

Request for Proposals

A Precision Medicine Approach to Improve the Prevention, Diagnosis, and Treatment of Depression



Governor's Office of Planning & Research September 22, 2023 If you or someone you know experiencing a mental health crisis, dial 988 to reach the Suicide and Crisis Lifeline, or go to the nearest emergency room. More information can be found at <u>988lifeline.org</u>

California Initiative to Advance Precision Medicine (CIAPM) Request for Proposals 2023 for Demonstration Projects Summary

Key dates

RFP Release: 09/22/2023

 RFP Informational Webinar:
 10/02/2023 at 3:00 p.m. PT

 LOI Question Submission:
 10/27/2023 by 12:00 p.m. PT

 Letters of Intent Due:
 10/30/2023 by 12:00 p.m. PT

 Con. Prop. Question Submission:
 11/27/2023 by 12:00 p.m. PT

 Concept Proposals Due:
 12/1/2023 by 12:00 p.m. PT

Notification of Finalists: January 2024

Full Proposals Due: 02/15/2024 by 12:00 p.m. PT

Awardees Announced: March 2024
Project Start Date: June 2024

Eligibility

- 1. The Lead Principal Investigator (PI) must be affiliated with a California nonprofit academic research institution (including tribal institutions).
- 2. Current and former CIAPM lead PIs are ineligible to act as a lead PI but may serve other roles within the project team. Team members who are not current or former lead PIs but have served other roles on a CIAPM-funded project are eligible to apply as a lead PI.
- 3. Only one proposal per team will be accepted. An individual may serve as lead PI for only one proposal but may contribute to multiple proposals.
- 4. There will be no more than one award per primary institution, but several lead PIs may apply from one primary institution. There is no limit to the number of submissions receivable from any single institution.
- 5. Demonstration projects must take place in California.

Collaboration Requirements

- 1. At least one PI must be from a nonprofit community-based organization, patient advocacy group, community clinic, or public or tribal entity that provides support to people with or at risk for depression. Up to 10 PIs may be designated in addition to the Lead PI.
- 2. By the full proposal stage, projects must include at least one private-sector collaborator who contributes in-kind, financial, or other resources. The private sector collaborator should not be a PI and CIAPM funds may not be allocated to support salaries of private sector collaborators.

Project Budget

CIAPM will award 3-5 projects, at \$1.8-3 million per team, funded over a three-year project term.

Selection Criteria

- 1. Significance (Program Fit)
- 2. Innovation (Potential for Public Benefit)
- 3. Approach, including implementation plan (Project Plan)
- 4. Project Team (Qualifications and Expertise in Focus Area/Community)
- 5. Community Partnership (Engagement and Partnership)

Contact Us

Program inquiries: Email <u>ciapm@opr.ca.gov</u> with subject line "Depression RFP." CIAPM staff will respond within 48 business hours; response times may be longer as deadlines approach.

A Precision Medicine Approach to Improve the Prevention, Diagnosis, and Treatment of Depression

I. Overview

The California Initiative to Advance Precision Medicine (CIAPM) will award \$9 million across three to five independent research teams (\$1.8 to \$3 million per team) over three years to further understanding about the prevention, diagnosis, and treatment of depression. Precision medicine calls for the modern application of scientific data and clinical practice toward the individualization of prevention, diagnosis, measurement, and treatment of disease and wellbeing. This funding opportunity aims to drive innovation with a precision medicine approach to improve outcomes for patients with or at risk for depression and reduce health inequities.

Research teams must be co-led by at least one California non-profit academic research institution and at least one nonprofit community-based organization, patient advocacy group, community clinic, or public or tribal entity that provides support to people with or at risk for depression. A key component of these projects is authentic community partnerships with patients and other stakeholders who have a connection to, expertise in, or lived experience related to depression from project conception to project completion and beyond.

By the full proposal stage, projects must also include at least one private sector collaborator that contributes in-kind, financial, or other resources. The private sector collaborator should not be a PI and CIAPM funds may not be allocated to support their salaries. Projects must take place in California, and funds may not be used for indirect costs. Additional matching funds and in-kind contributions are highly encouraged and will be considered during the selection process.

All proposal materials will be accepted electronically by the Governor's Office of Planning and Research (OPR) via the online CIAPM submission portal, according to the timeline below.

II. Timeline

Release of the Notice of Funding Intent 01/31/2023

Request for Information & Listening Sessions July-August 2023

Announcement of the RFP 09/22/2023

Informational Webinar 10/02/2023 at 3:00 p.m.

