CIAPM Depression RFP 2023 – Full Proposal Instructions

Lead Principal Investigators (PIs) of Concept Proposals selected through a peer-review process to advance to the final stage of review are invited to submit a Full Proposal, as outlined in this guidance.

I. Timeline

Notification of Finalists	January 2024
Full Proposals Due	February 15, 2024 at 12:00 p.m. PT (Noon)
Awardees Announced	March 2024
Project Start Date	June 2024
Duration of Projects	36 months

II. Application Instructions

All application materials must be submitted electronically via the CIAPM online submission portal. The application form will become available in the online submission portal when finalists are announced. Use minimum Arial 11 font and 0.5-inch margins. Frequently Asked Questions will be updated as needed.

1. **Cover Page**: 1-page maximum
   a. Title of the proposal
   b. Name of the Primary Institution
   c. All Principal Investigators' names, affiliated institutions, and signatures. Indicate PIs and institutions that have been added since the Concept Proposal stage.
   d. For the Primary Institution only, include name, email address, and signature of the Vice Chancellor of Research (VCR), Chief Executive Officer (CEO), Principal Grant Officer, or equivalent authorized institutional official.
   e. Key team members, collaborators, and contractors/consultants listed by institution/organization

   Note: The signature specified in item d. indicates that the host institution agrees to administer an award resulting from this proposal and acknowledges that any award will not cover indirect costs for academic institutions.

2. **Scientific/Technical and Public Abstracts**: 1-page maximum
   a. Scientific/Technical Abstract
   b. Public Abstract: In lay language, briefly describe the proposed work and how it will contribute to the RFP topic, "A Precision Medicine Approach to Improve the Prevention, Diagnosis, and Treatment of Depression." If selected as an Awardee, the public abstract will become public information and will be available online; therefore, do not include information that is proprietary or confidential.
3. **Full Project Plan**: 6-page maximum

   Expand on the information you provided in your Concept Proposal (items a.-h. below), taking into consideration Selection Committee feedback. Please also respond to the two new categories of questions that have been added since the Concept Proposal phase (items i.-j. below). Please include the headings for these items (a.-j.) in your proposal.

a. Impact on health outcomes and health inequities

Describe how the proposed project will improve health outcomes and reduce inequities among populations experiencing or at risk for depression. Provide rationale for the project by outlining existing strengths, resources, and opportunities available (e.g., preliminary data, an existing participant cohort, data collection capabilities, access to existing biobanks, databases, or medical records, or established mechanisms for responsible data sharing). Describe why the topic was selected and why the approach is impactful.

Populations may include, but are not limited to, those defined by access to care, age, ancestry, comorbidities, culture, developmental stage, disability status, ethnicity, gender, genetics, geography, health literacy, housing status (including current or former wards of the state), immigration status, justice-involved, language, racial group, religion or faith, sex, sexual orientation, socioeconomic status, treatment resistance and other health history, and any combination of these populations.

b. Project plan

Describe the components of the proposed project, including specific aims and research strategy.

We encourage activities and training in health equity, cultural competency, and community engagement for members of the research team that have not previously engaged in these topic areas.

c. Data

Each proposal should demonstrate its commitment to the use of robust data. Use of multiple data sets is encouraged (e.g., electronic health records, mobile health device data, registries, and research databases). Briefly describe the data set(s) you propose to use or create, the rationale for integrating the selected data, and how the data set(s) may contribute to better outcomes by improving preventive, diagnostic, measurement, and/or treatment approaches. Also briefly describe the data ownership, use, and sharing plan, including how the data will not be used or shared. We will consider the extent to which community members are engaged, in part, by considering how data are shared, used, and/or owned by community partners. Please also consider a communication plan for sharing resources, outreach materials, data, etc. for non-technical audiences.

d. Precision medicine assets

Describe the precision medicine assets that will be developed as a result of this project, such as infrastructure and tools that will be built, including, but not limited to, new applications, collaborations, consortia, databases, datasets, intellectual property, models for responsible data sharing, participant communities and networks, patient cohorts, personnel competencies, resources, and software.

