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Race-Insurance Disparities in Prostate Patients' Magnetic Resonance Imaging Biopsies and their Subsequent Cancer Care; A New York State Cohort Study [PROTOCOL]

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Protocol Template for Investigator-Initiated Studies

Template Instructions

Sections will expand to fit your responses.

Keep an electronic copy to modify when making changes either as directed by the IRB, or for amendments/modifications.

Mark sections NA if they are not applicable to your research.

Please use lay language, avoid professional jargon and define all abbreviations when they first appear.

PROTOCOL TITLE:

PROTOCOL TITLE:

Response: *Prostate Cancer Care in New York State*

PROTOCOL VERSION/AMENDMENT # AND DATE

Response: *Version 1 (August 4, 2020)*

PRINCIPAL INVESTIGATOR:

Response: *A. Laurie Shroyer, PhD and John Fitzgerald, MD*

DATE:

Response: *August 4, 2020*

1.0 Objectives

1.1 Describe the purpose, specific aims, or objectives of this research. Specifically, explain why it is important to do the study.

Response: *Using the publicly available de-identified Statewide Planning and Research Cooperative System database, this study will compare patient risk characteristics, geographic variations and trends over time for in- hospital rates of prostate diseases, with a primary focus on the diagnosis, treatment, and outcomes for prostate cancer. This study will examine variations in healthcare delivery and the subsequent outcomes from the time of prostate biopsy through diagnosis and treatment. By gathering patient records from a relatively long timeline, 2005-2018, from a large population, we hope to capture trends in prostate cancer management in a more comprehensive way than previous studies.*

1.2 State the hypothesis to be tested, if applicable.

NOTE: A hypothesis is a specific, testable prediction about what you expect to happen in your study that corresponds with your above listed objectives.

Response: *The following null hypotheses will be tested:*

H(0) There will be no geographic variability (based on the NYS county-based regions, rural-urban continuum; also, New York City metropolitan areas will be separately analyzed) in the overall prostate cancer diagnosis, intervention, imaging, and outcome codes for patients who receive prostate biopsies as noted above.

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H(0) There will be no trends over time (based on the NYS county-based regions or rural-urban continuum; also, New York City metropolitan areas will be separately analyzed) in the overall prostate cancer diagnosis, intervention, imaging, and outcome codes for patients who receive prostate biopsies as noted above.

H(0) There will be no trends over time (based on the NYS county-based regions or rural-urban continuum; also, New York City metropolitan areas will be separately analyzed) in the overall prostate non-cancer diagnosis codes for patients who receive prostate biopsies as noted above.

Sub-hypotheses/Specific Interests:

H(0) There is no differences in patients' race or insurance status as to their likelihood to receive a robot-assisted/laparoscopic versus open radical prostatectomy, after adjusting for other patient risk factors. Additionally, a potential interaction between race and insurance coverage will be examined.

H(0) There is no difference in perioperative complications such as increased length of hospital stay, 30 day mortality, 30-day readmissions, and major or minor surgical complications based on whether patients received robotic assisted laparoscopic prostatectomies versus open prostatectomies and when examining for an interaction with race and insurance status.

H(0) MRI Guidance Demographics: For patients < 75 who received an initial MRI-Guided biopsy vs. a non-MRI guided biopsy in the state of NY between 2010-2017, there will be no variation in patient demographics as defined by age, race/ethnicity, source of payment, or surgical risk factors (Charlson/Elixhauser Comorbidity Scores).

H(0) MRI Guidance and Post-Biopsy Diagnosis: For patients < 75 who received an initial MRI-Guided biopsy vs. a non-MRI guided biopsy in the state of NY between 2010-2017, there will be no variation in initial diagnosis rates of PCa (metastatic and non-metastatic) within 2 months adjusting for race/ethnicity and source of payment, provider based effects as appropriate (SPARCS = NPI). Patients diagnosed with other non-cancer diagnoses or a missing diagnoses will be analyzed separately for MRI vs. non-MRI guided biopsy groups.

H(0) MRI Guidance and Post-Biopsy Treatment: For non-metastatic prostate cancer patients < 75 in the state of NY between 2010-2018 who received a diagnostic MRI-Guided biopsy vs. a non-MRI guided biopsy, there will be no variation in initial 1-year frequencies of surgery and/or radiation vs. chemotherapy, active surveillance, and/or no known treatment adjusting for age, race, patient risk factors, and Charlson and Elixhauser comorbidity scores.

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H(0) MRI-Guidance and Post-Diagnosis Wait-Times: For non-metastatic prostate cancer patients < 75 in the state of NY between 2010-2018 who received a diagnostic MRI-Guided biopsy vs. a non-MRI guided biopsy, there will be no variation in mean wait-time from prostate cancer biopsy and/or diagnosis to initial intervention (surgery and/or radiation) within 1-year adjusting for age, race, patient risk factors, Charlson and Elixhauser comorbidity scores, and advanced prostate cancer variables.

2.0 Scientific/Safety Endpoints

2.1 Describe the scientific endpoint(s), the main result or occurrence under study.

NOTE: Scientific endpoints are outcomes defined before the study begins to determine whether the objectives of the study have been met and to draw conclusions from the data. Include primary and secondary endpoints. Some example endpoints are: reduction of symptoms, improvement in quality of life, or survival. Your response should not be a date.

Response: The major scientific endpoints are relative frequency of prostate cancer biopsy, utilization of MRI-guidance in biopsy, prostate cancer diagnosis, frequency of prostate cancer interventions including prostate surgery type (robotic vs. open prostatectomy), radiation interventions, and use of chemotherapy. We will also examine specific outcomes after interventions such as 30-day mortality, time to death, later hospital or ER death, in-hospital death, 5-year survival, total length of hospital stay, post-operation admissions, repeat cancer surgery, and major surgical complications causing increased short-term mortality/morbidity. Additionally, the study will consider rates of prostate biopsy-specific, prostatectomy-specific, and prostate radiation complication diagnoses such as urinary tract infections, deep venous thrombosis, obturator nerve injury, erectile dysfunction, radiation sickness etc. Lastly, the study will track the frequency of non-cancerous diagnoses that patients receive subsequent to biopsy.

