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TITLE: Long-Term Outcomes of Localized Prostate Cancer Survivors

PRINCIPAL INVESTIGATOR: Ronald C. Chen, MD, MPH

CONTRACTING ORGANIZATION: University of Kansas Medical Center

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13. SUPPLEMENTARY NOTES

14. ABSTRACT

Background: Patients with localized prostate cancer face a confusing decision among many options. The standard options in current guidelines range from active surveillance, surgery, and radiation therapy (RT, various forms). Surgery and RT have evolved/improved significantly. Patients need long-term outcomes (quality of life, cancer control/recurrence, and survival) of modern treatments in order to help them make a treatment decision; however, these data do not exist. The current literature includes outcomes of older surgery and RT modalities no longer commonly used today, or short-term outcomes of modern treatments. This means that patients today do not have the information they need to make an informed decision, and must use outdated data of older prostate cancer treatments. In 2010, the study team worked with a national group of stakeholders including patients to design this study to provide data that are directly relevant to patients and stakeholders. With funding from AHRQ, PCORI and NCI, we enrolled a population-based cohort of newly-diagnosed patients, and have followed them prospectively/annually. Here, we propose to study 8-10 year outcomes.

Hypothesis/Objective: The overall objective of this study is to continue studying an established population-based cohort of localized prostate cancer patients to yield up to 10 years of long-term outcomes among different modern treatment options. The central hypothesis is that long-term quality of life (QOL), treatment-related morbidity, cancer control and survival outcomes differ among the treatment options. Because short-term outcomes are not sufficient in prostate cancer, this proposed study represents significant “value added” to the prior funding which built this cohort, and will provide meaningful results that directly address important current knowledge gaps.

Specific Aims: 1) Directly compare patient-reported outcomes within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and radiation therapy; this will include bowel, urinary and sexual QOL; prostate cancer anxiety; and treatment regret. 2) Directly compare sexual, urinary and bowel morbidity requiring medical intervention and hospitalizations within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT. 3) Directly compare cancer recurrence and survival within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT.

Study Design: The North Carolina Prostate cancer Comparative Effectiveness & Survivorship Study (NC ProCESS) enrolled a unique, population-based cohort of 1,519 newly diagnosed localized prostate cancer patients across all 100 counties of North Carolina from 2011-2013. Patients have been prospectively followed since enrollment with QOL surveys and abstraction of medical records. The current study proposes to collect data at 8-10 years of follow-up, and create a comprehensive data set that includes these data linked with cancer registry data and insurance claims from Medicare, Medicaid and private insurers to examine the Aims. We are not aware of the existence of another fully prospective, population-based prostate cancer cohort; or another data set that includes these comprehensive, detailed, linked data elements to allow examination of these outcomes.

Impact: This study directly addresses a highest priority research topic identified by the National Academy of Medicine, and studies outcomes most important for patients and other stakeholders. Thus, this study is expected to produce results that are clinically relevant and immediately usable by patients and clinicians to inform treatment decision-making. NC ProCESS is recognized as a well-conducted and high impact study. Our short-term (2-year) published results were made into decision aids for patients and physicians, incorporated into the most recent/2018 ASCO prostate cancer guidelines, and cited in ASCO’s Annual Progress Report Against Cancer as one of the highest impact studies in 2017. We expect the long-term outcomes resulting from this proposed study will make a similarly major (and possibly greater) impact. Results from this study will immediately help advance prostate cancer patient care by impacting treatment decisions. The long-term impact from helping patients make informed decisions is improved quality of life (from reducing overtreatment and post-treatment regret), thus enhancing the well-being of all patients, and reducing the mortality from this disease. We will work with national prostate cancer organizations to directly disseminate study findings to patients and their families. This study directly addresses the PCRP Overarching Challenges, “Improve the quality of life for survivors of prostate cancer” and “Reduce lethal prostate cancer in African American, Veterans, and other high-risk populations”.

