California Initiative to Advance Precision Medicine

CIAPM Request for Proposals 2016

Request for Proposals Announced	July 7, 2016
Concept Proposals Deadline	**August 8, 2016**
CIAPM Convening - Proposal Presentations	August 26, 2016
Notification of Finalists	August 31, 2016
Full Proposal Deadline	**September 30, 2016**
Awardees Announced	First week of November, 2016
Projects Commence	December 2016
Duration of Projects	18 months
Funding	Approximately 6 projects, likely up to $1.2M total per project; no indirect costs

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.

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, $7.2 million is provided by the state for approximately 6 proof-of-principle demonstration projects. Projects will be hosted by a lead public, private academic or non-profit institution in California and rely on integral partnerships with and contributions from other non-profit or for-profit partners. Projects will be selected through a two-stage process involving (1) concept proposal submission and optional presentation at an August 26, 2016 CIAPM convening and (2) development of selected concept proposals into full proposals from which the final selection of awards will be made. It is highly recommended that applicants attend the August 26 convening. After the selection committee makes their recommendations on awards CIAPM will work with awardees to

develop concrete metrics and goals to track the progress of the demonstration projects over the 18-month project period. The selection committee and its processes are described below.

Depending on the availability of funds, CIAPM may offer an opportunity for a competitive renewal to all awarded CIAPM demonstration projects. This would occur within 12-24 months of release of this RFP.

IV. Applications

A. Application process

Stage 1: Concept proposals

Applicants will be asked to submit short concept proposals and will have the opportunity to pitch and discuss their proposal at the CIAPM convening on August 26, 2016 in Los Angeles. This convening will provide an opportunity to help strengthen and build partnerships, and to present to the members of the selection committee. There will be an opportunity to provide a video instead of participating at the event.

Stage 2: Full proposals

The selection committee may select approximately 10-15 concept proposals to move onto the full proposal stage. Recommendations for submission of full proposal materials will be made available on the CIAPM website for the finalists advancing to the next stage after the convening on August 26, 2016.

The committee will recommend a number of final projects based on appropriated funds that may include up to six projects for funding to the Governor's Office of Planning and Research (OPR), which will approve and announce the final funding decision.

B. Eligibility - *Eligibility criteria are set forth in Sections 65057 and 65058 of the California Government Code. Those criteria include:*

1. Public and private academic and non-profit institutions are invited to submit proposals as principal investigators.
2. Demonstration project proposals should advance greater understanding in one or more focus areas, including:
    - The application of precision medicine to specific disease areas.
    - The challenges of system interoperability.
    - Economic analysis.
    - Standards for sharing data or protocols across institutions.
    - The federal and state regulatory environment.
    - The clinical environment.
    - Challenges relating to data, tools, and infrastructure.
    - The protection of privacy and personal health information.
    - The potential for reducing health disparities.
    - Methods and protocols for patient engagement.
3. The demonstration project should be located in California.

In addition to the eligibility requirements described above, the statute also allows the selection committee, and the Office of Planning and Research, to consider additional factors in weighing the proposals for recommended awards including the completeness of the application proposal, described below in Sections C and D. Additionally, at least one award should be made in both northern and southern California. To enable the selection committee to make fully informed award recommendations, applicants are strongly encouraged to include the information described below in Sections C and D in their written proposals.

C. Logistical Considerations

Each submitting institution, please provide answers for Section C1, C2 & C3, in a maximum one-page Institutional Cover Letter; minimum Arial 11 font; 0.5 inch margins; no appendices. For questions, please contact ciapm@ucsf.edu.

1. Host institutions: Identify the institution that is submitting one or more proposal(s) and will administer grant(s) if awarded.
2. Lead investigator(s): For each proposal submitted from your institution, identify a lead investigator who will serve as principal investigator (PI), and describe their capacity to serve the PI function. Capacity includes past success with previous and/or current scientific funding such as National Institute of Health and National Science Foundation funding.
3. Institutional focus: Describe your institution's commitment to each of the demonstration projects submitted from your institution. For example, limiting submissions to no more than two proposals per institution may be evidence of commitment. If more than two proposals are submitted, submitting a rank order of applications by the institution may be evidence of the relative level of commitment.
4. Authorized submission: The institutional letter (C1-C3) and the proposals (section D) should be submitted electronically by the vice chancellor for research or other equivalent or designated authorized institutional official.
5. Convening: Applicants, or their designees, are highly encouraged to participate in a convening on August 26, 2016, in Los Angeles. Due to limited availability of administrative funds, CIAPM will not be able offer travel support to applicants or their designees.