3.0 Background

3.1 Provide the scientific or scholarly background, rationale, and significance of the research based on the existing literature and how it will contribute/fill in gaps to existing knowledge.

Response: Prostate cancer is the most common invasive cancer among American men, and the second most common cause of cancer death for American men (1). There are many treatment options available to patients with prostate cancer and clinicians must consider patient risk factors, cancer stage, and individual preferences when choosing treatment (2). Given the large burden of the disease, and the everchanging breadth of treatment options, it is increasingly important for clinicians and researchers to understand how prostate cancer care varies over time or across regions.

Several studies have previously documented geographic variations in prostate cancer screening and treatment. One study of prostate cancer patients in eight U.S. states from 2004-2006 found that patients who live in rural counties were less likely to receive any definitive treatment for their prostate cancer (3). Another national study of prostate cancer patients from 2005-2008 observed similarly lower overall treatment rates among patients in less populous rural counties versus those in more populated urban counties, although there was no difference in the likelihood of receiving radiation versus surgery among those treated (4).

Many studies have also observed large-scale changes in prostate-cancer care over time. One study found that overall rates of radical prostatectomy as treatment for localized prostate cancer has increased from 26% to 42% between 2004 to 2013, while external beam radiation has decreased from 49% to 42% over the same time period (5). A study of radical prostatectomy found that since 2009 robot assisted radical prostatectomy has become the surgery approach used in a majority of prostate cancer surgeries (6).

Our study intends to examine the changes in prostate cancer incidence, screening, and treatment throughout the entire state of New York over a larger time span (14 years) than many previous studies. By using the SPARCS database, we can track patients from the time of prostate biopsy through diagnosis, treatment, and outcomes. As a result, our study can capture trends in prostate cancer management and subsequent outcomes comprehensively in a large population, while also comparing sub-populations based on SPARCS NYS county-based regions.

One specific interest is how MRI-guidance has been incorporated into standard transurethral-ultrasound (TRUS) prostate biopsies over time. The use of MRI technology for the diagnosis, treatment, and management of prostate cancer has highly evolved over the last 15 years including the publication of the Prostate Imaging Reporting and Data System (PIRADS) as well as development of techniques such as MRI-TRUS Fusion biopsy, cognitive registration biopsy,

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and direct (in-bore) MRI-guided biopsies(7). While most research on MRI-guidance for prostate biopsies has centered on cancer detection rates(8,9,10), our research will examine whether using MRI-guidance correlated with specific trends in prostate surgical or non-surgical interventions.

Finally, we will also examine and define wait-times between diagnostic prostate biopsies and prostate cancer interventions in NYS from 2005-2018. We specifically want to know whether there were variations in wait-times for prostate cancer patients in NYS for surgical vs. non-surgical (radiation, chemotherapy) prostate cancer interventions. Past research has examined whether longer or shorter wait-times affect prostate surgery outcomes (11,12), but to our knowledge, a characterization of wait-times for different interventions using multi-institutional data has yet to be done. This analysis will be useful for not only characterizing actors affecting prostate cancer care in NYS but also establishing a baseline to compare future trends of increasing wait-times for prostatectomies due to the COVID-19 pandemic.

Another specific question of interest is whether patient race or insurance status influences whether patients were more likely to obtain a robot-assisted/laparoscopic prostatectomy versus an open approach. Previous research has demonstrated that there are disparities in prostate cancer survival based on patient race, and the mortality difference between black and white men, for example, is explained in large part by differences in access to treatment(13). A 2017 study found that African American and Hispanic men are less likely to receive definitive treatment for prostate cancer than white men, and the rates of treatment declined throughout their study period from 2004-2011(14). When comparing specific treatments, research on prostate cancer patients from 1992 to 1999 and from 2004 to 2011 has found that there are lower rates of radical prostatectomy among black and Hispanic prostate cancer patients compared to white men(15)(16).

As for insurance status, uninsured prostate cancer patients were less likely to receive any definitive treatment for prostate cancer in the era before the Affordable Care Act (17), and uninsured radical prostatectomy patients monitored over almost three decades were more likely to have biochemical recurrence than those with private or public health insurance (18). Given these well documented disparities in prostate cancer treatment and outcomes by race and insurance status, this study hopes to examine whether differing access to newer prostatectomy technology may contribute to these disparities. Furthermore, our study will examine whether there are differences in frequency of surgical complications based on patient race or insurance status, and whether they interact with surgery approach (laparoscopic/robotic versus open). This study will also control for hospital characteristics such as academic versus community hospital, hospital volume, and other variables determined to be important for analysis.

While the focus of our study is on prostate cancer, our study population will start with all

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patients who receive a prostate biopsy. Therefore, our study will also record non-cancer prostate diagnoses, post-biopsy. In the future, we may consider expanding the focus of our study to include treatment variations and outcomes of patients with non-cancer prostate diseases.

