Dec 31 2016	Total Specimens Collected
Serum	
Pre-Radical Prostatectomy	30
Active Surveillance	14
Metastatic	22
Total	66
Tissue	
Radical Prostatectomy	30
Fluids	
Prostatic fluid	27
Seminal Vesicle fluid	25
Urine (Pre-Radical Prostatectomy)	24
Total	172

Table 3b: Biospecimen Acquisition Jan 1 – March 31 2017	Total Specimens Collected
Serum	
Pre-Radical Prostatectomy	37
Active Surveillance	3
Metastatic	7
Total	47
Tissue	
Radical Prostatectomy	37
Fluids	
Prostatic fluid	35
Seminal Vesicle fluid	27
Urine (Pre-Radical Prostatectomy)	23
Total	169

Table 3c: Biospecimen Acquisition Apr 1– June 30 2017	Total Specimens Collected
Serum	
Pre-Radical Prostatectomy	35
Active Surveillance	18
Metastatic	21
Total	74
Tissue	
Radical Prostatectomy	48
Fluids	
Prostatic fluid	35
Seminal Vesicle fluid	23
Urine (Pre-Radical Prostatectomy)	28
Total	208

Table 3d: Biospecimen Acquisition Jun 1– Sept 30 2017	Total Specimens Collected
Serum	
Pre-Radical Prostatectomy	41
Active Surveillance	11
Metastatic	4
Total	56
Tissue	
Radical Prostatectomy	45
Fluids	
Prostatic fluid	38
Seminal Vesicle fluid	36
Urine (Pre-Radical Prostatectomy)	29
Total	204

Biospecimen procurement for year 3 has expanded both in clinical patient volume and subject recruitment to assure variety of cohorts (increased beyond radical prostatectomy to include more active surveillance and metastatic cancer case). We continue to establish collaborations with partners at different facilities to reach out for select cohorts (advanced prostate cancer and African American cases).

This past year we have obtain regulatory and institutional approval for access to Lutheran Hospital in Brooklyn

and are in process of identifying archival material via data searches of the LIS and HIS systems. We have also obtained IRB approval (via BRANY, a commercial IRB that serves H&H) to various additional H&H facilities. Our efforts to obtain access to archival material from these sites are in progress through a step wise process via partners at each facility.

A. Specimen Characterization and Data annotation:

In 2016, NYU PCBN migrated its entire database into a REDCAP database.

Some advantages of REDCAP are: a) Allows secure and HIPAA compliant sharing of data by seamlessly removing identifiers b) Provides more security and quality assurance checks than current system offers c) Allows multiple individuals of our team to work on the database at the same time

The migration of data consisted of implementation of data quality assurance steps, logic checks and algorithms and design of surveys that provide functionality to the database. The process of migration of data to REDCAP was started (9/1/16) with quality assurance steps to harmonize data and completed in May 2017. NYU PCBN staff continue to regularly update clinical data through access to electronic medical records (EPIC, Quadramed and CPRS), Pathology databases (Powerpath & CoPath), Urology research databases and tumor registry records. Clinical data update is performed on a regular ongoing basis, with quality control checks (relook at a subset of cases) to assure accuracy.. Additionally, tissue microarray data updates are now enabled through link with REDCAP.

NYU PCBN continues to define spatial orientation of prostate cancer using pathology “maps” which provide 2 dimensional representation and characterization of focality (in preparation for multifocal TMA). During the last year, maps have been provided for the majority of radical prostatectomy cases and are accessed as images in the REDCAP database.

B. Specialized processing (Derivatives of biospecimens):

Tissue Microarrays (TMAs): The NYU site continues to provide several TMA sets to PCBN that are regularly requested by investigators. These efforts are described below and also summarized in a table (see Table 4)

Over 2017 an additional TMA set (135 case Grade/stage RP TMA – see below) has been completed while others are currently under construction (see Table 4). The completed TMA is a 135 Radical Prostatectomy (RP) TMA: This TMA, with tumor tissue from 135 consecutive radical prostatectomy cases was constructed, underwent quality assurance validation studies and released in September for PCBN disbursement to investigators.

