

# Funding Opportunity (No Match Required) Inclusion and Diversity in Cancer Clinical Trials Grant (Cycle 1) Request for Proposals

# Andy Hill Cancer Research Endowment

The Andy Hill Cancer Research Endowment (CARE) Fund was established in 2015 by the state legislature as a bold public-private partnership to promote cancer research in Washington. With the establishment of the CARE Fund, the state is making a commitment to enrich the cancer research ecosystem with sustained investment to promote cancer research, aimed at improving the quality of life of the people of Washington.

The objectives of the Andy Hill CARE Fund (from RCW 43.348.005) include the following:

- Optimize the use of public funds by giving priority to research utilizing the best science and technology with the greatest potential to improve health outcomes;
- Increase the value of our public investments by leveraging our state's existing cancer research facilities and talent, as well as clinical and therapeutic resources;
- Incentivize additional investment by requiring private or other non-state resources to match public funds;
- Create jobs and encourage investments that will generate new tax revenues in our state; and
- Advance the biotech, medical device, and health care information technology industries in Washington.

# Inclusion and Diversity in Cancer Clinical Trials Grant Overview

The intent of the Inclusion and Diversity in Screening, Diagnosis, and Cancer Clinical Trials grant is to support projects that have the potential to increase participation and diversity in cancer clinical trials. Many barriers exist to clinical trials participation, including but not limited to initial screening and diagnosis, the capacity and infrastructure at clinical trial sites, and understanding and addressing the needs of potential clinical trial participants. As such, this grant may support projects that enhance clinical trial site capacity or infrastructure to conduct cancer clinical trials or address patients' barriers to participation. The grant may not be used to purchase real property.

## Scope

There are many areas in the health care system and along the cancer care continuum where an intervention could improve participation in cancer clinical trials. Below are a few examples of potential project areas; however, any project that has high potential for increasing inclusion and diversity, particularly for populations that are historically underrepresented in clinical trials, is eligible. (Underrepresented groups may be characterized by such factors as race/ethnicity, age, primary language, income, rurality, insurance status, gender, sexual orientation, etc.)

- Health services research to improve screening, diagnosing, and enrolling patients in cancer clinical trials
- Improve understanding of health-related social needs and how addressing these needs might lessen the burden for patients and increase participation in cancer clinical trials.

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- Health-related social needs may include but are not limited to language services, financial support and services, transportation, housing, etc.
- Improve cancer clinical trials staff capacity and infrastructure aimed to increase participation and diversity of patients, particularly among underrepresented groups
- Contribute to the understanding of how promoting the value and importance of cancer clinical trials impacts participation and diversity of patients
- Translate current knowledge into innovative interventions to increase inclusion and diversity of cancer clinical trials participants
- Develop infrastructure and resources aimed to support investigators planning and conducting cancer clinical trials that are inclusive and diverse, representative of the cancer of interest
- Expand the network of cancer clinical trials health care sites, including mobile sites, to increase participation and diversity of clinical trials participants, through improved screening, diagnosis, enrollment, and access to clinical trial treatment.

Accordingly, projects that address inclusion and diversity in cancer clinical trials, either through hypothesis-driven research or interventions, are eligible for consideration. Projects are encouraged to involve collaborations with the relevant stakeholders in the population groups to be impacted by the research (e.g., researchers, public health organizations, community organizations, patient advocacy groups, etc.). Additionally, as appropriate, engagement of key stakeholders in the development and implementation of the research plan is encouraged but not required.

# **Application Characteristics**

#### Eligibility

- Organizations in Washington State, including companies, universities, research institutions, local health jurisdictions, tribal governments, tribal entities, and Urban Indian Organizations are eligible to apply. Applicants must have a substantial presence in Washington, as determined by the CARE Board based on factors including, but not limited to, the following: number and type of staff in Washington; state of incorporation; location of headquarters, research, or manufacturing facilities in Washington; or any combination of such factors.
- Organizations may submit up to five (5) applications for this funding opportunity.
- Matching funds are not required.

#### Grant Award and Use of Funds

- The project period may be up to two years (24 months); Budget expenses may be allocated over the project period as needed, commensurate with the timeline and milestones.
- The total grant request (direct and indirect costs) over the project period may not exceed \$1,000,000.
- Grant funds may be used to enhance the capacity to conduct cancer clinical trials. Grant funds may NOT be used for the purchase of real property.
- Projects with collaborations outside of Washington State are allowed; however, the
  principal investigator and the primary research activities must be located in Washington
  State and the majority of the CARE Fund grant award must be allocated to recipients
  conducting research in Washington State.

• All grants will be made in accordance with the CARE Fund's policies and applicable laws, including the CARE Fund statute (Chapter 43.348 Revised Code of Washington).

# Timeline and Application Process

Organizations that intend to submit a full application must submit a letter of intent (LOI) for each proposal through the CARE Fund grants management system. The Inclusion and Diversity in Cancer Clinical Trials LOI can be accessed via the Inclusion and Diversity in Cancer Clinical Trials Grant page on the CARE Fund website. The LOI must be submitted by Thursday, October 27, 2022, 5:00 p.m. (PT).