Due: LOI Questions 10/27/23 by 12:00 p.m. (Noon)

Due: Letters of Intent to Submit a Proposal 10/30/2023 by 12:00 p.m. (Noon)

Due: Concept Proposal Questions 11/27/23 by 12:00 p.m. (Noon)

Due: Concept Proposals 12/1/2023 by 12:00 p.m. (Noon)

Notification of Finalists

12/ 1/2023 by 12:00 p.m. (Noon)

January 2024

Due: Full Proposals (for Finalists only) 02/15/2024 by 12:00 p.m. (Noon)

Awardees Announced March 2024

Anticipated Project Start

June 2024

Duration of Projects 36 months All times listed are in Pacific Time.

III. Background

Precision medicine

Precision medicine holds promise to profoundly transform health, health care, and biomedical research. As envisioned in the National Academy of Sciences (NAS) 2011 report, Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease, this approach 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 develop and deliver more precise preventive measures, diagnostics, and therapeutics. Precision medicine also considers the social determinants of health and the whole person, such as age, cultural background, disability status, ethnicity/race, gender identity, geographic location, religion or faith, sexual orientation, and socioeconomic status. Creating models of access for precision care for all communities will be vital to address health inequities and positively impact clinical outcomes across subpopulations.

California Initiative to Advance Precision Medicine

CIAPM was established by the State of California to help coordinate public, private, and nonprofit partners to advance precision medicine approaches and foster the creation of new technologies and therapies that can improve the health of Californians (Gov. Code, §§ 65055-65059.). The initiative, administered by the Governor's Office of Planning and Research (OPR). coordinates precision medicine efforts across sectors and supports research projects that demonstrate the power and promise of precision medicine to the people of California, with a focus on advancing health equity, including racial equity, by funding programs designed to address health inequities.

This CIAPM request for proposals (RFP) is one of many strategies in a multi-pronged approach that the Newsom Administration and the California State Legislature have taken to improve the mental health of Californians. For example, the Master Plan for Kids' Mental Health and Children and Youth Behavioral Health Initiative (CYBHI) provide funding to support mental health infrastructure for youth, including greater healthcare coverage, increased numbers of school counselors, statewide mental health call centers, and training programs for workforce development^{1,2,3}. The Mental Health Services Oversight and Accountability Commission oversees the implementation of the Mental Health Services Act by distributing grants. conducting research, collecting and sharing data, spreading best practices, and ensuring that all people are receiving timely, comprehensive, effective, and culturally competent care4. The behavioral health system is undergoing changes to expedite outpatient, crisis, and inpatient care, reduce inequities between groups accessing care, reduce the risk of homelessness and

https://www.gov.ca.gov/2022/12/07/governor-newsom-announces-an-unprecedented-480-5-million-ingrants-for-youth-mental-health/

4

¹ Office of Governor Gavin Newsom (2022, December 7). Governor Newsom Announces an Unprecedented \$480.5 Million in Grants for Youth Mental Health.

² Phil Ting (2022, October 13). California Announces Investments in Statewide Mental Health Call Centers. https://a19.asmdc.org/press-releases/20221013-california-announces-investments-statewidemental-health-call-centers

³ Governor Newsom's Master Plan for Kids' Mental Health (2022, August). https://www.gov.ca.gov/wpcontent/uploads/2022/08/KidsMentalHealthMasterPlan_8.18.22.pdf?emrc=6d3847

⁴ About MHSOAC (2023). https://mhsoac.ca.gov/about/

housing insecurity, and reduce stigma and discrimination for seeking care^{5,6}. The Newsom Administration and legislators have also proposed revisions to the Mental Health Services Act to provide greater coverage to unhoused communities, among other goals⁷. Additionally, the California Surgeon General has prioritized improving mental health, with a focus on CYBHI⁸. This CIAPM RFP aligns with and builds upon these state-wide efforts to improve mental health in California.

Background on Depression

Depression is a complex disorder, characterized by symptoms including, but not limited to, a sad or "empty" mood, diminished interest in activities, fatigue and loss of energy, changes in sleep and/or appetite, aches or pains, difficulty concentrating, feelings of worthlessness and guilt, and thoughts of death and suicide^{9,10}. Depression can manifest differently according to many different factors.

