CIAPM Request for Proposals 2018
Reducing Cancer Disparities through Collaborative Precision Medicine Care

Request for Proposals Announced	July 2, 2018
Letter of Intent to Submit a Proposal Due	**July 27, 2018**
Concept Proposal Deadline	**August 15, 2018**
Notification of Finalists	September 10-17, 2018
Full Proposal Deadline	**November 2, 2018**
Awardees Announced	December 10-14, 2018
Projects Commence	January, 2019
Duration of Projects	36 months
Funding	For 2-4 projects, approximately $1.8 million to $3.5 million total per project; no indirect costs. Additional matching funds are highly encouraged and will be considered as part of the selection process. An additional $1.5 to $2 million will be available for awarded project teams to examine and potentially select and use a common data-sharing platform.

I. Precision Medicine

Precision medicine holds promise to profoundly transform health, healthcare, and biomedical research. As envisioned in the [2011 National Academy of Sciences' (NAS) report](#), "Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease", precision medicine aims to use advanced computing tools to aggregate, integrate, and analyze vast amounts of data from research, clinical, personal, environmental, and population health settings, to better understand diseases and develop and deliver more precise diagnostics, therapeutics, and prevention measures.

Although precision medicine approaches hold promise, creating models of access for all communities will be important for precision medicine to address health disparities and have a positive impact on health outcomes across various socio-economic and ethnic groups.

II. California Initiative to Advance Precision Medicine

The [California Initiative to Advance Precision Medicine (CIAPM)](#) was established by the State of California to help coordinate public, private, and non-profit partners to advance precision medicine approaches and foster the creation of new technologies and therapies that can improve the health of diverse populations. The initiative brings together state precision medicine leaders as well as supports projects aimed at demonstrating the power and application of precision medicine to the people of California.

III. Precision Medicine Demonstration Projects

The NAS report emphasizes the need for strong partnerships and collaboration to achieve the vision of precision medicine and recommends that pilot projects be undertaken at various levels to identify barriers, define effective practices and achieve some early, albeit modest scale, successes. Therefore, one of CIAPM's main approaches is to support collaborative demonstration projects that leverage the state's expansive and diverse patient data, research expertise, and technological capabilities to advance precision medicine.

For this RFP, up to $9 million will be provided by the state for two to four proof-of-principle demonstration projects with the aim to improve access to precision medicine cancer care approaches, for patient populations that suffer from cancer health disparities, through collaborations between academic, community, and nonprofit and private partners. Within the available funds, approximately $1.5 million to $2 million will be available to awarded demonstration projects to examine and potentially select and use a common data-sharing platform.

Projects should be co-hosted by at least one public, private academic or non-profit institution in California and at least one community or county institution in California that provides cancer treatment for patient populations that suffer from cancer health disparities.[1] These entities will also rely on contributions from other non-profit or for-profit organizations in the community as well as industry partners. Demonstration projects will be selected through a three-stage process involving (1) submission of letters of intent to submit concept proposals; (2) submission of concept proposals; and (3) submission of full proposals, based on selected concept proposals, from which the final selection of awards will be made. After the Selection Committee makes its recommendations on awards, CIAPM will work with awardees to develop concrete metrics and goals to track the progress of the demonstration projects, examine and potentially select a common data-sharing platform, and enter into contracts with the agency providing oversight.[2]

IV. Applications

A. Application process

Stage 1: Letter of intent to submit a concept proposal
Applicants should submit a brief letter of intent. Letters should note the expected host institution(s) and (co-)PIs, provide tentative title and/or brief description (no more than 5 sentences) of the proposal, and give a tentative total budget.

Stage 2: Concept proposals
Applicants should submit short concept proposals; see section D below.

Stage 3: Full proposals
The Selection Committee will select a subset of submitted concept proposals to move onto the full proposal stage. Instruction for submission of full proposal materials will be made available on the CIAPM website for the finalists advancing to the next stage.[3]

The Selection Committee will recommend up to four final projects based on appropriated funds for funding to the Governor's Office of Planning and Research, which will approve and announce the final funding decision.

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[1] See https://www.cancer.gov/about-cancer/understanding/disparities.

[2] Contracts may be established through the Governor's Office of Planning and Research, an affiliated Institute, or an academic center.

[3] CIAPM and the Selection Committee may add additional questions for the full application.

For questions, please see the [FAQ document](#) or contact ciapm@ucsf.edu.

B. Eligibility

1. Applicant teams should include co-principal investigators (PIs) from at least one public or private academic or non-profit institution, together with one or more community or county health institutions that provide cancer care for populations that experience cancer health disparities (e.g., community hospitals, county health agencies, Federally Qualified Health Centers). Additional partnerships with other non-profit and industry partners are encouraged. An individual may serve as PI or co-PI for more than one application, but there will not be more than one award per PI or institution.