e. Participant and community engagement

Describe strategies to engage patients, families, and communities for authentic partnership, such as developing opportunities to build trust, approaches to ensuring consent, or practical principles for data sharing, privacy, and security. To help facilitate

participant and community engagement, **projects must include a community advisory board**. The community advisory board should consist of patients and other stakeholders who have a connection to, expertise in, or lived experience related to depression. Projects may also employ patient navigators, host focus groups to better understand patient/community issues or describe efforts to allow patients access to their medical data, and/or present opportunities to contribute data from this demonstration project to other research studies.

f. Impact for patients and other participants

Describe opportunities to improve patient outcomes within two to five years—and beyond, and how this might be scalable or generalizable to other patient populations and/or other health issues. Describe how research participants and/or communities will benefit from this project. What is your vision for how the project will impact patients and contribute to precision medicine beyond the project timeframe?

g. Approaches to improving training and/or education

Describe how the proposal will develop or amplify quality opportunities for trainees and/or students to better apply precision medicine approaches to health care or support mental health care workforce development, for example by creating or updating a curriculum for a graduate course or occupational certification program, engaging trainees in the implementation of the project, or assessing current training methods in clinical depression screenings.

h. 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, health literacy barriers, cultural or language access barriers, or mobile patient populations), and describe potential solutions to these challenges.

i. Private sector collaboration statement

By the full proposal stage, projects must also include at least one private sector collaborator that contributes in-kind, financial, or other resources to the project. The private sector collaborator should not be a PI, and CIAPM funds may not be allocated to support salaries of private sector collaborators. The intent of the private sector collaborator is to add capability, scalability, and/or sustainability to the project, research team, and community partners.

Please answer the following questions for the Private Sector Collaboration Statement.

Describe the role of the private sector collaboration and the value add to the research project and community and patient population. List the resources and/or deliverables that the private sector collaborator(s) will provide and describe how those resources/deliverables will advance the aims – both academic and community engagement – of the proposed project. Please describe the relationships between the academic institution(s), community organization(s), and private sector collaborator(s). How will the private sector collaboration contribute resources or capacity building for community partners during and after the three-year CIAPM funding period?

j. Equity and accountability statement

Selection criteria in CIAPM's enabling statute includes "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" and "the potential to reduce health disparities."

Please answer the following questions in the Equity and Accountability Statement that allow for elaboration beyond the Project Plan.

Describe how this project will advance equity in terms of the research question, population of interest, process of carrying out the research, how data are collected, used, and shared, research outcomes, and community impact. What qualifications do the team members have related to the proposed project in terms of equity expertise and experiences? Describe how the academic research team has and continues to build trust with the community partners and how the research team will be held accountable for community impacts.

4. **References**: no page limit

   List references cited in the project plan.

5. **Milestones**: 1-page maximum

   To track and deliver proposed project outcomes, it will be necessary to develop and institute meaningful and agreed-upon milestones. Funding of awarded projects is not guaranteed, but rather contingent on meeting agreed upon milestones and demonstrating measurable progress towards these milestones as evidenced through biannual progress reports, monthly conversations, and annual site visits, as determined by CIAPM.

   Provide draft milestones in the form of a table (see template below), listing each deliverable, the metric that indicates its successful achievement, and the anticipated start and end date for associated work, assuming a start date of **June 1, 2024**. This draft will be part of the assessment by the Selection Committee and will serve as a basis for a grant agreement with CIAPM, if funded.

   Milestone Table Template

   Note: Please modify according to your project/aims design and add rows as necessary. Each row should reflect the milestone/deliverable within each aim component or section.

Milestone/Deliverable	Description/Metric	Start Date	Due Date
Aim 1.1: Brief Title of Aim 1 Objective 1			
Aim 1.2: Brief Title of Aim 1 Objective 2			
Aim 1.3: Brief Title of Aim 1 Objective 3			
Aim 2.1: Brief Title of Aim 2. Objective 1			
Aim 2.2: Brief Title of Aim 2 Objective 2			
Aim 2.3: Brief Title of Aim 2 Objective 3			
Add additional Aims/Subaims as needed...			