3.2 Include complete citations or references:

- Response: (1) Noone AM, Howlader N, Krapcho M, Miller D, Brest A, Yu M, Ruhl J, Tatalovich Z, Mariotto A, Lewis DR, Chen HS, Feuer EJ, Cronin KA (eds). *SEER Cancer Statistics Review, 1975-2015*, National Cancer Institute. Bethesda, MD, https://seer.cancer.gov/csr/1975_2015/, based on November 2017 SEER data submission, posted to the SEER web site, April 2018.
- (2) Sanda MG, Cadeddu JA, Kirkby E, et al. *Clinically Localized Prostate Cancer: AUA/ASTRO/SUO Guideline. Part I: Risk Stratification, Shared Decision Making, and Care Options. Journal of Urology* 2018;199:683-90.
- (3) Baldwin L-M, Andrilla CHA, Porter MP, Rosenblatt RA, Patel S, Doescher MP. *Treatment of early-stage prostate cancer among rural and urban patients. Cancer* 2013;119:3067-75.
- (4) Cary C, Odisho AY, Cooperberg MR. *Variation in prostate cancer treatment associated with population density of the county of residence. Prostate Cancer Prostatic Dis* 2016;19:174-9.
- (5) Weiner AB, Matulewicz RS, Schaeffer EM, Liauw SL, Feinglass JM, Eggener SE. *Contemporary management of men with high-risk localized prostate cancer in the United States. Prostate Cancer Prostatic Dis* 2017;20:283-8.
- (6) Gandaglia G, Sammon JD, Chang SL, et al. *Comparative effectiveness of robot-assisted and open radical prostatectomy in the postdissemination era. J Clin Oncol* 2014;32:1419-26.
- (7) Streicher J, Meyerson BL, Karivedu V, Sidana A. *A review of optimal prostate biopsy: indications and techniques. Therapeutic advances in urology.* 2019;11:1756287219870074m.
- (8) Schoots IG, Roobol MJ, Nieboer D, Bangma CH, Steyerberg EW, Hunink MG. *Magnetic resonance imaging-targeted biopsy may enhance the diagnostic accuracy of significant prostate cancer detection compared to standard transrectal ultrasound-guided biopsy: a systematic review and meta-analysis. Eur Urol.* 2015;68(3):438-450.
- (9) Kvale R, Moller B, Wahlqvist R, et al. *Concordance between Gleason scores of needle biopsies and radical prostatectomy specimens: a population-based study. BJU international.* 2009;103(12):1647-1654.
- (10) Jayadevan R, Felker ER, Kwan L, et al. *Magnetic Resonance Imaging–Guided Confirmatory Biopsy for Initiating Active Surveillance of Prostate Cancer. JAMA Network Open.* 2019;2(9):e1911019-e1911019.
- (11) Stevens C, Bondy SJ, Loblaw DA. *Wait times in prostate cancer diagnosis and radiation treatment. Canadian Urological Association journal = Journal de l'Association des urologues du Canada.* 2010;4(4):243-248.
- (12) Patel P, Sun R, Shiff B, Trpkov K, Gotto GT. *The effect of time from biopsy to radical prostatectomy on adverse pathologic outcomes. Res Rep Urol.* 2019;11:53-60.
- (13) Fletcher SA, Marchese M, Cole AP, et al. *Geographic Distribution of Racial Differences in Prostate Cancer Mortality. JAMA Network Open* 2020;3:e201839-e.

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(14) Moses KA, Orom H, Brasel A, Gaddy J, Underwood W, 3rd. Racial/Ethnic Disparity in Treatment for Prostate Cancer: Does Cancer Severity Matter? *Urology* 2017;99:76-83.

(15) Underwood W, DeMonner S, Ubel P, Fagerlin A, Sanda MG, Wei JT. Racial/Ethnic Disparities in the Treatment of Localized/Regional Prostate Cancer. *The Journal of urology* 2004;171:1504-7.

(16) Moses KA, Orom H, Brasel A, Gaddy J, Underwood W, 3rd. Racial/ethnic differences in the relative risk of receipt of specific treatment among men with prostate cancer. *Urologic oncology* 2016;34:415.e7-.e12.

(17) Mahal BA, Aizer AA, Ziehr DR, et al. The association between insurance status and prostate cancer outcomes: implications for the Affordable Care Act. *Prostate Cancer and Prostatic Diseases* 2014;17:273-9.

(18) Awasthi S, Gerke T, Williams VL, et al. Interrelationship Between Health Insurance Status and Prostate Cancer Grade Can Have Critical Impact on Prostate Cancer Disease Control: A Retrospective Cohort Study. *Cancer Control : Journal of the Moffitt Cancer Center* 2019;26:1073274819837184.

4.0 Study Design

4.1 Describe and explain the study design (e.g. case-control, cross-sectional, ethnographic, experimental, interventional, longitudinal, and observational). Indicate if there is randomization, blinding, control group, etc. If randomizing, explain how this will be achieved.

Response: This will be a retrospective observational cohort study using the SPARCS Health Facts publicly available dataset. The SBU SOM Bioinformatics Department and Biostatistics Core Lab will assist us to match the SPARCS database to our attached protocol's coding lists, to create a study-specific de-identified database of prostate cancer/biopsy patients. The Bioinformatics and Biostatistics team members will also provide the descriptive statistics for the study as well as providing a study-database for future analyses. For this study's primary hypotheses related to geographic variability and trends over time, a p-value of 0.05 will be used. All secondary and tertiary analyses, as well as all exploratory analyses, will use a p-value of < 0.01. SAS version 9.4 will be used to complete all the necessary statistical tests.

5.0 Local Number of Subjects

5.1 Indicate the total number of subjects who will be enrolled or records that will be reviewed through Stony Brook.

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Response: *The SPARCS database has over 100 million records. The exact number of patients between 2005-2016 who have undergone prostate biopsy is 38604 while the exact number of patients who received radical prostatectomies between 2006-2018 is 66836.*

5.2 *If this study is only being conducted through Stony Brook, provide statistical justification (i.e. power analysis) for the number of subjects provided in 5.1 above. If qualitative research, so state, and provide general justification for the total number of subjects proposed.*

Response: This study will use deidentified patient data from the Statewide Planning and Research Cooperative (SPARCS) database for the state of New York from 2005-2018. This study will include all patients who received a prostate biopsy and/or who had a radical prostatectomy from 2005-2018. Given that the SPARCS database has over 100 million records, the sample size or power are not relevant considerations for this study.