D. Concept proposals

Each applicant, please provide answers for Section D in a maximum of two-page Concept Proposal; minimum Arial 11 font; 0.5 inch margins; no appendices. For questions, please contact ciapm@ucsf.edu.

1. Impact on precision medicine: Describe how the proposed project will address a knowledge gap or need in a specific disease area(s), health issue, technology or fundamental biological process and, in doing so, demonstrate the promise of precision medicine. 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, etc.).
2. Focus area: Describe which relevant focus areas(s) the project will address (see section IV,B, 2 above). Provide rationale for the selected focus area(s) by outlining the current associated challenges to and opportunities for the advancement of precision medicine.
3. Project plan: Describe the components of your proposed project (specific aims and research strategy).
4. Patient data: Each proposal should demonstrate its commitment to the use of robust data. For example, your proposal could make use of patient data from at least two data sources, such as eligible institutions, health care providers, or other sources of health-related data. Use of additional data sets is encouraged. Briefly describe the data set(s) you propose to use and the rationale for their choice.

5. Precision medicine capabilities: Describe the precision medicine capabilities that will be developed as a result of this project (i.e., infrastructure and tools that will be built as a result of this project including physical capacity, new consortia, collaborations, personnel competencies, databases, software or computational development, startup company opportunities, intellectual property, patient cohorts, participant communities and networks, models for responsible data sharing, etc.).
6. Participant engagement: Describe strategies to engage patients (e.g. opportunities to build trust, approaches to ensuring consent, approaches to data sharing, privacy, security, etc.).
7. Impact for patients: To the extent it is applicable to the project, describe opportunities to improve patient outcomes within the 18-month project timeframe—and beyond.
8. Economic impact / value analysis: As appropriate for your project, describe the anticipated clinical utility and the economic impact (impact on healthcare spending) of your proposed intervention or platform, if implemented into clinical practice (see e.g., http://meetinglibrary.asco.org/content/152750-156 and Lamond et al., Expert Rev Pharmacoecon Outcomes Res. 2013, 243-50).
9. Health disparities: Describe the impact the project will have on reducing health disparities.
10. Anticipated challenges and proposed solutions: Describe potential barriers to the project's success, especially those that could delay the launch, progress or completion (e.g., human subjects), and describe potential solutions to these challenges.
11. Project Team: Provide a brief description of the PI, team, and key collaborators. Partnership is highly valued. Describe collaborations with at least two additional California non-profit or for-profit organizations as part of your proposal. Additional partners are highly encouraged. Describe the nature and strength of any existing collaborations.
12. Budget overview: Briefly outline how CIAPM funds (approximately up to $1.2M) will be used and how other resources will be leveraged. 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, or high-performance computing; mobile platforms to reach patients between medical encounters, to track their health and outcomes, etc. Please see existing CIAPM demonstration projects for examples.

    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.

E. Submission – Concept proposals must be submitted electronically as a single PDF to ciapm@ucsf.edu by 5:00pm PT on Monday, August 8, 2016.

V. Selection

A. 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 establish its procedures for reviewing the proposals and making award recommendations. CIAPM will strongly recommend a process consistent with NIH practices to ensure proposals are evaluated in a manner that is fair, equitable, timely and free of bias.

B. 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 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 potential for leveraging non-state funding.
- The clinical and commercial potential of the project.
- The potential to reduce health disparities.
- 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 may also choose to consider additional factors in reviewing the proposals such as:

- The potential for positive economic impact of the proposed intervention or platform, if implemented into clinical practice.
- The innovative concepts, approaches or methodologies, instrumentation, or interventions to advance precision medicine.
- The feasibility of the project (can the project plan be achieved within the proposed timeline).
- The quality and extent of patient engagement.
- Where the project is located in California to balance geographic equity of awards.
- Overall impact to advance precision medicine.

C. 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 those proposals that are selected will be asked to enter into an agreement with CIAPM through the University of California, San Francisco. The agreement will address project implementation, including the following:

A. Indirect Costs: Due to statutory limits of funding, no indirect costs will be provided with CIAPM funds. Awardees are asked to waive indirect expenses.

B. Intellectual Property Agreement: Agree to terms of previously established patent agreement for existing CIAPM projects.

C. Start Date: Initiate work, if funded, within 30 days of receiving the award notification.

D. Reporting: Submit quarterly progress reports, work with CIAPM 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.

E. Use of Data: Investigators and demonstration teams are expected to share data and research findings consistent with academic standards.

F. 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.