15. SUBJECT TERMS

NONE LISTED

16. SECURITY CLASSIFICATION OF:			**17. LIMITATION OF ABSTRACT**	**18. NUMBER OF PAGES**	**19a. NAME OF RESPONSIBLE PERSON** USAMRDC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	Unclassified	20	**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified			

TABLE OF CONTENTS

1. **INTRODUCTION:** *Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.*

Patients with localized prostate cancer face a confusing decision among many options. The standard options in current guidelines range from active surveillance, surgery, and radiation therapy (RT, various forms). Surgery and RT have evolved/improved significantly. Patients need long-term outcomes (quality of life, cancer control/recurrence, and survival) of modern treatments in order to help them make a treatment decision; however, these data do not exist. The current literature includes outcomes of older surgery and RT modalities no longer commonly used today, or short-term outcomes of modern treatments. This means that patients today do not have the information they need to make an informed decision, and must use outdated data of older prostate cancer treatments. In 2010, the study team worked with a national group of stakeholders including patients to design this study to provide data that are directly relevant to patients and stakeholders. With funding from AHRQ, PCORI and NCI, we enrolled a population-based cohort of newly-diagnosed patients, and have followed them prospectively/annually. Here, we propose to study 8-10 year outcomes.

2. **KEYWORDS:** *Provide a brief list of keywords (limit to 20 words).*

Prostate cancer, cancer registry, active surveillance, quality of life, cancer outcomes, patient reported outcomes.

3. **ACCOMPLISHMENTS:** *The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.*

What were the major goals of the project?
List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

Specific Aim 1: Directly compare QOL and decisional regret within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and radiation therapy (RT).	**Month**	**Personnel**	**Site (KUMC/UNC)**	**Percent Complete**
Major Task 1: Complete patient surveys				
Subtask 1: IRB modification to allow extended follow-up of NC ProCESS cohort (University of North Carolina IRB). (Month 1)	1	Dr. Chen	KUMC & UNC	100%
Subtask 2: Modify study databases, including patient tracking database to include new data elements for this proposed study. Obtain USAMRDC ORP HRPO regulatory approval.	1-3	Dr. Chen	UNC	100%
Subtask 3: First round of annual survey	3-14	Dr. Chen	UNC	100%

Subtask 4: Second round of annual survey	15-26	Dr. Chen	UNC	100%
Subtask 5: Data analysis	7-30		KUMC	50%
Milestone(s) Achieved: By the end of month 26, all patients will have patient-reported outcomes data collected at 8-10 years of total follow-up to provide long-term results. By the end of month 30, data analysis will be completed for Specific Aim 1.				In progress
Specific Aim 2: Directly compare sexual, urinary and bowel morbidity requiring medical intervention within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT.				
Major Task 2: Linkage of NC ProCESS patient cohort data with data from the NC Central Cancer Registry and insurance claims				
Subtask 1: Data linkage by UNC CIPHR core facility staff	25-30	Dr. Kuo	UNC	100%
Subtask 2: Creation of analytic data set from linked data	31	Dr. Katz	KUMC	100%
Subtask 3: Data analysis	31-36	Dr. Katz	KUMC	50%
Milestone(s) Achieved: Completion of Aim 2 will provide data on long-term treatment-related morbidity that require medical intervention.				In progress
Specific Aim 3: Directly compare cancer recurrence and survival within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and RT.				
Major Task 3: Assess prostate cancer recurrence				
Subtask 1: Collect patient medical records	16-27	Dr. Chen	UNC	100%
Subtask 2: Abstract medical records to assess prostate cancer recurrence	16-30	Dr. Chen	UNC	100%
Subtask 3: Data analysis	31-36	Dr. Katz	KUMC	100%
Milestone(s) Achieved: Completion of Major Task 3 will provide data on long-term cancer control and recurrence rates for patients in different initial management groups				Complete
Major Task 4: Assess survival and mortality				

Note, this is accomplished by the data linkage step described above (Major Task 2, Subtask 1). Survival/mortality information is contained in the NC Central Cancer Registry data	21-24	Dr. Kuo	UNC	100%
Subtask 4: Data analysis	25-30	Dr. Katz	KUMC	50%
Milestone(s) Achieved: Completion of Major Task 4 will provide data on overall survival/mortality for patients in different initial management groups				In progress

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

1) Major Activities: In Year 1 of the award period, PI Dr. Ronald Chen transitioned from the University of North Carolina at Chapel Hill (UNC) to the University of Kansas Medical Center having accepted a position as chair of the Department of Radiation Oncology. Phone surveys with participants continued with little disruption and we were able to complete 95% of year 1 follow-up surveys. Regulatory activities included obtaining IRB approval to continue up to 10 years of follow-up (surveying and medical records collection) with the NC ProCESS cohort; establishing an IRB Reliance Agreement with KUMC for study team members located at KUMC; and obtaining USAMRDC ORP HRPO regulatory approval. Programming updates were made to the Computer-Assisted Telephone Interview (CATI) software (for software-guided telephone interviews) and the web-based tracking system.