2. Demonstration projects should be located in California; however, partners may be located outside of California if they are providing their own funding.

3. Demonstration projects should aim to improve cancer outcomes and reduce disparities in the county or community setting(s), and increase understanding of how to apply precision medicine approaches in commonly diagnosed, high prevalence, or high mortality cancers (e.g., breast, colorectal, lung, prostate, pancreatic cancer).[4]

4. Applicant teams must agree to participate in one or more hosted meetings or calls for the awarded demonstration project partners to examine and potentially select a common data-sharing platform.

C. Institutional Cover Letter

For each application, the submitting (host) _institution_ should provide answers for Section C1, C2 & C3, in a brief (limit one page) _Institutional Cover Letter_; minimum Arial 11 font, 0.5 inch margins, no appendices.

1. Host institution: Identify the institution that is submitting the proposal and will administer the grant if awarded. This is not a limited submission. However, no more than one project will be awarded per host institution or per PI.

2. Institutional focus: Describe each institution's commitment to the proposed demonstration project (each participating institution should sign the Cover Letter).

3. Principal investigator(s): Identify the investigators who will serve as (co-)PIs. Please briefly describe each PI's capacity (~3 sentences each), including success with previous and/or current scientific funding such as National Institute of Health and National Science Foundation funding, strength of community and patient engagement activities, and history of successful cross-institutional partnerships.

4. Authorized submission: The Institutional Cover Letter (C1-C3) and the concept proposal (section D) should be submitted electronically by the Vice Chancellor for Research, Chief Executive Officer, or other equivalent or designated authorized institutional official. Only one application should be submitted for each proposal team.

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[4] These cancers cover a broad range of cancer diagnoses. CIAPM recognizes that the organ-based classification system is shifting, but the intent of this RFP is to address the most prevalent cancer diagnoses or cancers that have a high mortality rate within the current classification system.

D. Concept proposals

For each application, please provide answers for Section D in a short <u>Concept Proposal</u>: maximum <u>two pages</u> for the concept description (items 1-8 below) and maximum <u>one page</u> for items 9-11 below; minimum Arial 11 font, 0.5 inch margins, no appendices.

1. <u>Impact to reduce disparities through precision medicine cancer care for patients in the county or community setting(s)</u>: Describe how the proposed project will improve understanding in providing precision medicine approaches to populations that suffer from cancer health disparities. Provide rationale for the project by outlining existing strengths, resources, and opportunities available (e.g., ability to obtain molecular measurements, remotely collect behavioral or other data, subtype the disease, link genomic data to EHR; access to existing biobanks, databases, medical records; an engaged participant community; established mechanisms for responsible data sharing). Describe why this is the area your team is choosing to focus on and why this approach is impactful.

2. <u>Project plan</u>: Describe the components of your proposed project (i.e., specific aims and research strategy).

3. <u>Patient data/other data</u>: Each proposal should demonstrate its commitment to the use of robust data. Use of multiple data sets is encouraged (e.g., electronic medical records, mobile health device data, registries, research databases). Demonstration projects should integrate two or more types of "omics," (e.g., genomics, exposomics, proteomics, pharmacogenomics, behavior/lifestyle factors) into a single project. Briefly describe the data set(s) you propose to use or create, the rationale for integrating these data, and how they may contribute to better outcomes by improving preventative, diagnostic, or treatment approaches. Please provide rationale for use of designated standards that are already recognized, for example by the College of American Pathologists.

4. <u>Precision medicine capabilities</u>: Describe the precision medicine capabilities that will be developed as a result of this project (e.g., infrastructure and tools that will be built as a result of this project including new consortia, collaborations, personnel competencies, databases, datasets, applications or software or computational development, intellectual property, patient cohorts, participant communities and networks, models for responsible data sharing).

5. <u>Participant engagement</u>: Describe strategies to engage patients (e.g., opportunities to build trust, approaches to ensuring consent, approaches to data sharing, privacy, security). For example, integrating a patient advisory board, having patient navigators, hosting focus groups to understand patient issues. Describe efforts to allow patients access to their medical data and/or opportunities for patients to contribute data from this demonstration project to other research studies.

6. <u>Impact for patients</u>: To the extent it is applicable to the project, describe opportunities to improve patient outcomes within the 36-month project timeframe—and beyond.

7. <u>Economic impact / value analysis</u>: Describe the anticipated utility and how you will perform an economic impact analysis (i.e., impact on healthcare spending) of your proposed intervention versus other interventions/standards of care. Who will you partner with to do the analysis, what data will you analyze, etc.?

8. <u>Anticipated challenges and proposed solutions</u>: Describe potential barriers to the project's success, especially those that could delay the launch, progress, or completion (e.g., human subjects, health literacy barriers, mobile patient populations), and describe potential solutions to these challenges.

