LIVER CANCER DISPARITIES (Li-CAD)
in American Indian/Alaska Native People P20

Notice of Availability of Funds for Pilot Projects

Deadline for receipt of proposals is 5:00 PM PST on Friday, April 15, 2022

The Liver Cancer in American Indian/Alaska Native (AI/AN) Disparities (Li-CAD) program is a P20 mini-SPORE developed to address gaps in understanding as to the drivers of disparities in liver cancer risk and outcomes. **The purpose of the Developmental Research Program (DRP) for Li-CAD is to support early-phase projects in the area of translational cancer disparities research related to liver cancer in American Indian and Alaska Native people. This program is meant to develop potential future full projects to be included in a disparities-focused full SPORE application we intend to submit within the next 2 years.** The DRP provides a flexible means of funding basic, clinical, and population sciences research with outstanding translational promise.

The main focus of our **Li-CAD** in AI/AN people P20 program is to eliminate disparities in **EARLY DETECTION** of HCC. We believe that the most critical disparities and deficiencies in the HCC care continuum, and the greatest opportunities for improvement, lie in early detection. The **overarching aim** of this P20 Program is to apply novel, innovative, translational approaches to surveillance and early detection of HCC, that are informed by unique aspects of HCC pathophysiology and epidemiology in AI/AN people, in order to eliminate disparities, improve early detection and ultimately reduce HCC-related mortality. The **overarching strategy** is to introduce "**Precision HCC Screening"** based on risk stratification and risk-based surveillance.

The **Developmental Research Program** is interested in translational cancer disparities research proposals across a range of fields, including molecular biology, epidemiology (primary and secondary prevention), early detection, prognosis, therapeutics, and survivorship. In addition to financial support, funded DRP Projects will receive strong infrastructure support, access to biospecimens (see below), and expertise related to novel technologies through our Biospecimen and Data Repository Cores, and Biostatistics Core. Given this support, investigators do not need to have experience, but must bring a strong interest in conducting research that will lead to reduction in liver cancer health disparities.

Priority Research Areas

The immediate goal of the DRP is to identify impactful projects with the potential to advance to a full SPORE project. The ultimate goal of the program is to fund projects that will lead to a reduction in the morbidity and mortality from liver cancer among AI/AN people.

Targeted research areas include, but are not limited to, the following topics as related to liver cancer disparities:

- Risk factors and risk stratification for HCC in AI/AN people
- Novel biomarkers for early detection in underserved populations
- Genetic and environmental factors that enhance susceptibility
- Factors that contribute to cancer progression or recurrence
- New prognostic or predictive markers
- Novel treatments or therapeutic approaches
- Population, behavioral, or psychosocial studies that address mechanistic aspects of the cancer biology

All proposals must be applicable to health disparities in liver cancer, but otherwise can cover the full spectrum of basic, population, and clinical research.

Available Resources

The Liver Cancer in AI/AN Disparities Program will try to help investigators identify needed resources for DRP Projects. In addition to resources as part of the Biostatistics Core, Alaska Native liver disease cohorts-

biorepositories are a major resource available to the Li-CAD Program. New American Indian cohorts-biorepositories are being established at the Cherokee Nation Health Service as part of this program. Access to two large, existing comparison/control datasets-biorepositories derived from multiethnic/multiracial patient populations with chronic liver disease, cirrhosis, and hepatocellular carcinoma (HCC) at the University of Washington (Seattle, WA) and the University of Texas Southwestern (Dallas, TX) may also be available. **If this is of interest, we encourage investigators to reach out to us ASAP at spark@medicine.washington.edu.**

Funding Priority
Priority for funding will be given to proposals for studies that are feasible within the award period, multi-disciplinary, likely to lead to a project for a full SPORE application, and have translational potential ultimately affecting liver cancer disparities. The DRP will fund translational research in various areas of cancer prevention, early detection, diagnosis, and treatment with human endpoints.

Applicant Eligibility Requirements
Applications are invited from any researcher who is eligible to apply for NIH R01 grants. Investigators new to the field of liver cancer disparities demonstrating an interest in working in this field, junior faculty with evidence of exceptional talent during postdoctoral residency or fellowship training, and senior faculty with a track record for conducting significant original research are encouraged to apply.

Awards
All proposals in compliance with the stated requirements will be peer-reviewed and scored on the basis of scientific merit and the degree to which the proposal meets the DRP's primary purposes. If selected for funding, a formal award letter outlining the terms and conditions of this award will be sent to both the applicant and applicant's Institutional Official. UW awardees may receive funds via a project ID; external awardees will receive funds via subaward with additional terms.

