Our Patient Project
Request for LOI (Phase 1 of 2)

Purpose and Overview

Our Patient Project (OPP) is an important translational research element of the MCW Cancer Center (CC) Precision Oncology high-impact initiative that is expected to drive discovery over the next three years. The OPP has two goals: 1) To answer a significant unanswered question in the cancer research field or address a major challenge in clinical care by fully characterizing and analyzing samples from a discrete, clinically annotated cancer patient cohort; 2) To develop a rich experimental data set on patient samples annotated with high quality clinical data that can be leveraged by the Principal Investigator (PI), study team, and MCW CC members to foster new multi-disciplinary collaborative research projects funded through extramural sources (e.g., Multi-PI R01s, P-, U- or M-type grant awards, sponsored clinical trials) and that will lead to novel practice-changing cancer prevention and/or therapeutics. This funding program opportunity is anticipated to be open through 2025, with 2-3 full applications funded per year. Each meritorious application will receive up to 4-5 years of funding. Projects will be selected for funding using a two-stage process a letter of intent (LOI; Phase 1) followed by a full proposal (Phase 2) from invited teams. This document provides a program description and instructions for submitting LOI. Resubmission of revised LOIs and full proposals are allowed in subsequent rounds.

Program Description

OPP will be a long-running research endeavor of the MCW CC's Precision Oncology high-impact initiative. Funding for the first round of applications is expected to start by September 2022; additional projects will be funded on a rolling basis through 2025 or until further notice.

Successful LOIs will address the following project attributes. Attributes 1 and 2 are the most important at the LOI stage. A detailed statistical analysis need not be presented in the LOI but data supporting that sufficient accrual can be achieved (or that sufficient high-quality data exists for retrospective analyses) is necessary.

1) The project will answer a major scientific question: Each project will be designed to answer a major question about cancer etiology, cancer prevention, cancer biology, cancer disparities, and/or cancer diagnosis, treatment or survival. The research question must address an unmet need where a definitive answer to the question has not been published.

2) The study cohort will be clearly defined: Central to OPP is the definition of a patient cohort that is represented in or is representative of our catchment area (eastern Wisconsin area; see

indication of team membership or composition. Also, the teams should describe the approximate number and type of trainees (undergraduate students, graduate students, postdocs, staff scientists, clinical fellows) expecte participate and be supported by the project; exact team composition can be finalized during full propos preparation.

4) The project will interrogate omic-scale molecular features of the cohort and integrate comprehensive data analysis. OPP seeks to fund projects that analyze molecular features of their cohort consisting of genom transcriptomic, epigenomic, proteomic, metabolomic, metagenomic, immunologic, lipidomic and/or glycomic tests. This may also include some permutation of somatic mutations, cytogenetics and chromosomal aberrati It is understood that some of these assays may have already been performed in the course of routine clinical or as part of a trial. The project will propose to perform additional assays on patients' samples and include a general description of data analyses needed to answer the question posed. Feasibility of assays proposed must in expected recruitment rate, statistical evaluation of sample size and technical replicates, evaluation of sam quantity and quality, sample preparation and compatibility with established methods, and pathological assessment of patient samples to be analyzed. The program should consider additional assays that may be desired or needed in the future and related feasibility parameters necessary to expand the initial scope of the project ar combine with other projects' data sets.

Additional Considerations

Amendments to a master protocol may be needed. A master protocol will be in place and IRB approved for these studies; however, protocols for projects requiring consent for procedures, data or other items not cove by the master protocol will need to be developed by the team through amendment of the master protocol.

Team formation, cohort definition, assay specification and proposal for data analyses will continue for teams invited to submit a full proposal. For maximal impact and chance of success, reviewers, CC and CTS leaders, CTO leaders, and Shared Resource directors will work with the PI and senior project team members optimize investigator team composition; specifics regarding cohort definition, clinical annotation and specime procurement, processing and storage requirements; specified assays; and proposed data analyses.

Priority Areas

Researchers working in all areas of cancer science are invited to apply. Priority will be given to projects that u multi-disciplinary technologies and approaches, propose to study topics related to understanding or addres cancer disparities in WI, and address clinically important challenges faced by the WI population and their cancer caregivers. Inclusion of correlative studies that utilize MCW Shared Resources are highly encouraged, and when shared resources outside of MCW are proposed, appropriate justification is required.

Eligibility and Evaluation

Eligibility

- Proposed research must be cancer relevant.
- MCW faculty members are eligible to apply. At least one team member must be a CCC member.
- Research can take place, and expenditures incurred, only at MCW, Children's Wisconsin, Froedtert Hospital, Versiti BRI, Children's Research Institute or the Zablocki VAMC.
- A clear case for the feasibility of completing the project in a 4-year time frame must be made.

Evaluation

LOIs will be evalu62.43 0 Td .x alal L F] Ä"¤óÓä Gääê Â,#`Àåê # B"1^¡Yé -0Ôb"<¤bbÒÒ¢0Ô"#Ò-¢ÝF"#T F

- Importance of the question: impact of the proposed research question on cancer biology or patient care
- Cohort characteristics: relevance to CC catchment area (see attached Wisconsin map and list of counties) and need for reducing cancer health outcome disparities
- Standard NIH criteria (significance, innovation, approach and investigative team)
- Likelihood that sufficient patients can be accrued or already exist in an accessible database in the timeframe of the research study
- Likelihood that clinical annotation will be available in sufficient detail and quality controlled
- Likelihood that patient samples will be of high quality
- Likelihood that molecular data derived from the study will be high quality
- Validity of statistical analysis plan, including estimates of sample size and power
- Discussion of pitfalls and alternatives
- Likelihood that preliminary results will lead to externally funded research projects, protocols, a LOI from pharma and/or extramural grant funding
- PI and key personnel participation in CC programs (e.g., attend Research Program meetings, serve on CC grant review panels, participate in CC High Impact Initiatives, participate in recurring seminars or symposia).

Budget

Maximum project budget is $1M total (see also below) over a maximum 5 years. LOI must include anticipated “best estimate” budget for the following categories: personnel (staff, trainees), supplies; sample retrieval, preparation and analysis; assay development px-6ata p4 ( )-10 (a)4 (l)-2 (ys)-1 (i)-2 (s)-1 (;)-6atau

through iLab.

- Feasibility (1-page limit): Provide information about cohort size; availability of detailed clinical data; anticipated recruitment rate; identity of institutions where patients were and/or will be seen; samp procurement, processing and storage; labs or parties to be performing study assays; and data QC that feel will be helpful in evaluating project feasibility in the allotted time and veracity of conclusions.
- Future Funding Plans (250-word limit): State the federal agencies, corporations, profit-organizations, mechanisms, and timing of planned future trials or grant applications that will use the preliminary data produced under this award. State how data from this application will be used to support specific extramural proposals by PI and/or study team.
- Budget (1-page limit): A general budget outline is required for the LOI, but full proposal (if selected)