

Prostate Cancer Foundation 2024 PCF Challenge Awards For Metastatic, Lethal Prostate Cancer REQUEST FOR LETTERS OF INTENT / FULL APPLICATIONS

<u>IMPORTANT</u>: Applying for a Challenge Award involves a 2-stage process. PCF requires a Letter of Intent (LOI), followed by full application submission upon our approval. See pages 2-3 for online submission details.

The Prostate Cancer Foundation (PCF) is pleased to announce a Request for Team Science Applications for PCF Challenge Awards for investigations of metastatic, lethal prostate cancer. These awards will be funded depending on the level of innovation in applications received. PCF seeks high-risk, currently unfunded projects from academic institutions around the world.

We especially encourage applications on prostate cancer disparity research that will help to define the origins of differential outcome for prostate cancer patients in men of under-represented populations, including those focusing on biology or health care access policy. We also seek applications conducting research in VA hospitals where research directly affects veterans with advanced prostate cancer.

PCF Challenge Awards:

- Composed of a team of at least three (3) investigators from non-profit academic research centers, including one young investigator (see PCF Challenge Award Team requirements below).
- Support large-scale research projects concerning metastatic, lethal prostate cancer over a duration of two years.
- Provide up to a total of \$1 million per team.
- Cover only direct research costs and travel to the Annual PCF Scientific Retreat.
- Clinical trial direct costs are not allowed; however, correlative research to support high impact clinical trials for advanced prostate cancer is encouraged. IRB submission and preferably approval is desired at time of application.
- All studies involving patients must include plans for including diverse participant populations with appropriate representation of ethnic and racial minority groups. Comprehensive statistical plans and power calculations are required.

Research proposals in the following topic areas are preferred:

- Immunotherapy for the treatment of metastatic, lethal prostate cancer.
- Targeted radionuclide therapy for advanced prostate cancer.
- New systemic precision treatments for metastatic, lethal prostate cancer including those targeting the currently 'undruggable'.
- First-in-field research on new targets for systemic treatment of metastatic, lethal prostate cancer.
- Mechanisms of resistance to current and investigational drugs targeting the androgen receptor and androgen axis, immune system, chemotherapy, and other targeted agents.
- Correlative research around either clinical trials of novel agents or strategies or standard of care.
- Determinants of survivorship that will improve the lives of patients with metastatic prostate cancer.
- Developing or validating biomarkers that guide therapy in patients or further our understanding of the mechanisms by which therapies work.
- Tumor microenvironment signaling related to cancer progression including the immune component.
- New data science technologies for analysis of genomic information to advance precision medicine.
- Research to define causes and solutions for racial and ethnic prostate cancer health disparities.

The PCF Challenge Award Team:

- Should be composed of at least 3 investigators capable of providing unique scientific expertise to the solution of this significant problem in prostate cancer research.
- May be assembled from one institution, or several institutions.
- Must embed at least one young investigator as an integral contributor to the team. The young investigator may hold the title
 of Postdoctoral Fellow, Instructor, Research Associate, Assistant Professor, or equivalent and should be within six- years
 following completion of a professional degree (MD, DO, PhD, MD-PhD, DSc, ScD, DDM, DDS, DMD, MBBS, or equivalent)
 or subsequent mentored academic or clinical training program. He or she should not have been granted commitments for
 more than \$1,000,000 in direct research funding from all sources including institutional funds at the time of this application.
- Applicants who are under-represented in biomedical research are highly encouraged to apply.

Veterans Administration (VA) Hospital Applicants and Projects:

In order to improve the health and wellness of our treasured US military veterans, applicants with Veterans Administration (VA) appointments are highly encouraged to apply. Projects that involve a VA Medical Center in their research proposal planning will be appreciated. These may include but are not limited to (1) creation of defined cohorts of prostate cancer patients annotated with the VA electronic medical record for the purpose of population science research; (2) blood, tissue or other body fluid specimens collection from VA prostate cancer patients for translational or clinical trial correlate research; (3) development of new biotechnologies for the diagnosis or treatment of prostate cancer patients within the VA healthcare system; (4) unique genomic investigations of tumor or germline specimens from VA prostate cancer patients with the goal of understanding the unique mutations that might have occurred due to battlefield exposure to specific toxic materials.

Eligibility:

Investigators representing non-profit academic research centers are eligible to apply for PCF Challenge Awards. Investigators from for-profit companies and government-sponsored institutions, with the exception of the VA, are ineligible.

Letter of intent (LOI) Online Submission Guidelines:

A Letter of Intent is required in advance of full application submission.

The Principal Investigator (PI) should create a profile or log into their existing one at <u>https://pcf.smartsimple.com</u>. Click the 'Open RFAs' tab and complete the 2024 Challenge Award Letter of Intent form. If the 'Reviewer' portal is accessed upon login, please click the <u>square icon</u> at the top right of the page to switch to the 'Researcher' portal using the dropdown. *Please enable pop-ups on your browser to ensure that the 'Application Preview' button works properly*.

The LOI form requires the input of names, contact information and project roles for all team members (project participants) listed in the Research Proposal. Collaborators who are not team members, but will collaborate on the project, wrote letters of recommendation or otherwise contributed to the application, must also be listed on the Letter of Intent.

