AWARD NUMBER: W81XWH-22-2-0023

TITLE: The University of Chicago Prostate Cancer Clinical Research Program

PRINCIPAL INVESTIGATOR: Russell Szmulewitz

CONTRACTING ORGANIZATION: University of Chicago, Chicago, IL

REPORT DATE: October 2023

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release; Distribution Unlimited

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	**2. REPORT TYPE**	**3. DATES COVERED**
October 2023	Annual	30Sep2022-29Sep2023

4. TITLE AND SUBTITLE

The University of Chicago Prostate Cancer Clinical Research Program

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-22-2-0023

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

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5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

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

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Development Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

The University of Chicago Prostate Cancer Clinical Research Program award, Grant number W81XWH-22-2-0023, is an infrastructure grant to support the prostate cancer clinical research program at the University of Chicago as part of the Prostate Cancer Clinical Trials Consortium (PCCTC). Per the approved SOW, the overarching goal of the award is to support the program such that it will meet or exceed PCCTC metric requirements and thereby contribute meaningfully to the development of new therapies for men with prostate cancer. Major tasks in the award are to (1) adhere to performance metrics of PCCTC program announcement (2021), including accrual of adequate numbers of patients, including those of underserved minority populations, and presentation of trials for inclusion in the PCCTC, and (2) full participation in the consortium. Within this reporting period we report significant progress towards these Aims. The program has accrued 25 patients to PCCTC studies, with 9 additional patients consented and screening as of this report. Furthermore, 24% of accrued patients are from underserved patient populations (Hispanic ethnicity or Black). The Chicago Program has submitted 2 studies to the consortium during this reporting period and has two concepts in development. Participation of Program members in the consortium is robust, with 2 members on the Prostate Cancer Working Group 4 committee and 2 on the genomics committee, along with consistent attendance at meetings and EAB. Thus, the University of Chicago Prostate Cancer Clinical Research Program has made considerable progress and currently meeting requirements as per the program announcement. One challenge has been in protocol activation. Due to staffing shortcoming in University pharmacy and contracting offices, startup of studies, including PCCTC studies has been slower than anticipated. This is expected to improve based on staff growth in these areas in last 6 months.

15. SUBJECT TERMS
Prostate Cancer, PCCTC, Clinical Research

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	14	**19b. TELEPHONE NUMBER** *(include area code)*
Unclassified	Unclassified	Unclassified			

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

The University of Chicago Prostate Cancer Clinical Research Program award, Grant number W81XWH-22-2-0023, is an infrastructure grant to support the prostate cancer clinical research program at the University of Chicago as part of the Prostate Cancer Clinical Trials Consortium (PCCTC). The overarching goal is to initiate and contribute to meaningful early phase prostate cancer clinical trials, and to promote clinical research equity through enrollment of underserved patient populations into prostate cancer clinical trials. Per the approved SOW, the award is to specifically support the program infrastructure such that it will meet or exceed PCCTC metric requirements and thereby contribute meaningfully to the development of new therapies for men with prostate cancer. Major tasks in the award are to (1) adhere to performance metrics of PCCTC program announcement (2021) and (2) full participation in the consortium.

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

Prostate cancer, clinical trials, PCCTC

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.

There are two major tasks, with associated subtasks as per the SOW to achieve the overarching goal of conducting early phase prostate cancer clinical trials and contributing to prostate cancer clinical research equity.

- Major Task 1. Adhere to performance metrics defined by FY21 program announcement
    - Subtask 1: Accrual of at least 25 patients/year to consortium trials
    - Subtask 2: Participation in a minimum of 8 trials over 4 years
    - Subtask 3: Presentation of at least two trials per year (or 8 over 4 years) to the consortium for consideration
    - Subtask 4: Accrual of at least 5% of patients from high risk, underserved or military populations
    - Subtask 5: Timely submission of quality data as outlined by the coordinating center
- Major Task 2. Full participation in the consortium as a member of the Clinical Consortium Committee/Scientific Oversight Committee
    - Subtask 1. Participate in at least 1 PCCTC committee
    - Subtask 2. Attend all face-to-face meetings of the PCCTC
    - Subtask 3. Participate in scheduled consortium conference calls
    - Subtask 4. Participate in review meetings/evaluations by the EAB
    - Subtask 5. Compliance with applicable standard operating procedures of the consortium

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.

This research award is an infrastructure grant to support prostate cancer-specific clinical research. The Major Tasks outlined within the SOW reflect the impact of the award through performance metric and Consortium participation. These metrics/tasks are outlined in the program announcement and are standards set across the PCCTC. Within Major Task 1, adherence to performance metrics, the University of Chicago Prostate Cancer Program (UCPCP) is meeting or exceeding expectations. Broken down by subtask, the following accomplishments are reportable:

