



Request for Applications

Grand Challenge: Enhancing Accrual of Underserved and Minority Patients to DF/HCC Clinical Trials

Application Deadline: **June 15, 2020**

Program and administrative contact: doris_sempasa@dfci.harvard.edu

Submit applications by email to: dfhcc@partners.org

Informational Zoom meeting (open forum) at **4 PM on Thursday, April 28, 2020**

Zoom meeting ID: **925 0197 7372** (password 837096) – please don't distribute on social media
<https://zoom.us/j/92501977372?pwd=NGdwZ1VuRUxyQWFySG94SnNGM2N4QT09>

BACKGROUND

Clinical trials are the cornerstone of new cancer therapies. However, most clinical trials to date have significant under-representation of patients from racial and ethnic minority groups (URMs). As a result, sizable populations of underserved patients lack early access to innovative treatments and it unclear whether the tested therapy has similar efficacy or toxicity across sub-groups. Although there is increasing national awareness that cancer clinical trials should encompass more patient diversity and better represent the U.S. population, this goal has been difficult to achieve. DF/HCC has therefore made it a leading priority. *A key element of the Center Strategic Plan is the primary goal to attain clinical trial enrollment proportions that reflect the racial and ethnic composition of the Center's catchment area: the Commonwealth of Massachusetts.*

Numerous barriers stand in the way of this aspiration, some known and others unknown, and previous DF/HCC investments in studying or solving the problem have had insufficient impact. The underlying societal, medical, cultural, and economic complexities demand thoughtful study and creative, bold, and novel solutions. *The Center will therefore divert its full 2020 budget for Developmental Projects* (usually divided between basic, clinical, population, and behavioral sciences) toward **a single Grand Challenge award of \$250,000**. These funds will be awarded to one DF/HCC team that proposes the best combination of the following:

- (a) Critical investigation of socio-cultural barriers to minority enrollment in cancer clinical trials,
- (b) Creative, practical, and community-facing solutions to overcome these barriers, and
- (c) Achievable milestones in an exemplary disease, clinical trial or minority community.

The overarching goal is to stimulate a new paradigm to frame and solve a longstanding and serious problem: the under-representation of minority populations in research.

OVERVIEW OF THE AWARD MECHANISM

The funding is intended to stimulate new ways to investigate and increase diversity among participants in DF/HCC clinical trials. Appropriate studies include the development of methods to enhance diverse participation in cancer clinical research, including implementation of innovative approaches, collection of pilot data, and secondary data analyses that will improve existing enrollment strategies.

The award mechanism is integral to the Center's mandate to interact constructively with MA communities. *Proposals must therefore demonstrate collaborative engagement with community partners and/or organizations beyond DF/HCC; meaningful interaction is required with at least one community stakeholder organization.*

By its nature and intent, the award favors *interdisciplinary research and implementation*. The goals include stimulating new faculty collaborations and *creative partnerships that will generate a new paradigm, excite national interest, and sustain beyond the period of the award*. Research stemming from this mechanism is expected to position awardees for future extramural funding. *Review criteria will therefore include the quality of proposals for near-term increases in clinical research diversity; articulation of long-range plans; and competitiveness for national grants.*

Any team of DF/HCC investigators is eligible to apply. Although teams are not required to have members from multiple DF/HCC institutions, this is strongly encouraged. The principal review criteria will be scientific excellence, innovation, and achievable milestones. Teams that represent multiple DF/HCC institutions and engage a DF/HCC disease-based and/or population sciences Program will receive preference. **The award is not restricted to investigators from a particular discipline. Creative assembly of non-traditional teams with representation from fields such as Economics, Sociology, Business, and Psychology is encouraged**, provided the Principal Investigator is a DF/HCC member throughout the award period and will commit appropriate effort toward the project.

The Grand Challenge award may encompass, but is not limited to:

1. Innovative approaches that can be broadly implemented to diversify patients enrolled in clinical trials across DF/HCC.
2. Dramatic improvements in patient navigation, health systems integration, and building relationships of trust with community partners to identify and engage with patients eligible for cancer clinical trials.
3. Improved identification, follow-up, and monitoring of URM patients with specific molecular or clinical phenotypes that could be eligible for molecularly defined clinical trials.
4. Approaches to engage patients and communities who do not currently receive care at DF/HCC hospitals but may benefit from DF/HCC trials. These approaches could include developing partnerships with non-DF/HCC institutions and the community at large.
5. Creative partnerships with private foundations that focus on minority health and/or with legislative bodies that aim to reduce barriers to improved minority access to health care.
6. Innovative partnerships with health care systems that care for more URM patients than DF/HCC hospitals.