5.3 *If applicable, indicate your screen failure rate, i.e., how many subjects you expect to screen to reach your target sample.*

Response: NA

5.4 *Justify the feasibility of recruiting the proposed number of eligible subjects within the anticipated recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
Response: NA

6.0 Inclusion and Exclusion Criteria

NOTE: If your study is more than minimal risk, you must also upload a copy of your inclusion/exclusion checklist (with space for specific subject values) to be completed at time of enrollment of each subject.

6.1 *Describe, in bullet points, the criteria that define who will be included in this study:*

Response: *From SPARCS database:*

- patients over 18 who received prostate biopsy*
- patients over 18 who had a radical prostatectomy*

6.2 *Describe, in bullet points, the criteria that define who will be excluded from this study:*

Response:

- Any patients without prostate biopsy or radical prostatectomy*

PROTOCOL TITLE:

-Any patients under 18
-Any female patients
-Any non-NY residents

6.3 Describe how individuals will be screened for eligibility. Upload all relevant screening documents with your submission (screening protocol, script, questionnaire). Identify who will certify that subjects meet eligibility requirements.

Response: NA

6.4 Indicate whether you are specifically recruiting or targeting any of the following special populations in your study using the checkboxes below. (You will be asked for additional information in Section 7 if you check any of these boxes)

Response: N/A

- Adults unable to consent
- Minors (under 18 years old)
- Pregnant women
- Prisoners

6.5 Indicate if you will include minorities (American Indians, Alaskan Native, Asian, Native Hawaiian, Pacific Islander, Black [not of Hispanic origin] and Hispanic) as Federal mandates require that you include minorities unless you can justify their exclusion

Response:

- Yes
- No, Justify:

6.6 Indicate whether you will include non-English speaking individuals in your study. Provide justification if you will specifically exclude non-English speaking individuals. Review <http://research.stonybrook.edu/human-subjects-standard-operating-procedures/policy-non-english-speakers-research-subjects> for SBU policy on inclusion of non-English speakers. Upload any translated materials (consent, questionnaires, etc).

Response: NA

7.0 Vulnerable Populations

PROTOCOL TITLE:

7.1 For research that involves pregnant women, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates , or Neonates of Uncertain Viability.

- Confirmed
 N/A: This research does not involve pregnant women.

7.2 For research that involves neonates of uncertain viability or non-viable neonates, review, complete and upload Supplemental Form A: Pregnant Women, Fetuses, Non-Viable Neonates, or Neonates of Uncertain Viability.

- Confirmed
 N/A: This research does not involve non-viable neonates or neonates of uncertain viability.

7.3 For research that involves prisoners, review, complete and upload Supplemental Form H: Prisoners

- Confirmed
 N/A: This research does not involve prisoners.

7.4 For research that involves minors (under 18 years), review, complete and upload Supplemental Form F: Minors

- Confirmed
 N/A: This research does not involve persons who have not attained the legal age for consent to treatments or procedures (“children”).

7.5 For research that involves adults who cannot consent for themselves, you will be asked additional information in Section 25 (“Informed Consent”)

- Confirmed
 N/A: This research does not involve this population

7.6 Consider if other specifically targeted populations such as students, employees of a specific firm, or educationally or economically disadvantaged persons are vulnerable. Provide information regarding their safeguards and protections, including safeguards to eliminate coercion or undue influence.

Safeguards include:

- N/A

8.0 Eligibility Screening

PROTOCOL TITLE:

8.1 Describe screening procedures for determining subjects' eligibility. Screening refers to determining if prospective participants meet inclusion and exclusion criteria.

 Include all relevant screening documents with your submission (e.g. screening protocol, script, questionnaires) as attachments.

Response:

N/A: There is no screening as part of this protocol.

9.0 Recruitment Methods

N/A: This is a records review only, and subjects will not be recruited. NOTE: If you select this option, please make sure that all records review procedures and inclusion/exclusion screening are adequately described in other sections, including date range for records that will be reviewed.

9.1 *Describe source of subjects: When, where, and how potential subjects will be recruited.*

NOTE: Recruitment refers to how you are identifying potential participants and introducing them to the study. These may include, but are not limited to: ResearchMatch.org, physician referral, Office of Clinical Trials database, West Campus departmental pools, reviewing medical charts, Research Participant Groups/help groups, advertising companies, call centers, in person announcements / presentations

Response: We will obtain de-identified patient records from the publicly available New York State SPARCS database.

9.2 *Describe how you will protect the privacy interests of prospective subjects during the recruitment process.*

NOTE: Privacy refers to an individual's right to control access to him or herself. This is NOT asking about confidentiality of data.

Response: NA. We will obtain de-identified patient records from the publicly available New York State SPARCS database.

9.3 *Identify/describe any materials that will be used to screen/recruit subjects and upload copies of these documents with the application. They may include, but are not limited to Telephone scripts for calling, flyers, Questionnaires, Posters, Letters or*

PROTOCOL TITLE:

written material to be sent or emailed, pamphlets, posted advertisements, email invitations.

Response: NA. We will obtain de-identified patient records from the publicly available New York State SPARCS database.

10.0 Research Procedures

Provide a detailed description of all research procedures or activities being performed on the research subjects. **This should serve as a blueprint for your study and include enough detail so that another investigator could pick up your protocol and replicate the research.** For studies that have multiple or complex visits or procedures, consider the addition of a schedule of events table in in your response. Be sure to include:

- Procedures being performed to monitor subjects for safety or to minimize risks.
- All drugs and devices used in the research and the purpose of their use, and their regulatory status

Response: Please see the attached protocol

10.1 Describe what data, including long-term follow-up, will be collected.

NOTE: For studies with multiple data collection points or long-term follow up, consider the addition of a schedule or table in your response.