In the U.S., 18% of adults reported being diagnosed with depression in their lifetime¹¹ and around 2% of children aged 3-11 and 9% of youth aged 12-17 have been diagnosed with depression (via parent-reported diagnosis)¹². Around 21% of youth ages 12-17 self-reported having had a major depressive episode in their lifetime¹². 50% of all lifetime mental illness begins by age 14, and 75% of all lifetime illness begins by age 24¹³. Differences in depression occurrence, course, and intervention effectiveness are influenced by age, cognition, culture, education level, genetics, income, personality, physiology, sexual orientation, gender identity, and environmental factors such as experiences and social circumstances^{14,15,16}, and may be

⁵ Susan Talamantes Eggman (2023, January 6). *California Senate's New Health Chair to Prioritize Mental Health and Homelessness*. https://sd05.senate.ca.gov/news/california-senates-new-health-chair-prioritize-mental-health-and-homelessness

⁶ Policy Brief: Understanding California's Recent Behavioral Health Reform Efforts (2023). https://www.chhs.ca.gov/wp-content/uploads/2023/03/CalHHS-Behavioral-Health-Roadmap-_-ADA-03.02.23.pdf

⁷ Governor Newsom and Legislative Partners Unveil Transformation of California's Mental Health Services Act (2023, June 20). https://www.gov.ca.gov/2023/06/20/governor-newsom-legislative-partners-unveil-transformation-of-californias-mental-health-services-act/

⁸ Mental Health (2023). https://osg.ca.gov/mentalhealth/

⁹ American Psychiatric Association. *What is Depression?* https://www.psychiatry.org/patients-families/depression/what-is-depression

¹⁰ NIMH. Depression. https://www.nimh.nih.gov/health/topics/depression

Lee B, Wang Y, Carlson SA, et al. National, State-Level, and County-Level Prevalence Estimates of Adults Aged ≥18 Years Self-Reporting a Lifetime Diagnosis of Depression — United States, 2020.
 MMWR Morb Mortal Wkly Rep 2023;72:644–650. DOI: http://dx.doi.org/10.15585/mmwr.mm7224a1.
 Bitsko RH, Claussen AH, Lichstein J, et al. Mental Health Surveillance Among Children — United States, 2013–2019. MMWR Suppl 2022;71(Suppl-2):1–42. DOI: http://dx.doi.org/10.15585/mmwr.su7102a1.

¹³ Mental Health By the Numbers. https://www.nami.org/mhstats

National Research Council (US) and Institute of Medicine (US) Committee on Depression, Parenting Practices, and the Healthy Development of Children; England MJ, Sim LJ, editors. Depression in Parents, Parenting, and Children: Opportunities to Improve Identification, Treatment, and Prevention. Washington (DC): National Academies Press (US); 2009. 3, The Etiology of Depression. Available from: https://www.ncbi.nlm.nih.gov/books/NBK215119/

Senft, N., Doucerain, M. M., Campos, B., Shiota, M. N., & Chentsova-Dutton, Y. E. (2022). Within- and between-group heterogeneity in cultural models of emotion among people of European, Asian, and Latino heritage in the United States. *Emotion*. Advance online publication. https://doi.org/10.1037/emo0001052
 Living Well / Reducing Adult Depression. https://letsgethealthy.ca.gov/goals/living-well/mental-health-and-well-being-reducing-adult-depression/

compounded by the intersection of these many determinants. Disparate access to appropriate treatment for depression can create and exacerbate existing health¹⁷. Additionally, depression often co-occurs with other behavioral and physical health disorders, which complicates diagnosis and disorder¹⁸.

To address the state's mental health challenges in new and innovative ways, the California Legislature approved the Governor's proposed budget allocation to support depression research 19,20. To ensure that this RFP for depression research is responsive to community needs, CIAPM released a request for information (RFI) from July 17 through August 18, 2023 and held listening sessions throughout the state in partnership with the Mental Health Services Oversight and Accountability Commission and with support from the Office of the California Surgeon General. Based on the feedback from the RFI and listening sessions as well as a gap assessment, landscape analysis, and informational interviews with out-of-state subject matter experts, CIAPM developed the scope of this RFP on precision medicine approaches to study the prevention, diagnosis, and treatment of depression.

Funding Opportunity for Depression Research

This funding opportunity seeks to inspire collaborative research throughout the state, using precision medicine approaches to improve our understanding of prevention, diagnosis, and treatment of depression across domains, and identify or improve upon interventions for subpopulations who experience depression at a disproportionate rate. In line with the purpose of CIAPM and the intention the Newsom Administration, this funding opportunity aims to support research projects that **advance health equity, including racial equity**. Health equity envisions that all people have full access to opportunities that enable them to lead healthy lives regardless of the social determinants of health²¹. While physical and mental health may be impacted by a variety of social determinants, data show that race and ethnicity are some of the greatest predictors of higher rates of illness across all conditions²².