During Year 2, annual telephone surveys to collect participants' prostate-specific quality of life, anxiety, and assessment of treatment decision regret continued: we completed the first round of annual follow-up surveys (8 years after treatment for prostate cancer); we completed approximately 50% of the second annual follow-up surveys (9 years post-treatment), and initiated the final (10 years post-treatment) follow-up survey to study participants. Processes for initiating the survey included programming updates to the Computer-Assisted Telephone Interview (CATI) software (for software-guided telephone interviews) and the web-based tracking system. We continued to provide gift cards to participants who completed annual follow-up surveys and returned medical records release and HIPAA authorization forms. Additionally in Year 2, we continued collecting current medical records for approximately a third of enrolled participants and began abstracting clinical variables (e.g., documented prostate cancer recurrence and associated salvage treatment). To reduce attrition of participants enrolled in our study, we developed and mailed a newsletter to all currently enrolled participants with updates on the study progress. Finally, the process for linking the NC ProCESS patient cohort with claims data (Major Task 2) began. Data use agreement applications were submitted to the applicable data owners for their review and approval and regulatory processes were implemented.

During Year 3 of the award period, annual telephone surveys with the research participants continued. We completed the first and second round of annual follow-up surveys (8 years & 9 years after treatment for prostate cancer). The final follow-up telephone survey (10 years post-treatment) continued in Year 3 of the award period with surveys being finalized for approximately two-thirds of the cohort. Annual telephone surveys include questions about participants' prostate-specific quality of life, anxiety, and assessment of treatment decision regret. To reduce attrition of participants enrolled in our study, incentives (gift cards) were provided to enrolled participants for completing annual follow-up telephone surveys and signing and returning medical record release forms and HIPAA authorizations.

We completed collection of medical records for the majority of the cohort. We completed abstracting clinical variables from medical records (e.g., documented prostate cancer recurrence and associated salvage treatment).

Also in Year 3, staff from the UNC Lineberger Comprehensive Cancer Center's Cancer Information & Population Health Resource (CIPHR) successfully linked the NC ProCESS primary patient data with more recent cancer registry and insurance claims data to provide long-term outcomes. CIPHR specializes in using big data (e.g., cancer registry and claims data) for patient-centered outcomes research and staff have extensive experience linking claims data with cancer registry data and primary patient data. CIPHR maintains up-to-date data holdings including a decade of insurance claims data from private insurers, Medicare, and Medicaid – and links these claims data to North Carolina Central Cancer Registry data on a yearly basis, emulating the NCI's SEER-Medicare data resource. CIPHR includes data for patients younger and older than 65, reflecting 85% of NC cancer cases.

2) Specific Objectives: The North Carolina Prostate cancer Comparative Effectiveness & Survivorship Study (NC ProCESS) is a prospective, population-based cohort designed specifically to examine the impact of different modern treatments on the lives of patients with early (localized, non-metastatic) prostate cancer. Prior funding allowed assembly of the NC ProCESS cohort and short-term follow-up. The *overall objective* of this award was to continue following this established cohort to yield up to 10 years of follow-up to examine long-term patient-reported outcomes (PRO; including quality of life, QOL), treatment-related morbidity, cancer control and survival among different treatment options.

Specific objectives of the research study are to directly compare patient-reported quality of life outcomes and decisional regret; sexual, urinary and bowel morbidity requiring medical intervention and hospitalizations; and cancer recurrence and survival within 10 years of follow-up in men managed by initial active surveillance, radical prostatectomy and radiation therapy (RT).
We successfully completed the data collection and linkage subtasks and will begin data analyses to meet these objectives.