7. Cancers that represent the major burdens in Massachusetts (see table). While all worthy applications will be considered, proposals that address one or more of the cancer sites or topics marked here in red may receive priority.

Community-identified Priorities						
	Increasing Rate	Elevated Rate	Clinical Trials	Leading Disparities	Risk Factors & Other	Populations
Data- and Policy-Driven Priorities	Oral	Bladder	Racial Minorities	Breast ^S	HPV	Racial Minorities
	Liver ^S	Brain ^S		Cervical	Tobacco	Central MA
	Uterine	Breast ^S		Colorectal ^S	Survivorship	Boston
		Esophagus ^S		Liver	Barriers to Care	
		Lung ^S		Myeloma ^S		
		Oral		Prostate ^S		
		Thyroid		Stomach		
		Uterine		Uterine		

REVIEW PROCESS AND CRITERIA

A committee of DF/HCC faculty will review proposals and a *sub-committee of the DF/HCC Executive Committee will interview the top 2 or 3 teams before reaching a decision.* The Award encourages collaboration among teams of investigators from diverse disciplines. Reviewers will assess applications on the merits of ideas, applicants’ understanding of the landscape, and the following criteria:

Innovation. Transformative potential and measurable progress beyond the incremental. New ideas and new approaches are favored. Token expansion of existing approaches is discouraged in the absence of a clear demonstration of novelty and a creative path toward formulating new state-wide or national models.

Anticipated impact. Identify the specific barriers to be evaluated and specific aspirations and anticipated impact. Identify the needs and potential outreach to particular underserved populations with well-defined strategies.

Approach. Explain how the team will work together to leverage individual strengths. *Engagement of at least one community partner—individual or, preferably, an organization—is required.* Explain how community input will be sought and how this partnership contributes to the overarching vision. Demonstrate feasibility and provide realistic estimates of the numbers of clinical trial participants who will be involved in –or impacted by– the research.

Investigators. Demonstrated academic achievement and/or community impact, and evidence that the PI can lead a multi-disciplinary team to generate and implement an action plan. Prior involvement with minority initiatives will be an asset.

Milestones. *Provide clear, tangible measures to evaluate the success of the proposed program.* Identify possible means for sustenance beyond the award period, e.g., federal grants, private foundations, community and MA organizations.

BUDGET

A single \$250,000 award (direct costs) will be made for 1 year, to be divided among members of the team as requested in the application. Full indirect costs will be awarded, at the federally negotiated rate for the awardee institution. External collaboration is permitted, with a clear investigational or community rationale. The application must include a letter describing collaborators' commitment toward specific tasks and the scope of contribution.

PROPOSAL CONTENT AND FORMAT

A single PDF should be compiled with the following components:

- Applicant contact information
- Applicants' and collaborators' degrees, academic titles, and institutional affiliations
- A 200-word (maximum) Abstract plus Hypothesis and annotated Specific Aims (total 1 page)
- Project Proposal: **Maximum of 5 pages**, including Background, Rationale, Significance, Approach, Anticipated impact, Innovative elements, and Potential sources of future funding or implementation. Figures are included in the 5-page limit; references are not. Appendices will not be considered in the initial application but may be requested at a later stage.
- Biosketch in the [NIH](#) or a comparable format for each participating investigator.
- Budget, submitted on [NIH PHS 398 detailed budget form](#). Investigators may include effort and salary support commensurate with that effort. Anticipated budget start date is July 1, 2020.
- Budget Justification
- Letters of commitment from collaborators and, where applicable, non-DF/HCC institutions.

SUBMISSION PROCESS

An electronic (PDF) copy of application is due **by 5 PM Monday, June 15, 2020**.

Submit to Doris Sempasa by e-mail at dfhcc@partners.org

Address questions to Doris Sempasa, (857) 215-1231, doris_sempasa@dfci.harvard.edu

REPORTING

Awardees will be expected to meet at least quarterly with DF/HCC leadership or the Executive Committee. Written progress reports are required 6 and 12 months after the award start date. These reports should summarize the progress and address the specific proposed milestones. Dissemination of findings is expected in the form of research publications, white papers, community-facing materials, legislative initiatives, etc.