6. **Project Team Biographical Sketches and Resumes**: no page limit

   Provide NIH-format biographical sketches for all scientific project team members, up to five pages per individual. Any community member of the project team may instead provide a resume (no strict format beyond a limit of five pages per individual).

7. **State Law Compliance**: no page limit

   Please complete the form shown in Appendix A, which will be provided in Submittable.

8. **Protection of Human Subjects**: no page limit

   Applications must designate whether Human Subjects Research is proposed. If your work involves human subjects, please see Appendix B for further instructions. If your work does not involve Human Subjects Research, the "Protection of Human Subjects" section is not required.

   Please complete the form shown in Appendix B, which will be provided in Submittable.

9. **Budget Narrative**: 1-page maximum
   a. Propose a budget between $1.8 and $3.0 million.

      Note: Indirect costs to academic institutions will not be supported by CIAPM funds, but indirect costs may be proposed and supported for community organizations. The budget may differ from that included in the Concept Proposal.

   b. Budget overview: Briefly outline how CIAPM funds will be used and how other resources will be leveraged, including total amount of matching funds from partners and other entities, such as philanthropic organizations. Comment on why CIAPM funds are needed, compared to other funding sources, such as federal or philanthropic grants. Examples of other resources that may be leveraged include experts' time; molecular characterization; computational platforms, including genetic analysis, data visualization, innovative databases, data sharing, data privacy and security, and high-performance computing; mobile platforms to reach patients between medical encounters to track their health and outcomes; and others.
   c. Describe how, if at all, a portion of funds will be used to compensate research participants and community advisory board members for their time and/or expertise.

      See examples of resources leveraged by former CIAPM demonstration projects in the 2019 Evaluation Report of previously funded grants.

      Note: All project PIs and key team members must reside in California. A collaborator or consultant who resides outside of California may receive funds from a CIAPM grant. For amounts over $50,000 total per individual, written justification must be provided (maximum 1 additional page allowed).

10. **Detailed Budget**: 4-pages maximum (PDF only)

    Provide a detailed budget breakdown to support the narrative, using the CIAPM template in Appendix C (downloadable as an Excel Spreadsheet).

A ***minimum* 15%** of the budget must be allocated to one or multiple nonprofit community-based organizations, patient advocacy groups, community clinics, or public or tribal entities that provide support to people with or at risk for depression. We highly recommend that project teams strive for budget equity.

Include an allocation of $1,500 per year ($4,500 in total across three years) to cover costs associated with annual site visits and travel to CIAPM events, such as annual Depression Research Symposia and All-Teams Meetings in Sacramento.

Note: The Budget Section may deviate from the formatting requirements of all other sections in the following ways: landscape or portrait orientation accepted; Font Size 10 or 11 accepted.

11. **Modifications Since the Concept Proposal Stage**: 2-pages maximum

    Summarize any significant changes made since your Concept Proposal, including (if appropriate) new partner institutions and individuals, project team expertise, matching funds, and/or changes made in response to feedback from the Selection Committee. Please reference specific Full Proposal items in your response.

12. **Letters of Support**: no page limit

    Provide a letter of support from the private sector collaborator(s) (required) and letters of support from any others who are not members of the Project Team (optional). Letters of support from the private sector collaborator(s) should include details of the in-kind, financial, or other resources contributed to the project.

III. Administration

During the solicitation process, questions may be directed to CIAPM staff:

David Reiner, PhD, Science Officer
Governor's Office of Planning & Research
1400 Tenth Street, Sacramento, CA 95814
Telephone: (916) 323-9164
Email: ciapm@opr.ca.gov

Applicants may submit written questions via email or mail. All technical questions must be received on or by February 12, 2024. Non-technical questions (e.g., questions concerning format requirements or submission instructions) may be submitted to CIAPM staff at any time prior to the February 15, 2024 deadline for Full Proposals. As necessary, CIAPM staff will update a list of Frequently Asked Questions on the website.