Response: This study will collect de-identified records from the SPARCS database for patients who received a prostate biopsy or radical prostatectomy between 2005-2018. The study will collect data on patient risk factors (e.g. hypertension, congestive heart failure, diabetes mellitus, etc.), prostate cancer or non-cancer interventions (e.g. radical prostatectomy, radiation, or chemotherapy), and intervention complications (erectile dysfunction, obturator nerve injury, and deep venous thrombosis). Additionally, the study will measure long-term general outcomes such as 30 day mortality, repeat cancer surgery, and re-admissions, etc.

📎 List, and upload, any instruments or measurement tools used to collect data (e.g. survey, scripts, questionnaire, interview guide, validated instrument, data collection form).

Response: Please see attached protocol and coding sheets for diagnosis codes (ICD-9, ICD-10), imaging codes and procedure codes (CPT, HCPCS).

PROTOCOL TITLE:

10.2 Describe any source records that will be used to collect data about subjects (e.g. school records, electronic medical records) and include the date range for records that will be accessed..

Response: We will obtain de-identified patient records from the publicly available New York State SPARCS database from 2005-2018.

10.3 Indicate whether or not the results for individual subjects, such as results of investigational diagnostic tests, genetic tests, or incidental findings will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe how these will be shared.

Response: NA

10.4 Indicate whether or not generalized study results will be shared with subjects or others, and if so, describe how these will be shared.

Response: NA

11.0 Study Timelines

11.1 Describe the anticipated duration of the study needed to enroll all study subjects.

Response: The SPARCS database already contains the patient data. Therefore, no specific time needs to be spent enrolling subjects. Preliminary data extraction from the SPARCS database is expected to occur from August-September. Over September-January - revised database reports. From January-April -manuscript writing.

11.2 Describe the duration of an individual subject's participation in the study. Include length of study visits, and overall study follow-up time.

Response: NA

11.3 Describe the estimated duration for the investigators to complete this study (i.e. all data is collected and all analyses have been completed).

Response: NA

12.0 Research Setting

12.1 Describe all facilities/sites/locations where you will be screening and conducting research procedures. Include a description of the security and privacy of the facilities (e.g. locked facility, limited access, privacy barriers). Facility, department, and type of room are relevant. Do not abbreviate facility names.

Example: "A classroom setting in the Department of Psychology equipped with a computer with relevant survey administration software," "The angiogram suite at Stony Brook University Hospital, a fully accredited tertiary care institution within New York State with badge access,"

Response: The study will only use de-identified data files, so Dr. Fitzgerald, Dr. Shroyer, Dr. Yang, Dr. Li, and other team members can use office, university, or personal computers for the analysis and storage of data files. This study is classified as "not human subjects research," so no special precautions for record privacy and security are required.

12.2 For research procedures being conducted, for this study, external to SBU and its affiliates (e.g., in schools, out-of-state, internationally, etc.) describe:

- Site-specific regulations or customs affecting the research
- The composition and involvement of any community advisory board
- Local scientific and ethical review structure outside the organization.
- Local issues affecting the research and rights of research subjects.

NOTE: This question is not referring to multi-center research. If this research is being conducted internationally, Supplemental Form C must be completed and uploaded.

Response:

- N/A: This study is not conducted outside of SBU or its affiliates.

13.0 Resources and Qualifications

13.1 The Principal Investigator (PI) must confirm, in consultation with Chair and Dean as applicable, that adequate resources are present to conduct and complete the study compliantly and safely. Specifically:

NO YES The proposed subject population(s) are available in sufficient numbers to meet the study requirements

NO YES Sufficient funds are available to conduct and complete the study compliantly and safely

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- NO YES *The PI and study team have sufficient time to conduct and complete the study compliantly and safely*
- NO YES *The PI has determined that the named study team is qualified to conduct the research compliantly and to monitor the safety and welfare of the enrolled research subjects effectively.*
- NO YES *The PI ensures that the study team is fully aware of his/her involvement in this study and the details of the study protocol*
- NO YES *The PI ensures that the study teams will only be involved in research procedures for which they have been trained, and are currently certified and/or licensed, if required..*

13.2 *Describe the availability of medical or psychological resources that subjects might need as a result of anticipated consequences of the human research, if applicable. (e.g. "on-call availability of a counselor or psychologist for a study that screens subjects for depression").*

Response: NA

13.3 *Describe your process to ensure that all study team members are updated on the progress of the research and the regulatory requirements (including enrolled subjects, unanticipated problems etc.)*

Response: The team shares progress during weekly meetings as virtual calls. Preliminary reports, protocols, and literature reviews are shared amongst the team via email.

14.0 Other Approvals

14. *List approvals that will be obtained prior to commencing the research (e.g., University Hospital sign-offs per the UH Application, Cancer Center Scientific review, school, external site, funding agency, laboratory, Radiation Safety, IBC, SCRO, IACUC, RDRC).*

Response: NA. This study does not require additional approvals because it uses a de-identified database and thus is classified as "not human subjects" research.

- N/A: This study does not require any other approvals.

15.0 Provisions to Protect the Privacy Interests of Subjects

15.1 *Describe how you will protect subjects' privacy interests during the course of this research and any steps you will take to make the subject feel at ease.*

PROTOCOL TITLE:

NOTE: Privacy refers to an individual's desire/right to control access to or to place limits on whom they interact with or whom they provide personal information. Privacy applies to the person. Confidentiality refers to how data collected about individuals for the research will be protected by the researcher from release. Confidentiality applies to the data.

Examples of appropriate responses include: "participant only meets with a study coordinator in a private office setting where no one can overhear", or "the participant is reminded that they are free to refuse to answer any questions that they do not feel comfortable answering."