Award Terms
DRP Project awardees must agree in advance to the following funding requirements that are put in place to support the successful conduct of the Pilot Projects and overall success of the DRP:

- All awards are subject to the NIH Grants Policy Statement and the NCI P20 Program Announcement
- Participate in some P20-related educational and scientific activities
- Meet with the assigned DRP mentor at the initiation of the Project and quarterly thereafter
- Meet with the Co-Directors of the Biospecimen and Data Repository Core and the Biostatistics Core
- Present the proposal concept and specific aims to the Li-CAD Program investigators at the time of Project initiation
- Attend the regular scientific meetings of the Li-CAD Program
- Submit written progress reports on progress toward specific aims and milestones, primary findings, submitted and funded grants, and scientific meeting abstracts and publications at 6 months
- Submit an updated progress report at the end of the Li-CAD award period
- Present findings at the annual Li-CAD retreat

Support for Awardees
Awardees who are junior investigators and/or are new to liver cancer disparities research will be assigned a member of the Executive Committee (see below) or Internal Advisory Board (IAB) to work closely with as a DRP mentor. This DRP mentor will meet with the DRP Project leader(s) at the beginning of the Project to review the Project's specific aims, methodology, approach, and milestones, and to discuss details related to its execution and needed resources and approvals. Thereafter, they will meet quarterly to address any new issues regarding the proposed work. Awardees must also meet with the Co-Directors of the Biospecimen and Data Repository Core and Biostatistics Core at the initiation of funding to review plans for biospecimen use, needs for laboratory technologies, and statistical support. This is to ensure that the awardee is fully aware of the available resources and access to Shared Resources technologies, and becomes familiar with the needed IRB and study approvals

for projects utilizing the available biospecimens.

Proposal
Proposals should include the following documents, in this order, as one complete PDF:

- Biographical Sketch (NIH format) for the Principal Investigator (PI)
- NIH Form Page 2
- Budget (direct costs only)
- Budget Justification
- Research Plan (2-page maximum) – use the Continuation Format Page
- Human Subjects and/or Vertebrate Animals (as applicable) covering the proposed research
- Bibliography and References Cited
- Appendix (2-page maximum)

NIH Biographical Sketch
A Biographical Sketch in NIH format should be included for the PI only. For additional information regarding the format and content of the Biographical Sketch, please reference the NIH instructions.

NIH 398 Form Page 2
Complete Form Page 2 according to NIH instructions.

Project Summary
Provide a brief description of the proposed work: overall goals, specific aims, research design and methods.

Relevance
2-3 sentences summarizing the impact of the proposed work on public health.

Performance Site(s)
List the site(s) at which the proposed work will be completed. Complete all the applicable fields for each site. Note that subawards are not allowed for this funding mechanism.

Senior/Key Personnel
Complete all fields for the project PI and any additional individuals contributing effort and to the scientific development or execution of the proposed work.

Other Significant Contributors
Complete all fields for any individuals contributing to the scientific development or execution of the proposed work, but not committing measurable effort.

Human Embryonic Stem Cells
Complete the Human Embryonic Stem Cell section for the proposed work.

Budget
Complete a budget using the NIH 398 Detailed Budget Form/Form Page 4. Funds may be used for personnel (PI, postdoctoral fellows, students, and technical personnel), supplies, and other justifiable expenses. DRP funds *cannot be used for the purchase of any large equipment*.

A total of 1-2 projects will be funded. Awards will be given in the amount of $20,000-$50,000 in total costs. To maximize funding toward pilot projects, we recommend that non-UW institutions request institutional approval to reduce F&A costs to no more than 10%. The award period is 07/01/2022–06/30/2023. Competitive renewals for a second year of funding will be considered based upon progress-to-date and justification.

Budget Justification
Provide justification for each expense in sufficient detail to allow reviewers to determine that the budget is

appropriate for the proposed work. Include a short narrative for all personnel describing position, role, and requested level of effort. If consultants or subcontracts are requested, provide a description of the services to be performed. No specific form is required.

Research Plan
Using the PHS 398 Continuation Format Page, state the *Specific Aims* and detail the Research Strategy, including *Significance*, *Innovation*, *Approach*, and *Preliminary Results* (as applicable). The Research Plan should be no more than 2 pages. Substantial progress and promise must be demonstrated for consideration of continuation requests.

Human Subjects and/or Vertebrate Animals
An additional page should be included to address plans for Human Subjects and/or Vertebrate Animal use. No specific form is required. Consult NIH PHS 398 and SF424 Supplemental Instructions for additional details. An approved IRB protocol (or approved modification of an existing protocol) will be required in order for an award to be granted, although IRB approvals are not required at the time of application submission. Thus, proposals with IRB approvals already submitted or in place will be given higher priority during review.

Appendix
An Appendix limited to 2 pages for tables and figures may be included.

Bibliography and References Cited
Provide a bibliography of any references cited in the Research Plan. References are not included in any of the page limits.

Award Requirements/JIT

- Approved IRB protocol (or approved modification of existing protocol) for proposals that include human subjects research as defined by the NIH.
- Tribal approval (i.e., inclusion of American Indian and/or Alaska Native people and/or their biospecimens in proposal).
- Targeted/Planned Enrollment Table.
- Human Subjects Training Certification for all Key Personnel listed in proposals that include human subjects research.
- Approved IACUC protocol (or approved modification of existing protocol) for research including the use of vertebrate animals.
- Animal Care Training Certification for all Key Personnel listed in proposals that include vertebrate animals.

All **IRB**, **IACUC,** and/or **Tribal approval** files **must be fully approved** before an award can be made. Note that approvals are not required at the time of application submission.

Funding Period
The proposed period of funding for this cycle is 12 months, beginning July 1, 2022 and ending June 30, 2023.

Submission
One PDF copy of the complete proposal must be received no later than 5:00 PM PST on Friday, April 15, 2022 at the following email address: spark@medicine.washington.edu

For questions, contact:
Stephanie Park, spark@medicine.washington.edu

Li-CAD Executive Committee:

George Ioannou MD MS (MPI), University of Washington
William Grady MD (MPI), Fred Hutchinson Cancer Research Center
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