CIAPM is well-positioned to advance racial equity through data, partnerships, research, and input from key audiences. Meaningful engagement and involvement of **researchers and community partners representing Black, Native American, and communities of color** is vital to advance CIAPM's racial equity commitments and address these communities' disproportionate experience of mental health disparities and historic structural barriers to access mental healthcare.

¹⁷ McGregor, B., Li, C., Baltrus, P., Douglas, M., Hopkins, J., Wrenn, G., Holden, K., Respress, E., & Gaglioti, A. (2020) Racial and Ethnic Disparities in Treatment and Treatment Type for Depression in a National Sample of Medicaid Recipients. *Psychiatric Services*, *71*(7), 663-669. https://doi.org/10.1176/appi.ps.201900407

¹⁸ Gold, S.M., Köhler-Forsberg, O., Moss-Morris, R., Mehnert, A., Miranda, J. J., Bullinger, M., Steptoe, A., Whooley, M. A., & Otte, C. (2020). Comorbid depression in medical diseases. *Nature Review Disease Primers, 6*(69) https://doi.org/10.1038/s41572-020-0200-2

¹⁹ AB-179 Budget Act of 2022. https://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=202120220AB179

²⁰ Allocation of CIAPM Depression Research Funding for AB-179 Budget Act of 2022. https://esd.dof.ca.gov/Documents/bcp/2223/FY2223 ORG0650 BCP5011.pdf

²¹ California Health and Safety Code Section 131019.5 https://www.cdph.ca.gov/Programs/OHE/CDPH%20Document%20Library/Health_and_Safety_Code_131 019.5.pdf

²² Racism and Health (2023). https://www.cdc.gov/minorityhealth/racism-disparities/index.html

CIAPM seeks to fund research projects on precision medicine approaches for the prevention, diagnosis, and treatment of depression. The list below is **inspired by community perspectives** from the RFI and listening sessions and informational interviews with out-of-state subject matter experts. Projects **may include**, **but are not limited to**, the following areas or aspects:

- Adaptation of depression-related preventative, diagnostic, and treatment tools to fit a wider array of cultural needs, particularly for refugee and immigrant communities
- The impact of interventions and resources that are culturally appropriate, increase language access, increase accessibility for disabled communities (including deaf, hard-of-hearing, deaf-blind, and late deafened) or unhoused communities, or connect Native communities with their indigenous cultures and healing practices on depression related-outcomes
- Innovations in training opportunities in research or mental health care fields related to depression that focus on culturally appropriate and relevant care
- Strategies to build capacity within communities, such as community-based organizations, community clinics, community healthcare workers, and tribal organizations
- The impact of interventions or resources that minimize stigma or reduce barriers to seek care (e.g., language access, cultural capacity, virtual and/or hybrid care, simplifying access through community health workers or a similar model) on outcomes related to depression
- Improving youth outcomes related to depression, including specialized diagnostic and treatment tools, training for school professionals, and support for parents and caregivers
- The impact of mental health education in school curricula, leadership opportunities, skill building, or social media on outcomes related to depression in youth
- Early diagnosis of children with depression and implementation of appropriate interventions
- Development of a program to educate and/or support family members of those experiencing depression, to ensure long-term treatment support and success
- Connecting mental and physical health outcomes related to depression
- Assessments of whether treatment outcomes related to depression are sustained over time
- Measurements that assess outcomes related to social connectedness with family, friends, and community in people with or at risk for depression
- Measurements of depression treatment side effects and how this impacts treatment decision
- Strategies to increase the likelihood of a "good match" between a patient and provider
- Remote collection of behavioral, physiological, and other data and/or integration with electronic health record data
- Early identification of patients who are treatment-resistant
- Early identification of patients with depressive symptoms who later develop bipolar disorder
- Development of predictive tools, including but not limited to biomarkers, to determine which patients will respond best to a given treatment
- Development of machine learning techniques to interpret electronic health record data and determine the best diagnostic tools and treatment plans
- Populations of focus identified by the California Reducing Disparities Project²³ (i.e., African Americans, Asians and Pacific Islanders, Latinos, LGBTQIA+, Native Americans) or defined by characteristics other than race, ethnicity, and sexual orientation that are experiencing inequities in mental or behavioral health needs (i.e., justice-involved individuals, low-income, persons with physical, intellectual, and/or developmental disabilities, refugees, migrant

²³ California Reducing Disparities Project (2023). https://www.cdph.ca.gov/Programs/OHE/pages/crdp.aspx

workers, immigrants, rural communities, non-English speakers, those experiencing housing insecurity, homelessness, children in foster care, members of tribal nations)

IV. Purpose: Collaborative Demonstration Projects

The 2011 NAS report emphasizes the need for strong partnerships and collaboration to achieve the vision of precision medicine, and that pilot projects should be undertaken at various levels to identify barriers, define effective practices, and achieve some early, albeit modest scale, successes. Therefore, one of CIAPM's primary 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 while addressing health inequities, engaging communities, and working toward a healthier, more equitable society.