- Subtask 1: Accrual of at least 25 patients/year to consortium trials. In this reporting period, the UCPCP accrued 25 patients to PCCTC trials. This includes the following breakdown by PCCTC study ID(# accrued)- c23-319 (3), c16-183 (3), c21-285 (3), c22-296 (6), c22-305 (2), c20-250 (8). In addition, we have accrued 8 additional patients to c16-170, the IRONMAN registry, coordinated through PCCTC, and continue to support the PCCTC PROMISE genetics registry (13 patients referred in this reporting period). Moreover, the UCPCP has 9 patients that have consented to participate and are screening for studies at the time of this report.
- Subtask 2: Participation in a minimum of 8 trials over 4 years- Including C16-170 IRONMAN registry, we have already accrued patients to 8 PCCTC trials in year 1 alone. We have one additional PCCTC study that is IRB approved and in the contract finalization stage.
- Subtask 3: Presentation of at least two trials per year (or 8 over 4 years) to the consortium for consideration- Two studies in year 1 have been presented and activated within PCCTC sponsored by the UCPCP (c22-311 and c23-319). In addition, there are two studies planned for submission in the next reporting period, one of which has been awarded a Prostate Cancer Foundation Challenge Award to fund and is already at scientific review within University of Chicago.
- Subtask 4: Accrual of at least 5% of patients from high risk, underserved or military populations- This is a key subtask for UCPCP. Within this reporting period 24% of our enrolled participants are from underserved populations and another patient is a military veteran (28% in total).
- Subtask 5: Timely submission of quality data as outlined by the coordinating center- The UCPCP staff, supported by this award are meeting acceptable data quality and submission deadlines.

Major Task 2, full participation in the consortium as a member of the Clinical Consortium Committee/Scientific Oversight Committee is being achieved. Broken down by subtask:

- Subtask 1. Participate in at least 1 PCCTC committee. The PI (Szmulewitz) and UCPCP member Dr. Stadler are currently serving on the PCCTC Prostate Cancer Working Group 4 committee, and Dr. Szmulewitz is the chair of one of the subcommittees (Interventions) within this committee. In addition, Feighanne Hathaway (Genentic counselor) and Dr. Patnaik serve on PCCTC genomics committee. New faculty member Dr. Mohammad Atiq has volunteered to serve on one of the ADDAPT committees.
- Subtask 2. Attend all face-to-face meetings of the PCCTC. The PI and Dr. Patnaik have attended all face-to-face PCCTC meetings this reporting period and Dr. Atiq and F. Hathaway have also attended in person meetings.
- Subtask 3. Participate in scheduled consortium conference calls. Dr. Szmulewitz attends all monthly calls.
- Subtask 4. Participate in review meetings/evaluations by the EAB. Similar to face-to-face meetings, Drs. Szmulewitz and Patnaik have attended EAB meetings, including most recently at PCF scientific retreat, where Dr. Atiq was also present.
- Subtask 5. Compliance with applicable standard operating procedures of the consortium- No reportable deviations.

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."

This award has offered several opportunities for training and professional development. Specifically, new junior faculty member Mohammad Atiq has been integrated into the PCCTC. He attended the last in person meeting and has volunteered for PCCTC committee service. This has provided an opportunity for engagement, professional development, and mentorship by leaders in the field outside of the University of Chicago. We have also leveraged this award to enhance fellowship training experiences. Dr. Nabiel Mir is a geriatric oncology fellow with a focus on prostate cancer therapeutics development in the geriatric population. He has worked with the PCCTC directly, working with the IRONMAN registry study to analyze toxicity data and has developed a new toxicity model which was accepted for presentation at the ASCO Genitourinary Symposium in January 2024. This was enable through data and feedback from PCCTC consortium leadership. In addition, Dr. Mir is co-developing a new clinical trial with Dr. Szmulewitz, for which they received a PCF Challenge award, that will be presented to the PCCTC in the coming reporting period. This is an opportunity for mentorship and training of Dr. Mir both within UCPCP and the PCCTC, enabled by this research grant. A separate senior fellow, Dr. Desai, has worked with other consortium members, including Northwestern University, to analyze real-world Pluvicto outcomes data. These data have been accepted for presentation at the same ASCO congress. He is also working on a new clinical trial building off of these data for submission through PCCTC in 2024.

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

Within this reporting period, there was nothing to report. However, two abstracts, stemming from the DOD PCCTC mentioned in the preceding section have been accepted for presentation at GU ASCO this coming January.

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.

To accomplish the goals as stated in the SOW, the UCPCP will continue to participate actively and accrue to clinical trials, with 9 subjects already consented and screening in the first quarter of next reporting period. There are also two study concepts that will be presented to PCCTC for study consideration.

4. **IMPACT:** D*escribe 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.

There were no major challenges to report other than University-level staffing challenges in our pharmacy and contracting offices. This has led to delays in protocol activation, which have somewhat hindered protocol accrual. The pharmacy and contracting groups have greatly expanded their staff and throughput is anticipated to improve.

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

Not applicable/nothing to report

Significant changes in use of biohazards and/or select agents

Not applicable/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- two abstracts accepted for presentation January 2024

- **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".

Example:

Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): 1234567
Nearest person month worked: *5*

Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

1) PI: Russell Szmulewitz MD, no change in effort since submission
2) Key Personnel (those with minimum 1 person month/year). Note, all personnel associated with the award, and their associated contributions and person month effort are unchanged with the exception of Ashley Page (see "g"), who took the place of other staff who are no longer with the institution.
    a. Walt Stadler, MD (co-Investigator), no change since submission
    b. Akash Patnaik MD, PhD (co-Investigator), no change since submission
    c. Theodore Karrison PhD (biostatistician), no change since submission
    d. Michael Carpen (database coordinator), no change since submission
    e. Feighanne Hathaway (genetic counselor), no change since submission
    f. Deimante Banionyte (data manager), no change since submission
    g. *New*-Ashley Page
        i. Role: Clinical Research Coordinator
        ii. Nearest person month worked: 6
        iii. Contribution to Project: Ms. Page coordinates clinical research participants for PCCTC studies, including patient identification, screening, scheduling and general coordination of care

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.

No change in active/other support of PI or key personnel other than the staff change noted in the previous section.

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.

Not applicable

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.*