LOI Form Fields: Proposal title (fill-in), Topic Area (dropdown selection), Statement of Impact and Innovation (fill-in, 150 words max.), Abstract (fill-in, 500 words max.), Proposal Keywords (multiple selections), Add Team Members button (pop-up form for names, degree(s) institution, project role, contact information), Research Proposal with References (fill-in, 1800 words max.), Organization Details (fill-in, 180 words max.), VA Information (fill-in, if applicable), NIH Short Form Biosketch - Primary Investigator Only (PDF upload).

To save your work and return to it later, click 'Save Draft'. Upon clicking the 'Submit' button, a PDF of the form is generated and you may no longer revise your LOI. If you need to make changes to the LOI after you've submitted it, please submit a new LOI. PCF will use the version with the latest time stamp.

<u>Request for Revisions:</u> Upon our review of your submitted LOI, if we have any questions, or determine that one or more revisions are needed, you will receive an email from <u>pcfapplications@smartsimple.com</u> with specific instructions. Please allow emails from this sender. To respond, log into <u>https://pcf.smartsimple.com</u> and click 'Applications' in the top right corner of the page. Click the orange button to the right of the 2024 Challenge Award RFA, which displays the status 'LOI Revisions Requested'. Revision instructions are shown at the top of your LOI form. Click 'Submit' after making the requested changes, which generates a second LOI PDF. PCF will use this second submission.

The LOI submission portal (<u>https://pcf.smartsimple.com</u>) opens Monday, February 26, 2024. The LOI submission deadline is Monday, April 8, 2024, 3:00 pm, Eastern Daylight Time (EDT).

A team of advisors will review LOIs to determine the strength of each submitted proposal and alignment with the PCF mission. Applicants will receive a status notification email by **Friday, April 19, 2024**.

Applicants whose LOIs have been approved will receive an email from <u>pcfapplications@smartsimple.com</u> with instructions for full application submission.

Full Application Online Submission Guidelines – PCF Approval of LOI Required:

PDF upload fields 1-6 will only be visible to applicants whose LOIs have been approved by PCF for full application submission.

The Primary Investigator should log into <u>https://pcf.smartsimple.com</u>, click the 'Applications' tab', then click the orange 'Open' button for the 2024 Challenge Award RFA. Their completed LOI form is shown in 'Draft' status, which enables the upload of PDF files for full application submission. Upon submission, the completed LOI form will combine with the full application form into one PDF.

All documents listed below should be uploaded as <u>separate PDF files</u>. Please note that item 6 should be submitted only if your project involves clinical trial correlative research and item 7 is optional. **PCF does not fund direct clinical trial costs.**

- 1. Statement of Originality (1-page limit): This statement delineates why the work is first-in-field, original, and currently unfunded. PCF seeks new and never-before tested ideas, not derivatives of ongoing investigations or incremental research.
- 2. **Research Proposal:** The narrative text and any preliminary data supporting a 2-year research proposal, limited to 10 pages, plus a list of references cited (references not to be counted toward the 10-page limit). For investigations that involve clinical trials, inclusion of a statistician and a clear statistical plan to justify the size of the study population is mandatory.
- 3. **NIH Biosketches:** Please submit a NIH Biographical Sketch for each investigator (5-page max), including a list of relevant publications and currently funded research projects (include award or grant type, project title, funding source, amount, and beginning and end dates of funding). NIH Biosketches for all investigators (except collaborators) on the team award proposal should be combined and uploaded as a single PDF document.
- 4. Budget page(s): Please include an annual budget breakout grid and budget justification for the proposal. PCF will cover only direct costs (no overhead). The budget can be prepared using NIH Budget forms like PHS 398; however, use of these forms is not mandatory. All PCF Challenge Award PIs and Co-PIs must use funds from the PCF Challenge Award to cover travel and registration expenses to attend the Annual PCF Scientific Retreat. Attendance by at least one member of the team each year is required for the duration of the award in 2022 and 2023. The Retreat will be held in Carlsbad, CA. PCF does not fund direct clinical trial costs.
- 5. Clinical trial protocol and a timeline for activation of the clinical investigation: If applicable.
- 6. **Supplemental Information (Optional):** Supplemental information in support of the application such as previous highly relevant publications or accepted manuscripts, letters of collaboration and letters of support can be uploaded as a single PDF document.

If applicable, at the time of the award, an IRB-approved protocol <u>ready for activation</u> is required for all human-related studies, including specimen acquisition. In addition, documentation of the availability of the experimental agent to be studied is required.

Funding decisions will be made following peer and programmatic review. Reporting results and the budget process will be discussed at the time of announcement of the awards. Please note that the Challenge Award activation date will be determined later this year.

Visit https://pcf.smartsimple.com on or after **Monday, April 22, 2024,** to complete the online full application form and attach the PDFs.

The deadline for full application submissions is Monday, June 17, 2024, 3:00 p.m. Eastern Daylight Time (EDT) *** In fairness to all there will be no exceptions to this deadline. ***

Key Dates:

- April 8, 2024: Online submission deadline for Letters of Intent
- April 19, 2024: Applicants notified of their status via email
- April 22, 2024: Portal opens for full online application submission (https://pcf.smartsimple.com)
- June 17, 2024: Submission deadline for (invited) Full Applications (https://pcf.smartsimple.com)

Please direct questions to applications@pcf.org.

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