It consists of cases of RP cases from 104 Caucasian, 25 African American, 11 Asian and 10 other races, with prostate cancer of Gleason 7 and higher (Gleason 7 =107, 8 =10, 9 =24), distributed across the following stages pT2 =66 & pT3 = 80,

Biochemical Recurrence (BCR) \TMA: The current TMA that NYU provides to PCBN investigators is a 217 case BCR TMA that enables assessment of biomarkers strongly associated with known prognostic factors (e.g. stage, grade). It includes patients with versus without biochemical recurrence, to a total of 217 cases, 23 with adjacent normal (4-5 tumor cores, 4 normal cores) and 13 BPH cases (4 cores). Since this TMA is frequently requested, NYU PCBN is preparing an expanded cohort BCR TMA. The construction steps for this are complete – providing a 645 case biochemical recurrence TMA (over 12 TMA Blocks, 4 cores for each case). The associated clinical data for this cohort is currently in process of updating: to date the cohort demonstrates 9% with biochemical recurrence, mean age = 59 years, 75% > 5year PSA follow-up, mean follow-up duration = 135 months.

Hormone Sensitivity TMA: The NYU site provides a 56 case Hormone sensitivity TMA, which enables testing of biomarkers associated with androgen biology. It includes hormone naive versus hormone refractory cases totaling 56 cases; 18 hormone resistant, 18 hormone naïve, 10 radical prostatectomy (RP) cases with neo adjuvant treatment, 10 RP without neo adjuvant treatment. Due to the rarity of castration resistant prostate cancer tissue samples, this TMA required searching across the entire archive of hospital sites for candidate cases. NYU PCBN has identified an additional 15 castration resistant primary prostate cancer cases and is in progress toward expansion of this TMA. The additional cases that have been identified are currently undergoing block annotation for TMA construction and derivative sampling (tissue for DNA extraction).

Multifocal TMA: The NYU site is working to construct a TMA that allows comparison of biomarkers across separately identifiable tumor foci. Prostate maps (with graphical representation of cancer distribution in the prostate) prepared through slide reconstruction to annotate focality. Blocks have been retrieved and partly annotated in preparation for TMA construction.

HGPIN TMA: NYU PCBN has a current TMA however is preparing for expansion of this TMA cohort through an additional TMA. The challenges to this TMA are finding sufficiently large microscopic foci to allow accurate sampling into a TMA. The detailed work at identifying these tiny foci on slides and then matching to blocks is progressively underway in conjunction with other TMA projects.

The work at TMA construction has many rate limiting factors related to case identification, block retrieval and annotation and therefore several projects are in progress concurrently with a long gestational period until ultimate construction. The many steps in design and quality assurance of data and tissue are intended to provide a superior TMA product that will prove to have adequate quality and statistical power with a robust design to satisfy investigators biomarker validation studies.

Table 4: TMA preparation and construction

Type of TMA	Design	Cohort size	Steps to tissue collection	Data extraction	Other derivatives	Challenges	Status
Expansion/ Addition of Hormone sensitivity TMA	Castration resistant tumor tissue from channel TURPs	Prior group = 18 resistant cases, additional 12 cases identified	Search through multiple databases and paper chart records, Archival off-site retrieval	Search of > 10 Electronic records and older paper charts	Storage of tissue cores for DNA & RNA extraction planned	Identification of cases	Additional 15-20 castration resistant cases identified. Blocks retrieved and annotated
HGPIN TMA	Foci of HGPIN in RP specimens	60	Accurate pathologic characterization	Complete	None	Selection of minute foci and accurate TMA Sampling	Selection & pathologic characterization underway
Multifocal TMA	Select RP cases in 2015-16	30	Prostate cancer mapping (graphical representation of cancer foci)	Complete	Storage of tissue cores for DNA & RNA extraction planned	Demarcation of foci through reconstruction of prostate	Blocks annotated. Awaiting construction
Grade/stage TMA	Consecutive RP cases 2015-16	135 cases	Current RP cases	Complete			Completed (3 blocks = 135 cases)
Biochemical Recurrence TMA	Consecutive RP cases 2005-2010	645		PSA follow-up		Clinical Follow-up	Completed construction. Awaits accrual of follow-up data

c. Disbursement of Biospecimens (2016-17)

Tissue microarray sets were provided to investigators as follows:

DATE	SPECIMEN	RECIPIENT
1/12/17	56 case Hormone Sensitivity TMA (2 sets)	New York VA Medical Center
3/6/17	56 case Hormone Sensitivity TMA (2 sets)	University of Pittsburgh
3/29/17	119 case High-grade PIN (2 sets)	New York VA Medical Center
5/15/17	56 case Hormone Sensitivity TMA (3 sets)	University of Iowa
8/23/17	119 case High-grade PIN (2 sets)	New York University
10/23/17	56 case Hormone Sensitivity TMA (1 sets)	University of Iowa

Disbursement of biospecimens is primarily of tissue microarray sets. In order to make these more useful to

investigators we provide product datasheets which outline the design, layout, construction, quality assurance steps and control tissues of the tissue microarrays. These datasheets are available for the biochemical recurrence and hormone sensitivity TMAs and under preparation for TMA sets under production.