Response: NA. This study should be classified as "not human subjects" research.

16.0 Data Management and Analysis

16.1 Describe the data analysis plan, including any statistical procedures. This section applies to both quantitative and qualitative analysis.

Response: This protocol describes a retrospective observational cohort study using the SPARCS Health Facts publicly available dataset. The SBU SOM Bioinformatics Department and Biostatistics Core Lab will assist us to match the SPARCS database to our attached protocol's coding lists, to create a study-specific de-identified database of prostate biopsy/prostatectomy patients. The Bioinformatics and Biostatistics team members will also provide the descriptive statistics for the study as well as providing a study-database for future analyses. For this study's primary hypotheses related to geographic variability and trends over time, a p-value of 0.05 will be used. All secondary and tertiary analyses, as well as all exploratory analyses, will use a p-value of < 0.01. SAS version 9.4 will be used to complete all the necessary statistical tests.

16.2 If applicable, provide a power analysis.

NOTE: This may not apply to certain types of studies, including chart/records reviews, survey studies, or observational studies. This question is asked to elicit whether the investigator has an adequate sample size to achieve the study objectives and justify a conclusion.

Response: NA

17.0 Confidentiality

A. Confidentiality/Security of Study Data

Describe the local procedures for maintenance of security and confidentiality of **study data and any records that will be reviewed for data collection.**

PROTOCOL TITLE:

17.1 Where and how will all data and records be stored? Include information about: password protection, encryption, physical controls, authorization of access, certificates of confidentiality, and separation of identifiers and data, as applicable. Include physical (e.g. paper) and electronic files.

Response: NA. This study should be classified as "not human subjects" research.

17.2 How long will the data be stored?

Response: NA

17.3 Who will have access to the data?

Response:

Principal Co-Investigators: John P. Fitzgerald, MD, A. Laurie Shroyer, PhD

Co-Investigators: Jie Yang, PhD, Xiaoning Li, PhD, Aurora Pryor, MD

Trainees: Mansi Chandra and Seth Greenspan

17.4 Who is responsible for receipt or transmission of the data?

Response: John P. Fitzgerald, MD, A. Laurie Shroyer, PhD, MSHA

17.5 How will the data be transported/transmitted?

Response: Dr. Yang will transmit the data to Dr. Shroyer and Dr. Fitzgerald via an email link to a shared protected drive. Dr. Yang will download and analyze the data.

B. Confidentiality of Study Specimens

Describe the local procedures for maintenance of confidentiality of study specimens.

N/A: No specimens will be collected or analyzed in this research.
(Skip to Section 18.0)

PROTOCOL TITLE:

17.6 Where and how will all specimens be stored? Include information about: physical controls, authorization of access, and labeling of specimens, as applicable.

Response:

17.7 How long will the specimens be stored?

Response:

17.8 Who will have access to the specimens?

Response:

17.9 Who is responsible for receipt or transmission of the specimens?

Response:

17.10 How will the specimens be transported?

Response:

18.0 Provisions to Monitor the Data to Ensure the Safety of Subjects

N/A: This study is not enrolling subjects OR is limited to records review procedures only OR is a minimal risk study

18.1 Describe the plan to evaluate the data periodically regarding both harms and benefits to determine whether subjects remain safe. The plan might include establishing a data safety monitoring committee and a plan for reporting data monitoring committee findings to the IRB and the sponsor.

Response: NA. This study should be classified as "not human subjects" research.

18.2 Describe what data are reviewed, including safety data, untoward events, and efficacy data.

Response: NA. This study should be classified as "not human subjects" research.

18.3 Describe any primary or secondary safety endpoints.

Response: NA. This study should be classified as "not human subjects" research.

PROTOCOL TITLE:

18.4 Describe how the safety information will be collected (e.g., with case report forms, at study visits, by telephone calls with participants).

Response: NA. This study should be classified as "not human subjects" research.

18.5 Describe the frequency of safety data collection, including when safety data collection starts.

Response: NA. This study should be classified as "not human subjects" research.

18.6 Describe who will review the safety data.

Response: NA. This study should be classified as "not human subjects" research.

18.7 Describe the frequency or periodicity of review of cumulative safety data.

Response: NA. This study should be classified as "not human subjects" research.

18.8 Describe the statistical tests for analyzing the safety data to determine whether harm is occurring.

Response:

NA. This study should be classified as "not human subjects" research.

18.9 Describe any conditions that trigger an immediate suspension of the research.

Response: NA. This study should be classified as "not human subjects" research.

19.0 Withdrawal of Subjects

N/A: This study is not enrolling subjects. This section does not apply.

19.1 Describe anticipated circumstances under which subjects may be withdrawn from the research without their consent.

Response: NA. This study should be classified as "not human subjects" research.

19.2 Describe any procedures for orderly termination.

NOTE: Examples may include return of study drug, exit interview with clinician.

Include whether additional follow up is recommended for safety reasons for physical or emotional health.

Response: NA. This study should be classified as "not human subjects" research.

PROTOCOL TITLE:

19.3 Describe procedures that will be followed when subjects withdraw from the research, including retention of already collected data, and partial withdrawal from procedures with continued data collection, as applicable.

Response: NA. This study should be classified as "not human subjects" research.

19.4 Describe what will happen to data already collected.

Response: NA. This study should be classified as "not human subjects" research.

20.0 Risks to Subjects

20.1 In your opinion, what is the overall risk (physical and nonphysical) to research subjects in this study (minimal, greater than minimal or unknown)

Response: This study uses de-identified patient records from a database. It should be classified as "not human subjects" research.

20.2 Describe if any subjects are withdrawn from therapeutic procedures or drugs (e.g., washout periods) prior to, or during, their participation in the study.