9. <u>Project team</u>: Provide a brief description of the PI(s), team, and key collaborators. Describe collaborations between at least <u>two</u> California organizations as part of your proposal. Additional partners are highly encouraged. Describe the nature and strength of any existing collaborations. List which PI will be the primary contact. The primary contact must be affiliated with the host institute.

10. <u>Budget overview</u>: Briefly outline how CIAPM funds (approximately $1.8 million to $3.5 million) will be used and how other resources will be leveraged including total amount of matching funds from partners and outside entities. Comment on why CIAPM funds are needed as opposed to other funding sources such as federal or philanthropic grants. Examples of other resources that may be leveraged include: experts' time; molecular characterization, including DNA, RNA and genomic sequencing; computational platforms, including genome analysis, data visualization, innovative databases, data sharing, data privacy and security, and high-performance computing; mobile platforms to reach patients between medical encounters and/or track their health and outcomes.

    Note: CIAPM funds are intended to be used exclusively in California. If the project necessitates the use of CIAPM funds outside of California, provide a brief justification and estimate of the funding that will leave the state. The amount of funds that can leave the state will be subject to the final award agreement.

11. <u>Common data-sharing platform</u>: Teams must have a willingness to attend coordination meetings with all grantees, share lessons learned, discuss lessons with the use of designated data standards, and agree to examine and potentially select and use a common data-sharing platform.

E. **Submission: <u>Concept proposals must be submitted electronically as a single PDF to by 5:00pm PT on August 15, 2018.</u>**

V. Selection

Selection Committee: A committee will be established that includes subject matter experts representing the breadth of stakeholders involved in the overall initiative. Selection Committee members may include nominees of the Legislature, public solicitation, or academic referral. Selection Committee members shall not be deemed to be interested in any contract including any award of CIAPM funds and will be screened for conflict of interest consistent with NIH procedures. The names of Selection Committee members will be provided on the CIAPM website. The Selection Committee will use a process consistent with NIH procedures for reviewing the proposals and making award recommendations. CIAPM will use a process consistent with NIH practices to ensure proposals are evaluated in a manner that is fair, equitable, timely, and free of bias.

A. **Selection criteria:** *Section 65057 of the Government Code sets forth the following selection criteria:*

- The potential for tangible benefit to patients within two to five years, including the likelihood that the study will have an immediate impact on patients.
- The potential to reduce health disparities.

- The depth and breadth of data available in the disease focus areas across institutions.
- The prospects for efficient and effective data integration and analysis.
- The expertise of potential team members.
- The resources available for the project outside of the initiative, including the leveraging of non-state funding.
- The clinical and commercial potential of the project.
- The potential to scale and leverage multiple electronic health records systems.
- The potential to develop the use of tools, measurements, and data, including publicly generated and available data.

The Selection Committee will also consider additional factors in reviewing the proposals such as:
- The innovative concepts, approaches or methodologies, instrumentation, or interventions to advance precision medicine.
- The feasibility of the project (i.e., whether the project plan can be achieved within the proposed timeline).
- The quality and extent of patient/participant engagement.
- Approaches to protect privacy and personal health information.
- Methods to increase access and inclusion of populations that experience cancer health disparities.
- System interoperability.
- Sharing data and/or protocols across institutions.
- Where the project is located in California, to balance geographic equity of awards, and the diversity of awarded institutions.
- Diverse expertise and background of team members, including those underrepresented in biomedical research (e.g., underrepresented racial and ethnic groups, persons with disabilities, and women).
- Overall impact to advance precision medicine.

B. **Results:** The Selection Committee will report on the justification for selecting the demonstration projects that are awarded funding and will provide a list of the demonstration projects that were not selected on the CIAPM website. Therefore, do not include in the title of a project any proprietary or confidential information or information that could identify the PI and applicant institution, unless you do not object to being identified.

VI. **Applicants of proposals that are selected will be asked to enter into an agreement with the agency providing oversight. The agreement will address project implementation, including the following:**

1. **Indirect Costs:** No indirect costs will be provided with CIAPM funds.
2. **Intellectual Property Agreement:** Agree to terms of previously established patent and copyright agreement for existing CIAPM projects.
3. **Start Date:** Initiate work, if funded, within 30 days of receiving the award notification.
4. **Reporting:** Submit quarterly progress reports, work with oversight staff throughout their project, if funded, on milestone and budget development and adjustments, and participate in conference calls and convening activities. If awarded, precise post-award expectations will be specified in award agreements.
5. **Use of Data:** Investigators and demonstration teams are expected to share data and research findings consistent with academic standards.
6. **Protection of Privacy and Health Information:** Investigators and demonstration project teams are expected to follow state and federal law to protect privacy and personal health information, and rights of human subjects.