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

Emily Dube, research coordinator is studying toward a part-time Master's degree in Clinical Bioinformatics through NYU School of Medicine

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?

If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

We plan to 1) Continue accrual of biospecimens 2) To continue preparation of tissue microarrays with associated data 3) To continue updating clinical data of cohorts 4) To increase rapid autopsy case recruitment and to 5) To continue to bring on more partnering sites for access to archival prostate cancer tissue 6) To continue expansion of the resource to include active surveillance patients.

D. IMPACT: Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

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?

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Nothing to Report

What was the impact on society beyond science and technology?

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Nothing to Report

E. CHANGES/PROBLEMS: The Project Director/Principal Investigator (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:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Due to the low activity in the rapid autopsy program, our group has sought more opportunities to recruit patients with metastatic prostate cancer and approval for more frequent contact and communication with next of kin to maintain interest and cooperation in this program.

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Due to limited space in Manhattan facilities, the leadership of the cancer center at NYU has requested that we maintain cryostorage off site through a commercial company (Biostorage Inc. in Indianapolis). The company has recently provided us a charge estimate for cryostorage which is beyond capabilities of an average research budget and beyond DOD funding could enable. We are currently awaiting NYU leadership to renegotiate terms with Biostorage Inc. to avoid financial stress to the resource.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Nothing to report

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

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals.

Not applicable

Significant changes in use of biohazards and/or select agents

None reported

F. PRODUCTS: List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**

Journal publications

Lee JH, Yang B, Lindahl AJ, Damaschke N, Boersma MD, Huang W, Corey E, Jarrard DF, Denu JM. Identifying dysregulated epigenetic enzyme activity in castrate-resistant prostate cancer development. ACS Chemical Biology. 2017 Oct 11.

Varzavand, A., Hacker, W., Ma, D., Gibson-Corley, K., Hawayek, M., Tayh, O. J., ... & Stipp, C. S. (2016). α3β1 Integrin suppresses prostate cancer metastasis via regulation of the Hippo pathway. *Cancer research*, *76*(22), 6577-6587.

Tennill TA, Gross ME, Frieboes HB. Automated analysis of co-localized protein expression in histologic sections of prostate cancer. PloS one. 2017 May 26;12(5):e0178362.

Ettel M, Kong M, Lee P, Zhou M, Melamed J, Deng FM. Modification of the pT2 substage classification in prostate adenocarcinoma. Human pathology. 2016 Oct 31;56:57-63.

Jing Y, Nguyen MM, Wang D, Pascal LE, Guo W, Xu Y, Ai J, Deng FM, Masoodi KZ, Yu X, Zhang J. DHX15 promotes prostate cancer progression by stimulating Siah2-mediated ubiquitination of androgen receptor. Oncogene. 2017 Oct 9.

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 Product**

Research material: Biospecimen accrual – see table 2a

G. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?

Provide the following information for: (1) 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). If information is unchanged from a previous submission, provide the name only and indicate "no change."

Name: *Jonathan Melamed MD*
Project Role: *PI*
No change
Name: *Peng Lee MD PhD*
Project Role: *Co-investigator*
No change.
.
Name: *Emily Dube, BS*
Project Role: *Biorepository* manager
No change

Name: *Raveena Vakil, BS*
Project Role: *Research coordinator*
Nearest person month worked: *12*
Contribution to Project: *Ms. Vakil is* responsible for biofluid and tissue procurement, data extraction for the existing paraffin embedded cases in NYU archives and data entry of new cases into IRB compliant database.

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?

Organization Name: The Brooklyn Hospital
Location of Organization: Brooklyn, New York
Partner's contribution to the project: Collaboration

Organization Name: SUNY Downstate Hospital
Location of Organization: Brooklyn, New York
Partner's contribution to the project: Collaboration

Organization Name: Brooklyn VA Hospital
Location of Organization: Brooklyn, New York
Partner's contribution to the project: Collaboration

H. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: N/A

QUAD CHARTS: N/A

I. APPENDICES: N/A