Response: NA. This study should be classified as "not human subjects" research.

20.3 List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to their participation in the research. Consider physical, psychological, social, legal, and economic risks. Include a description of the probability, magnitude, duration, and reversibility of the risks.

NOTE: Breach of confidentiality is always a risk for identifiable subject data.

Response: NA. This study should be classified as "not human subjects" research.

20.4 Describe procedures performed to minimize the probability or magnitude of risks, including procedures being performed to monitor subjects for safety.

Response: NA. This study should be classified as "not human subjects" research.

20.5 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.

PROTOCOL TITLE:

Response: NA. This study should be classified as "not human subjects" research.

20.6 Indicate which research procedures, if any, may have risks to an embryo or fetus should the subject be or become pregnant.

Response: NA. This study should be classified as "not human subjects" research.

N/A

20.7 If you responded to 20.6 that there are such risks, how will you minimize the risk of a pregnancy occurring during the course of the study? (Select all that apply)

- Counseling on birth control and /or abstinence
- Pregnancy test during the study
- Pregnancy test prior to initiation of the study
- Other _____
- N/A

20.8 If applicable, describe possible risks to others who are not subjects.

Response: This study uses de-identified patient records from a publicly available database. It poses no risk to any patients or others.

21.0 Potential Benefits to Subjects

21.1 Describe the potential benefits that individual subjects may experience by taking part in the research. Include the probability, magnitude, and duration of the potential benefits.

Response: NA

21.2 Indicate if there is no direct benefit.

NOTE: Compensation cannot be stated as a benefit.

Response: NA

Indicate if there is a potential benefit to others, future science or society.

Response: This study will examine geographic and temporal variations in the screening, treatment, and surgery of primarily prostate cancer patients with a secondary focus on non-prostate cancer diagnoses after biopsy. As a result, short- and long-term patient outcomes will be

PROTOCOL TITLE:

examined. This study will improve society's understanding of disparities in prostate diseases and guide improved monitoring, treatment, and distribution of resources.

22.0 Compensation for Research-Related Injury

N/A: The research procedures for this study do not present risk of research related injury. This section does not apply.

22.1 If the research procedures carry a risk of research related injury, describe the available compensation to subjects in the event that such injury should occur.

Response: NA. This study should be classified as "not human subjects" research.

22.2 Provide a copy of contract language, if any, relevant to compensation for research related injury.

NOTE: If the contract is not yet approved at the time of this submission, submit the current version here. If the contract is later approved with different language regarding research related injury, you must modify your response here and submit an amendment to the IRB for review and approval.

Response: NA

23.0 Economic Burden to Subjects

23.1 Describe any costs that subjects may be responsible for because of participation in the research.

NOTE: Some examples include transportation or parking.

Response: NA. This study should be classified as "not human subjects" research.

N/A: This study is not enrolling subjects, or is limited to records review procedures only. This section does not apply.

24.0 Compensation for Participation

N/A: There is no compensation for participation. This section does not apply.

24.1 Describe the amount/nature and timing/scheduling of any compensation to subjects, including monetary, course credit, or gift card compensation. Describe any prorated payments based on participation.

Response: NA. This study should be classified as "not human subjects" research.

PROTOCOL TITLE:

24.2 *Justify the amount and scheduling of payments described above to ensure that they are reasonable and commensurate with the expected contributions of the participant. If multiple visits are involved payments should be prorated.*

Note: If using West Campus Departmental pools, participation in studies may be offered for credit in class but students MUST be given other options for fulfilling the research component that are comparable in terms of time, effort, and education benefit. Please list alternative activities

Response: NA

25.0 Informed Consent

25.1 *Will you be obtaining consent from subjects?*

- Yes** *(If yes, Provide responses to each question in this Section, and upload your consent documents where indicated in the electronic submission system)*
- No** *(If no, Skip to next section)*

25.2 *Describe how the capacity to consent will be assessed for all subjects. Review for guidance <http://research.stonybrook.edu/human-subjects-standard-operating-procedures/determining-potential-adult-subjects-ability-consent>:*

Response: NA. This study should be classified as "not human subjects" research.

25.3 *Describe the consent process that will be conducted to ensure that subject is fully informed regarding study details and subject rights. Include where the consent process will take place, with consideration of the need to protect the subject's right to privacy.*

Response: NA. This study should be classified as "not human subjects" research.

25.4 *Describe how you will ensure that subjects are provided with sufficient time to consider taking part in the research study. Detail if there is there any time period expected between informing the prospective subject and obtaining the consent.*

NOTE: It is respectful to the prospective subject to ensure that sufficient time is given to have their questions answered and to consider their participation

Response: NA. This study should be classified as "not human subjects" research.

25.5 *Describe the process to ensure ongoing consent, defined as a subject's willingness to continue participation for the duration of the research study.*

PROTOCOL TITLE:

Response: NA. This study should be classified as "not human subjects" research.

Non-English Speaking Subjects

N/A: This study will not enroll Non-English speaking subjects.

25.6 *Indicate which language(s) other than English are likely to be spoken/understood by your prospective study population or their legally authorized representatives.*

Response: NA. This study should be classified as "not human subjects" research.

25.7 *If subjects who do not speak English will be enrolled, describe the process to consent the subjects, as well as the process to be used to ensure their understanding of research procedures throughout the conduct of the study. Review SOP's section 17.8 for important policies in this regard: <http://research.stonybrook.edu/human-subjects-standard-operating-procedures/policy-non-english-speakers-research-subjects> for SBU policy on inclusion of non-English speakers.*

Response: NA. This study should be classified as "not human subjects" research.

Adults Unable to Consent

N/A: This study will not enroll adults unable to consent.

25.8 *Justify why it is necessary to include adult subjects who are unable to consent.*

Response: NA. This study should be classified as "not human subjects" research.