After the LOI is reviewed by the CARE Fund and/or contractors, selected applicants will be invited to submit a full application online via the CARE Fund grants management system. The full Inclusion and Diversity in Cancer Clinical Trials grant application will be available to applicants after they are invited. The full application must be submitted by Thursday, January 5, 2023, 5:00 p.m. (PT).

The LOI and full application prompts and questions are available on the Inclusion and Diversity in Cancer Clinical Trials Grant page on the CARE Fund website.

Award decisions for this opportunity are anticipated to be made in May 2023. Applicants will be notified of award decisions via email.

# Application Process and Estimated Timeline

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Call for Proposals Announced	October 6, 2022		
Letter of Intent (LOI) Deadline	October 27, 2022		
LOI Review and	November 2022		
Applicants Invited to Submit Full Application			
Full Application Deadline*	January 5, 2023		
Independent Scientific Peer Review	January-April 2023		
CARE Board Award Decision	May 2023		
Award Agreements Executed	June/July 2023		
Anticipated Start Date	July 2023		
Project Support	Up to 2 years from project start date		

<sup>\*</sup> By invitation only

#### **Application Review Process**

# Stage1: Letter of Intent (LOI) Review

CARE Fund and/or contractors will screen the LOIs to assess the following:

- Does the LOI contain all required elements?
- Is the applicant eligible to apply under this funding opportunity?
- Is the proposed project appropriate for this funding opportunity?
- The potential of the proposed project to meet CARE Fund objectives and priorities.

CARE Fund will then invite selected applicants to submit a full application. The full online application will be available to applicants after they are invited.

## Stage 2: Full Application Eligibility Screening

CARE Fund and/or contractors will screen submitted applications for eligibility and completeness to assess the following:

- Is the applicant organization eligible to apply under this funding opportunity (per the eligibility requirements listed in the RFP)?
- Is the application responsive to this funding opportunity?
- Does the proposal contain all required elements of the application?

If all questions above are answered "Yes," the application will move to Stage 3: Peer Review. An application may be returned to the Applicant for completion or clarification, then re-submitted, per the judgment of the CARE Fund Executive Director.

## Stage 3: Peer Review

Independent peer review will be conducted by the American Institute of Biological Sciences (AIBS), or a comparable organization. AIBS, or a comparable organization, will recruit a panel of independent, expert, scientific reviewers with expertise in technological resources used for cancer research. Reviewers will evaluate the merit of the applications against the review criteria listed below. The review panel will then discuss the initial review findings, taking into consideration the CARE Fund program objectives and priorities, to arrive at final scores and ratings for each application. Reviewers will summarize the review results for each application in a final review, which will include a justification of the final scoring, rating, and ranking (when applications are ranked) of the applications in the cohort.

The CARE Board will be provided with the final reviews, the cohort's ranked scores (when available) and associated ratings, and a narrative summary of the review panel's funding recommendations.

#### Stage 4: CARE Board Assessment and Award Decision

The CARE Board will make award decisions based on the scores and recommendations made by the independent scientific reviewers and will ensure that reviews align with the CARE Fund objectives and priorities. When deciding between applications of similar merit, the CARE Board may also consider program objectives and priorities, including but not limited to cancer research discipline, type of cancer or geographic distribution of grantee organizations. The CARE Board will act in accordance with its Conflict-of-Interest Policy as well as Chapter 42.52 RCW (Ethics in Public Service) to avoid actual, potential, or perceived conflict of interest.

After the independent scientific review of the research proposal, at the CARE Board's discretion, exceptional or promising proposals that are awarded a grant under this opportunity may be invited to submit a supplemental funding request. The supplemental funding request must aim to fund work that further advances or extends, but does not materially deviate from, the project that was reviewed by the independent scientific review panel.

#### Review Criteria

Eligible applications will be evaluated against each of the following criteria:

## Significance and Impact – 20 points

- What is the significance of the proposed research or intervention to address an important problem or a critical barrier to improving inclusion and participation in cancer clinical trials, especially in underrepresented populations with cancer health disparities?
- What is the degree to which successful completion of the proposed research or intervention will have an extended impact on improving inclusion and diversity in cancer clinical trials?

## Innovation – 10 points

- What is the degree to which the proposed project will translate results or current knowledge, concepts, methods, or technologies, into an innovative intervention to improve the inclusion and diversity in cancer clinical trials, especially among populations that are historically underrepresented in clinical trials?
- What is the potential of the project to result in transformational research that will extend understanding or open new pathways to address low participation and disparities in cancer clinical trials participation?

## Scientific and Technical Merit of Approach – 20 points

- What is the strength of the scientific premise of the project or intervention?
- What is the degree to which the approach and methodologies are appropriate to meet the proposed goals and objectives?
- Are the milestones, timeline, and benchmarks for success for completing the project goals and objectives feasible?
- Are potential barriers to success and alternative strategies presented?
- Is there a suitable strategy for adhering to any applicable regulations, including protection for human subjects?