Any verbal communication with CIAPM staff concerning this solicitation is not binding on the State and will in no way alter a specification, term, or condition of the solicitation. Therefore, all communication should be directed in writing, as indicated above.

If an ambiguity, conflict, discrepancy, omission, or other error is discovered in the solicitation at any time prior to a deadline, the proposer may notify CIAPM staff in writing and request modification or clarification. OPR, at its discretion, may provide modifications or clarifications either by an addendum to the solicitation or by a written notice to all parties who participate in the solicitation. At its discretion, OPR may re-open the technical question period to provide all

applicants the opportunity to seek any further clarification required. Any change would be reflected on the CIAPM website.

Appendix A

State Law Compliance Checklist

Please confirm that the project complies with California Law, including the following code sections relevant to research and child abuse and neglect reporting (check each box to confirm compliance):

☐ Health and Safety Code on Human Experimentation §24170 - 24179.5

☐ Penal Code on Biomedical and Behavioral Research §3500

☐ Child Abuse and Neglect Reporting Act §11164-11174.3

Appendix B

Protection of Human Subjects

You will need to know whether your research needs an IRB review in the case that your proposal is awarded CIAPM funding. Please use this simple questionnaire to determine whether your proposed project falls under the category of Human Subjects Research, as defined by the NIH[1].

If your project is awarded, you are required to submit the necessary paperwork for IRB review within one month from contract execution date. Exempt Research requires IRB review and acknowledgement, and Non-Exempt Research requires IRB review and approval (see Question 2 below). CIAPM does not require IRB submissions prior to Full Proposal submission.

1. Does your proposed work involve Human Subjects Research? If you are unsure, please use the NIH Human Subjects Research Decision Tool. Yes ☐ No ☐

   If you answered "Yes," please complete the following questions. If you answered "No", then no further response is required in this section.

2. Does your work qualify as "exempt"? Yes ☐ No ☐

   To answer this question, consider the results of the NIH Human Subjects Research Decision Tool (linked above) and the six categories listed in Federal Regulations Code §46.104 under "Exempt Research."

   2a. If you answered "Yes" to question 2, your project requires IRB review and acknowledgment, rather than an IRB review and approval.

   - Has IRB acknowledgment been obtained from your institution? Yes ☐ No ☐
     - If Yes: IRB acknowledgement date:
     - If No: I agree to submit an application to my IRB within one month of contract execution. Yes ☐

   2b. If you answered "No" to question 2, your project requires IRB review AND approval.

   - Has IRB approval been obtained from your institution to support your CIAPM-funded project? Yes ☐ No ☐
     - If Yes: IRB approval date:
     - If No: I agree to submit an application to my IRB within one month of contract execution. Yes ☐

3. Are you proposing a clinical trial? Yes ☐ No ☐

4. Does the project involve children? Yes ☐ No ☐

[1] Review the NIH definition of "human subjects".

☐ If you answered “Yes,” please check the box to confirm that the project complies with additional HHS Regulations related to involving children in research.

Please provide the following narratives in your full proposal if previous Prompts 2a, 2b, and/or 3 apply to your proposed work.

2a. If your work involves Human Subjects Research and qualifies as “exempt”, indicate which “exempt category” it falls under (Federal Regulations Code §46.104).

2b. If your work involves Human Subjects Research and does not fall into one of the exempt categories:

- Describe risks to subjects
- Describe adequacy of protection against risks
- Describe potential benefits of research to subjects and others
- Describe importance of knowledge to be gained
- Describe inclusion of women, minorities, and children

3. If you are proposing a clinical trial:

- Include information listed under 2b.
- Include a Data Safety and Monitoring Plan[2].

[2] Review https://www.nlm.nih.gov/ep/dsm.html and https://humansubjects.nih.gov/data_safety

Appendix C

CIAPM Budget Template

Please use this link to download the budget template. You may add (or remove) rows to fit the size of your project team, including the number of consultants/collaborators, the number of partner sites, and the number of individuals at each site.

Subcontractors are defined as partner sites where PIs and project team members not from the primary institution are based. Subcontracts could be awarded to other non-profit academic research institutions, nonprofit community-based organizations, patient groups, clinics, or public or tribal entities.