3) Significant Results: At the time of this report, we are still conducting data analyses to fully assess study outcomes (sexual, urinary, and bowel quality of life and treatment-related morbidity; prostate cancer recurrence and survival; and decisional regret). Data analyses will continue beyond the award period for this study; any published findings will acknowledge the Department of Defense as a sponsor of the research, referencing this award.

Among 1120 men who responded to survey questions on decisional regret, a total of 390 (34.8%) expressed regret about their treatment choice(s) within 8-10 years of follow-up. Of the 390 with decisional regret, 102 (26.2%) reported regret within the first year, 209 (53.6%) within three years, and 299 (76.7%) within five years of follow-up. Still, 21 of 390 (5.4%) men didn't express regret

about their treatment choice until the ninth or tenth year of follow-up, suggesting that some men may not experience regret until well after they made their treatment decision. Further, that over one-third of men expressed regret about their treatment decision within 10 years of follow-up is a clear indication that decision making practices and resultant treatment choices are not ideal for a notable proportion of men with localized prostate cancer, and that improvements in decision-making processes are needed to reduce the frequency of decisional regret.

When looking at decisional regret by initial treatment choice, approximately 29.2%, 39.5%, 35.7%, and 29.9% of men expressed regret within 8-10 years of follow-up after choosing active surveillance, radical prostatectomy (surgery), external beam radiation, or brachytherapy, respectively. The timing in which men reported regret was similar across the different treatment choices, with 20-30% having reported regret within the first year, 50-60% by the third year, and approximately 5% reporting regret for the first time in the ninth- or tenth-year survey.

In initial analyses, notable differences in decisional regret by patient race have been observed, with Black men being more likely to report decisional regret than White men. Overall, approximately 45.2% (123/272) of Black men and 30.7% (249/810) of White men reported decisional regret within 8-10 years of follow-up. During the first year of follow-up, about 13.7% of Black and 8.1% of White men reported regret, and by the fifth year of follow-up, the cumulative percentage of men who had reported regret increased to 38.4% and 22.4%, respectively. Approximately 3% (4/123) of Black men and 6% (16/249) of White men first expressed regret in the ninth- or tenth-year survey.

Among men who received initial treatment with brachytherapy, external beam radiation, or surgery, 196 men treated with radiation (brachytherapy and/or external beam) and 451 men treated with surgery had sufficient data to evaluate biochemical prostate cancer recurrence (i.e., recurrence defined by elevations in prostate specific antigen following receipt of treatment; dates and values of PSA tests were abstracted from patient medical records). Overall, 82 of 647 (12.7%) men had evidence of biochemical recurrence within 10 years of follow-up, including 12.8% of men treated with radiation (12.6% of men treated with external beam; 13.2% with brachytherapy) and 12.6% treated with surgery. Among men treated with radiation, approximately 11.5% (7/61), 10.1% (9/89), and 17.6% (6/34) of those with low, intermediate, and high-risk prostate cancer experienced biochemical recurrence over follow-up. Biochemical recurrence occurred in approximately 9.3% (15/161), 11.9% (23/193), and 29.3% (17/58) of men treated with surgery who had low, intermediate, and high-risk prostate cancer, respectively. Since biochemical recurrence is defined differently for patients treated with radiation versus surgery (i.e., different PSA criteria are used), and because there may be differences in the frequency of post-treatment PSA testing by type of therapy, which could create surveillance bias, the rates of biochemical recurrence should not be compared between radiation and surgery groups.

In initial analyses, no differences in biochemical recurrence were observed by race. Among patients treated with surgery, 44 of 337 (13.1%) White men and 10 of 100 (10%) Black men were identified as having biochemical recurrence of prostate cancer during follow-up. Among patients treated with external beam radiation or brachytherapy, 14 of 133 (10.5%) White men and 11 of 60 (18.3%) Black men were determined to have experienced biochemical recurrence. To date, only risk group has been identified as a statistically significant predictor of biochemical recurrence – and only so among patients treated with surgery. Patient rurality is also a potential factor for biochemical recurrence among those men who received surgery; approximately 17.9% (19/106) of men in a rural area of North Carolina experienced biochemical recurrence compared to just 10.6% (35/331) of men from urban areas, though this difference is not statistically significant (difference 7.3%, 95% confidence interval = -0.7% to 15.4%). The absence of significant differences in biochemical recurrence by other patient characteristics (e.g., race) is likely due in part to 1) the

smaller sample size of participants with sufficient data to examine biochemical recurrence, and 2) the relatively low (less than 15%) rate of biochemical recurrence observed.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Nothing to Report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

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.