#### Investigators and Research Environment – 10 points

- Is there evidence of the Principal Investigator's qualifications to address the research question(s) and manage the proposed project?
- Is there evidence of complementary collaborations that provide appropriate expertise and perspectives to strengthen the project approach?
- Is the time allocated to the activities by the investigators appropriate for accomplishing the project in the project period?
- Is the applicant organization's infrastructure (e.g., instrumentation, facilities, financial support, and other resources) adequate to support the proposed project?

## Budget - Required element, but unscored

In addition to the criteria listed above, the review panel will take into consideration:

- Is the proposed budget justified and cost-effective?
- Is the proposed budget aligned with the milestones and timeline and sufficient to support completion of the project?

Rating	Description of Rating	Total
		Score
Highly Recommended	Demonstrates very high potential to impact the goals of cancer research or cancer care, excellent scientific merit, and a strong approach. Meets or exceeds the stated goals and objectives of the funding opportunity. Extremely well-organized and well-constructed Proposal.	50–60

Recommended	Demonstrates high potential to impact the field of cancer research or cancer care and strong scientific merit and approach. Meets the stated goals and objectives of the funding opportunity. Well-constructed Proposal.	40–49
Worthy of Consideration	Demonstrates good scientific merit and some potential to impact the field of cancer research or cancer care and meet the stated goals and objectives of the funding opportunity. Sufficiently constructed Proposal.	30–39
Not Recommended	Demonstrates major weaknesses that will likely decrease the potential for successful completion of the proposed project and impact in the field of cancer research or cancer care. Limited potential to meet the stated goals and objectives of the funding opportunity. Insufficiently constructed Proposal.	0–29

## Overall Application Ranking

Applications within the cohort may be ranked numerically (1 = highest ranked) based on the (i) final score, (ii) rating, and (iii) the CARE Fund objectives and priorities for funding decisions. When applications are ranked, rankings will concur with the ratings assigned to all applications and will reflect the review panel's funding recommendations.

# Intellectual Property

Grantees must report all inventions developed through CARE grant-funded activities or research projects to the CARE Fund. The CARE Fund does not intend to assert ownership of any invention that is derived from CARE funded research. However, if the grantee organization, or any subcontractor, decides not to take title and file an application for intellectual property protection, the CARE Fund would then have the option to take title. The grantee must notify the CARE Fund prior to any publication of the invention to allow the CARE Fund to take title and pursue or maintain intellectual property protection.

The CARE Fund does not expect to require payback of grants awarded based on income generated from sale or commercialization of any inventions resulting from CARE grant-funded activities or research. This approach is intended to minimize intellectual property-related barriers for potential applicants and encourage pursuit of transformational research. Successful projects will stimulate economic development through job creation and infusion of additional research funds to Washington. Products derived from these inventions will then be available to the public, with the expectation that it will improve health outcomes for the people of Washington and globally.

The CARE Fund must be listed as a funder in all presentations, publications, and patent applications. Please contact the CARE Fund for specific guidelines.

#### Confidentiality

Information in grant LOIs and applications is received by the CARE Fund with the understanding that it shall be used or disclosed for the evaluation of applications or as required by law. The CARE Fund holds all applications confidential in accordance with its confidentiality procedures and subject to the public disclosure laws of the state of Washington. All applicants are advised that information provided to the CARE Fund, including an applicant's proprietary and confidential information, are considered public records under Washington's Public Records Act, Chapter 42.56

RCW. Generally, public records are subject to disclosure unless an exemption to disclosure applies. Information provided to the CARE Fund may be protected from potential Public Records request disclosure to the extent provided under RCW 42.56.270(29).

The CARE Fund may make use of information contained in applications for purposes of transparency and publicity, including, but not limited to applicant name; applicant organization; project title; funding amount requested; and applicant profile. For unfunded applications, the CARE Fund will not publicly release the abstract or narrative of the proposed work, budget details, or any identifiers regarding co-applicant organizations, to the extent disclosure of this information might reasonably be expected to result in private loss to the applicant organizations, and as is consistent with public disclosure laws of the state of Washington or otherwise required by law. If a proposal is funded, the CARE Fund may make public additional information from the application, including, but not limited to: project abstract; funding amount; names and profiles of the investigators or collaborating organizations.

The CARE Fund reserves the right to publicly disseminate information about a grantee's activities through public reports, its website, press releases, speaking engagements, and other public venues. To the extent allowable under Washington State law, the CARE Fund shall not publicly disclose information that has been marked as proprietary or confidential if such information has not been previously disclosed to the public, or other information to the extent that provision of such information would reasonably be expected to result in private loss to the providers of such information.

## Contact Information

Please contact Tasha Florez (<u>tasha@wacarefund.org</u>) for questions regarding this announcement.