25.9 *Describe how you will identify Legally Authorized Representatives (LAR) for the subjects that will be consistent with the NYS Family Health Care Decisions Act (FHCDA; see <http://research.stonybrook.edu/human-subjects-standard-operating-procedures/definitions-2>). Indicate why it is necessary to include subjects who are unable to consent.*

Note: For research conducted outside of New York State, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the research.

Response: NA. This study should be classified as "not human subjects" research.

25.10 *Describe the process for obtaining assent from the adult subjects. Indicate whether assent will be obtained from all, some, or none of the subjects. If some, indicate which adults will be required to assent and which will not.*

PROTOCOL TITLE:

Response: NA. The records from this study will be obtained from a de-identified publicly available database. There is no risk to patients and thus requires no assent. This study should be classified as "not human subjects" research.

If assent will not be obtained from some or all subjects, provide an explanation of why not.

Response: NA. This study should be classified as "not human subjects" research.

25.11 Describe whether assent of the adult subjects will be documented and the process to document assent.

Response: NA. This study should be classified as "not human subjects" research.

25.12 Describe how you will obtain consent from a subject to use their data if they later become capable of consent. How will competence be assessed and by whom?

Response: NA. This study should be classified as "not human subjects" research.

26.0 Waiver or Alteration of Consent Process

Complete this section if:

- Informed consent will not be obtained at all
 - Informed consent will be obtained, but not documented, or
 - consent will be obtained, but not all required information will be disclosed (e.g., in deception research)
- N/A:** A waiver or alteration of consent is not being requested.

26.1 Review, complete, and upload SUPPLEMENTAL FORM G: Consent Waivers

Confirmed

26.2 If the research involves a waiver of the consent process for planned emergency research, please contact the Office of Research Compliance for guidance regarding assistance in complying with federal regulations governing this activity (see: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=50.24>)

27.0 Multi-Site Research (Multisite/Multicenter Only)

N/A: This study is not an investigator-initiated, multi-site study. This section does not apply.

PROTOCOL TITLE:

27.1 *If this is a multi-site study where SBU is the lead site and/or the IRB of record, describe the processes to ensure communication among sites. Include:*

- *All sites have the most current version of the IRB documents, including the protocol, consent document, and HIPAA authorization.*
- *All required approvals have been obtained at each site (including approval by the site's IRB of record).*
- *All modifications have been communicated to sites, and approved (including approval by the site's IRB of record) before the modification is implemented.*
- *All engaged participating sites will safeguard data as required by local information security policies.*
- *All local site investigators conduct the study appropriately.*
- *All non-compliance with the study protocol or applicable requirements will be reported in accordance with local policy.*

Response: NA

27.2 *Describe the method for communicating to engaged participating sites:*

- *Problems*
- *Interim results*
- *Study closure*

Response: NA

27.3 *Indicate and statistically justify the total number of subjects that will be enrolled or records that will be reviewed **across all sites**.*

Response: NA

28.0 Banking Data or Specimens for Future Unspecified Use

N/A: This study is not storing data or specimens for research outside the scope of the present protocol. This section does not apply.

IMPORTANT: If you are proposing to bank specimens for future use, you may be subject to licensure requirements under the NYS Department of Health, and must be covered under the SBU license. See SOPs at <http://research.stonybrook.edu/human-subjects-standard-operating-procedures/data-tissue-registries-banks>

PROTOCOL TITLE:

28.1 If data will be banked for research outside of the scope of the present protocol, describe where the data will be stored, how long they will be stored, how will they be accessed, and who will have access to the data

NOTE: Your response here must be consistent with the information provided to subjects in your Consent Documents

Response: NA

28.2 If specimens will be banked (stored) for research outside of the scope of the present protocol, describe where the specimens will be stored, how long they will be stored, identifiers that will be associated with each specimen, how will they be accessed, and who will have access to the specimens

NOTE: Your response here must be consistent with the information provided to subjects in your Consent Documents

Response: NA

28.3 Describe the procedures to release banked data and/or specimens for future uses, including: the process to request a release, approvals required for release, who can obtain data or specimens, and the data to be provided with specimens.

Response: NA

29.0 Drugs and Devices

N/A: This study does not involve drugs or devices. This section does not apply.

29.1 Does this study involve use of radiopharmaceuticals? Yes No

29.2 For investigational devices (including marketed devices being used off label), Provide the following information below:

Where will the device(s) be stored? Note that the storage area must be within an area under the PI's control

Describe the security of the storage unit/facility

Provide full detail regarding how the dispensing of the device(s) will be controlled (accountability of removal/return of used devices, and disposition of remaining devices at the conclusion of the investigation) and documented (accounting records/logs)

Response: NA

PROTOCOL TITLE:

29.3 *For investigational drugs (including humanitarian use devices, and marketed drugs being used off label), will the services of the Investigational Drug Pharmacy be used for storage, dispensing, accounting the drug (required for research conducted at UH, HSC, Cancer Center, and Ambulatory Surgery Center)?*

- Yes**
- No** →PI Provide the following information below:
- *Where will the drugs/biologics be stored? Note that the storage area must be within an area under the PI's control*
 - *Describe the security of the storage unit/facility:*
 - *Provide full detail regarding dispensing of the drugs(s), how labeled, controlled (accountability, disposition of unused drug at the conclusion of the investigation) and documented (accounting records/logs):*

Response: NA

30.0 Sharing of Results with Subjects

30.1 *Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physicians) and if so, describe how it will be shared.*

Response: The results will be compiled into a manuscript and submitted to a peer-reviewed journal, most likely in the fields of urology or surgery. The study findings may also be presented at national or international conferences pending journal's embargo. The records from the study will be de-identified and come from a publicly available database; therefore, no results will be shared directly with subjects, and this study should be considered "not human subjects" research.