

# LIVER CANCER DISPARITIES (Li-CAD) IN AMERICAN INDIAN/ALASKA NATIVE PEOPLE P20 PROGRAM

*Funding opportunity announcement for new pilot projects and enhancements for existing pilot projects*

**Proposal deadline:** Friday, April 26, 2024 at 5:00 pm PT

**P20 program contact:** Valeria Cid Garza ([vcg3@medicine.washington.edu](mailto:vcg3@medicine.washington.edu)) and Trang VoPham ([trang@fredhutch.org](mailto:trang@fredhutch.org))

**P20 program** [website](#)

## OVERVIEW

The **Liver Cancer Disparities (Li-CAD) in American Indian/Alaska Native (AI/AN) People** program is a P20 mini-SPORE (Specialized Program of Research Excellence) developed to address gaps in understanding regarding the drivers of disparities in liver cancer risk and outcomes. The purpose of the Li-CAD **Developmental Research Program (DRP)** is to support early-phase projects in translational cancer disparities research related to liver cancer in AI/AN people. This program is meant to develop potential future full projects to be included in a disparities-focused full SPORE (P50) application that we intend to submit. The DRP provides a flexible means of funding basic, clinical, and population sciences research with outstanding translational promise.

The main focus of Li-CAD is to eliminate disparities in **early detection of hepatocellular carcinoma (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 primary 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 DRP is interested in **translational cancer disparities research proposals** across a range of scientific 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 Pathology Core and Biostatistics Core. Given this support, investigators do not need to have experience in liver cancer, but must bring a strong interest in conducting research that will lead to reduction in liver cancer health disparities.

## PRIORITY RESEARCH AREAS

The DRP seeks to identify impactful projects spanning the full spectrum of basic, population, and clinical research. 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 cancer biology

Priority for funding will be given to proposals that are feasible within the award period, multidisciplinary, have potential to advance to a full SPORE project that will lead to a reduction in morbidity and mortality from liver cancer among AI/AN people, and have translational potential ultimately addressing **liver cancer disparities**.

## AVAILABLE RESOURCES

The Li-CAD program is committed to helping 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 Services as part of this program. Access to two large-scale existing comparison/control datasets-biorepositories derived from multiethnic/multiracial patient populations with chronic liver disease, cirrhosis, and HCC at the University of Washington (Seattle, WA) and University of Texas Southwestern (Dallas, TX) may also be available. If this is of interest, we encourage investigators to contact us.

## 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, or 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 project meets the DRP's primary purposes. If selected for funding, a formal award letter outlining the terms and conditions of the award will be sent to both the applicant and applicant's Institutional Official. University of Washington awardees may receive funds via a project ID; external awardees will receive funds via subaward with additional terms.

**Award terms:** DRP pilot 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 P20 educational and scientific activities
- Meet with the assigned DRP mentor at the initiation of the pilot project and quarterly thereafter
- Meet with the Co-Directors of the Biospecimen and Pathology Core and the Biostatistics Core
- Present the proposal concept and specific aims to Li-CAD program investigators at the time of project initiation
- Attend regular scientific meetings of the Li-CAD program
- Submit a written progress report on progress towards 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 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 the Biostatistics Core at the initiation of funding to review plans for biospecimen use, needs for laboratory technologies, and/or 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 – FOR NEW PILOT PROJECTS

Proposals should include the following documents (in this order) as **one complete PDF**:

1. Biosketch for the Principal Investigator (PI) or PIs
2. NIH Form Page 2
3. Budget (direct costs only)
4. Budget Justification
5. Research Plan (2-page maximum)
6. Human subjects and/or vertebrate animals (as applicable) covering the proposed research
7. Bibliography and References Cited
8. Appendix (2-page maximum)

### Additional information:

1. A **biosketch** in NIH non-fellowship format should be included for the PI(s) only. NIH instructions with templates can be found [here](#).
2. Complete [NIH PHS 398 Form Page 2](#) according to [NIH instructions](#), including sections for:
  - *Project Summary*: Provide a brief description of the proposed work including overall goals, specific aims, research design, and methods.
  - *Relevance*: Provide 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 of the applicable fields for each site. Note that subawards are not allowed for this funding mechanism.
  - *Senior/Key Personnel*: Complete all fields for the PI and any additional individuals contributing effort 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*: Provide required information if applicable.
3. **Budget**: Provide a budget using the [NIH PHS 398 Detailed Budget Form](#) (Form Page 4; [NIH instructions](#)). 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.**

Please note: A total of 1-2 projects will be funded. Awards will be given in the amount of \$25,000 to \$50,000 in total costs. To maximize funding towards pilot projects, we recommend that **non-University of Washington institutions request institutional approval to reduce F&A costs to no more than 10%**. The award period is 07/01/2024 to 06/30/2025.

4. **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 the position, role, and requested level of effort. If consultant services are requested, provide a description of the services to be performed. No specific form is required.
5. **Research Plan**: Using the [NIH PHS 398 Continuation Format Page](#) ([NIH instructions](#)), 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**.
6. **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 Institutional Review Board (IRB) protocol (or approved modification of an existing protocol) will be required 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.

7. **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.
8. An **Appendix** limited to **2 pages** for tables and figures may be included.

## PROPOSAL – FOR EXISTING PILOT PROJECTS

Proposals should include the following documents (in this order) as **one complete PDF**:

1. Project modification (2-page maximum): Using the [NIH PHS 398 Continuation Format Page \(NIH instructions\)](#), summarize the specific aims of the existing pilot project, provide an explanation of how the additional funds would enhance the existing award, and describe any new objectives that the PI(s) propose to achieve.
2. Budget (direct costs only)
3. Budget Justification
4. Bibliography and References Cited

## AWARD REQUIREMENTS/JUST-IN-TIME (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)
- Planned Enrollment Table
- Human subjects research training certification for all Key Personnel listed in proposals that include human subjects research
- Approved Institutional Animal Care and Use Committee (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 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, 2024 and ending June 30, 2025.

## SUBMISSION

One PDF copy of the complete proposal must be received no later than 5:00 pm PT on Friday, April 26, 2024 at the following email addresses: [vcg3@medicine.washington.edu](mailto:vcg3@medicine.washington.edu) and [trang@fredhutch.org](mailto:trang@fredhutch.org)

## CONTACT

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## Li-CAD EXECUTIVE COMMITTEE

**George Ioannou, MD, MS (MPI)**, University of Washington  
**William Grady, MD (MPI)**, Fred Hutchinson Cancer Center  
**Brian McMahon, MD (MPI)**, Alaska Native Tribal Health Consortium  
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