Consultants or collaborators are defined as individuals who consult or collaborate on the project but are not affiliated with either the primary institution or any of the subcontracted partner sites.

California Initiative to Advance Precision Medicine
Budget Template for Proposals & Contracts

Lead Principal Investigator:
Period (Start - End Dates): 06/01/24 - 05/31/27

Primary Site	Y1 ($)	Y2 ($)	Y3 ($)	TOTAL ($)
PERSONNEL - Breakdown to the Right				
Salaries	$0	$0	$0	$0
Benefits	$0	$0	$0	$0
Personnel TOTAL	**$0**	**$0**	**$0**	**$0**
CONSULTANTS & COLLABORATORS				
Individual 1- Role/Affiliation	$0	$0	$0	$0
Individual 2- Role/Affiliation	$0	$0	$0	$0
Individual 3- Role/Affiliation	$0	$0	$0	$0
Individual 4- Role/Affiliation	$0	$0	$0	$0
Individual 5- Role/Affiliation	$0	$0	$0	$0
Consultants TOTAL	**$0**	**$0**	**$0**	**$0**
NON-PERSONNEL DIRECT COSTS				
Materials, Equipment, and Supplies TOTAL	$0	$0	$0	$0
Travel TOTAL	$0	$0	$0	$0
Other Direct Costs TOTAL	$0	$0	$0	$0
Non-Personnel Direct Costs TOTAL	**$0**	**$0**	**$0**	**$0**
SUBCONTRACTS - DIRECT COSTS - Breakdown Below				
Partner Site 1 - Breakdown Right	$0	$0	$0	$0
Partner Site 2 - Breakdown Right	$0	$0	$0	$0
Partner Site 3- Breakdown Right	$0	$0	$0	$0
TOTAL COSTS (ALL SITES)	**$0**	**$0**	**$0**	**$0**

Note: Please add or delete rows in the Consultants & Collaborators, Other Direct Cost, Subcontract, and Personnel Breakdown by site sections as it fits your project.

Note: Please add or delete rows in the Partner Site section as it fits your project. The Facilities and Administrative Costs TOTAL is only for Non-profit Community Partners.

Partner Site 1- Direct Costs - Breakdown	Y1 ($)	Y2 ($)	Y3 ($)	TOTAL ($)
PERSONNEL - Breakdown Below				
Salaries	$0	$0	$0	$0
Benefits	$0	$0	$0	$0
Personnel TOTAL	**$0**	**$0**	**$0**	**$0**
NON-PERSONNEL DIRECT COSTS				
Equipment TOTAL	$0	$0	$0	$0
Materials & Supplies TOTAL	$0	$0	$0	$0
Travel TOTAL	$0	$0	$0	$0
Other Direct Costs TOTAL	$0	$0	$0	$0
Non-Personnel Direct Costs TOTAL	**$0**	**$0**	**$0**	**$0**
INDIRECT COSTS				
Facilities and Administrative Costs TOTAL (for only Non-profit Community Partners)	$0	$0	$0	$0
TOTAL COSTS (Site 1 Only)	**$0**	**$0**	**$0**	**$0**

PERSONNEL BREAKDOWN BY SITE (Complete this section first and Partner Site-Direct costs Personnel Breakdown will autofill)
Note: Please add or delete rows in the Personnel Breakdown by Site section as it fits your project. Year 2 Salary formula assumes 3% increase in Salary from Year 1 Salary. Year 3 salary formula assumes 3% increase from Year 2 Salary. Please adjust according to institutional guidelines.

Lead Site - PERSONNEL	Full-Time Equivalency			Fringe Benefit Rate (%)	Y1 Salary Base ($)	Y1 Salary Request	Y1 Benefit Request	Y2 Salary Request	Y2 Benefit Request	Y3 Salary Request	Y3 Benefit Request	Total
	Y1 (%)	Y2 (%)	Y3 (%)									
Lead PI	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 6- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 7- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 8- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 9- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 10- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
TOTAL:						**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**