Not Applicable.

4. **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?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Nothing to Report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Nothing to Report

What was the impact on technology transfer?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:

- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:

- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*

- *improving social, economic, civic, or environmental conditions.*

Nothing to Report

5. **CHANGES/PROBLEMS:** *The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official 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.

Nothing to Report

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.

Nothing to Report

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
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Nothing to Report

Significant changes in use or care of vertebrate animals

Nothing to Report

Significant changes in use of biohazards and/or select agents

Nothing to Report

6. PRODUCTS: *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**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

Nothing to Report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

Nothing to Report

- **Website(s) or other Internet site(s)**
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Nothing to Report

- **Technologies or techniques**
  Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

  Nothing to Report

- **Inventions, patent applications, and/or licenses**
  Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Nothing to Report

- **Other Products**
  Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

  Nothing to Report

7. 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	Project Role	Researcher Identification	Nearest person month worked	Contribution to Project	Funding Support
Ronald Chen	PI		1	Leads the study, overseeing its execution. Holds weekly meetings with research staff and monthly meetings with co-investigators.	
Matt Nielsen	Co-I (subcontract PI)		1	Oversees the UNC subcontract; meet monthly with PI; provides clinical and research expertise.	
Aaron Katz	Co-I			Guides data linkage for this study; assists in overseeing and troubleshooting data collection progress; provides research expertise to the study.	
Deborah Usinger	UNC Project Manager		4	Manage all day-to-day aspects of the project; e.g., tracking of data collection, regulatory processes, liaison with Carolina Survey Research Laboratory and Sheps Center for	

				Health Services Research – Web Development Services	
Sarah Walden	UNC Research Assistant		12	Prepare mailings (e.g., gift card incentives to participants for each survey completion), contacting facilities for medical records collection, medical record abstraction; primary point person for NC ProCESS participants.	

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

- Dr. Chen currently receives support from the following:
  - Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Black and White Men with Prostate Cancer; # PCS-2017C1-0422; 2.4 calendar months
  - Prostate cancer comparative outcomes of new conceptual paradigms for treatment (PC CONCEPT); 1.8 calendar months
  - Novel Optimization Methods and Treatment Planning System for Clinically-Deliverable Truly-Hybrid Proton-Photon Radiotherapy, R37CA250921; 0.12 calendar months
  - Disseminating Decision Support to Men with Localized Prostate Cancer; UWSC13575; 0.6 calendar months
  - Simultaneous dose and dose rate optimization for clinical FLASH proton radiotherapy; R01CA261964; 0.3 calendar months
  - NRG Oncology Network Group Operations Center; NRG-Chen-GY9; 0.16 calendar months

- Dr. Nielsen is no longer supported by the following:
  - SCH: INT: AURA-Connecting Audio and Radio Sensing Systems to Improve Care at Home; #R01-LM013329-01-02

- Dr. Katz currently receives support from the following:
    - Prospective Comparative Study of Outcomes with Proton and Photon Radiation in Black and White Men with Prostate Cancer; # PCS-2017C1-0422; 6 calendar months.
    - Prostate cancer comparative outcomes of new conceptual paradigms for treatment (PC CONCEPT); 1.2 calendar months
    - Multilevel Determinants of Active Surveillance for Low Risk Prostate Cancer; 1.5 months

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Nothing to Report

8. SPECIAL REPORTING REQUIREMENTS

COLLABORATIVE AWARDS: *For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to* ***https://ebrap.org/eBRAP/public/index.htm*** *for each unique award.*

QUAD CHARTS: *If applicable, the Quad Chart (available on https://www.usamraa.army.mil/Pages/Resources.aspx) should be updated and submitted with attachments.*

9. APPENDICES:

Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.