For this RFP, up to \$9 million will be provided across three to five proof-of-principle demonstration projects (\$1.8 to \$3 million per team) over a three-year project term that aim to address depression through collaborations between academic, community, public, nonprofit, and private partners.

The Lead PI must be affiliated with a non-profit academic research institution (including tribal institutions) in California. Projects must be co-led by at least one nonprofit community-based organization, patient advocacy group, community clinic, or public or tribal entity that provides support to people with or at risk for depression. These partnerships are not required until the Concept Proposal but are recommended for the Letter of Intent. 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 will not be allocated to support salaries of private sector collaborators. Additional matching funds and in-kind contributions are highly encouraged and will be considered during the selection process.

A key component of these collaborative demonstration projects is authentic community partnerships with patients and other stakeholders who have a connection to, expertise in, or lived experience related to depression from project conception to project completion and beyond.

Demonstration projects will be selected through a three-stage process, involving (1) submission of letters of intent to submit a proposal; (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. Once an out-of-state expert selection committee delivers its recommendations for awards, OPR will make a final selection, post a public announcement, and work with awardees to develop concrete metrics and goals to track the progress of the demonstration projects.

V. Proposal Instructions

Proposal Process

All proposal materials must be submitted electronically by the deadlines listed in Section II.

Frequently Asked Questions will be updated periodically on the CIAPM website.

Stage 1: Letter of Intent to Submit a Proposal

Applicants must submit a brief letter of intent (LOI) on or before 10/30/2023 at Noon (12:00 p.m. Pacific Time) via the online CIAPM submission portal at

https://opr.ca.gov/ciapm/activity/research/depression/rfp.html. The webform will require the following information:

- Tentative Proposal Title (maximum 20 words)
- Primary Institution
- Lead PI (Name, Title, and Contact Details)
- Tentative project description (maximum 250 words)
- Optional, but recommended: Community Partner PI (Name, Title, and Contact Details)

LOIs are required, nonbinding, and not scored during the selection process, but must be received by the noted deadline. LOIs should reflect the general theme of the forthcoming concept proposal, but project team and details can be modified between the LOI and Concept Proposal. An institutional cover letter is not required at this stage.

Stage 2: Concept Proposals and Aim Development Process

On or before 12/1/2023 at Noon (12:00 p.m. Pacific Time), applicants must submit, via the CIAPM web portal:

- A three-page concept proposal in PDF format.
- A one-page Aim Development Process document in PDF format.
- A single, combined PDF of biographical sketches (in the <u>format of the National Institutes</u> of Health) for scientific team members and resumes for non-scientific team members.

Detailed parameters for each of these documents are presented below. All concept proposal titles will be listed publicly on the CIAPM website following the selection process, as per a statutory requirement.

An institutional cover letter is not required at this stage; however, PIs may only participate as members of the proposal if their institutions/organizations have committed to support the project, if awarded funding. Letters of support are not accepted at this stage but will be accepted in the full proposal stage.

Stage 3: Full Proposals

An out-of-state expert selection committee will identify a subset of submitted concept proposals to move on to the full proposal stage. In parallel, CIAPM will make available instructions for electronic submission of full proposals. By the full proposal stage, projects must 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 will not be allocated to support salaries of private sector collaborators.

The full proposal includes scientific and public abstracts (1-page maximum), a detailed project plan (5-page maximum with sections describing impact on health outcomes and inequities, project and data plans, precision medicine capabilities, participant and community engagement, impact for patients, approaches to improve training/education, anticipated challenges and proposed solutions, and the project team), references (no page limit), milestones and deliverables (1-page maximum), project team biosketches and resumes (no page limit), state law compliance (1-page form), protection of human subjects (1-page maximum), a budget narrative (1-page maximum), a detailed budget (2-pages maximum using a provided template),

and modifications since the concept proposal stage (2-pages maximum). Institutional cover letters will be required. Full proposals are due by 02/15/2024 at Noon (12:00 p.m. Pacific Time).

The selection committee will recommend three to five projects to award, and OPR will announce awardees by March 2024. The three-year projects are anticipated to begin around June 2024.

Eligibility

- 1. Applicant teams must designate a lead principal investigator (lead PI) from a nonprofit academic research institution (including tribal institutions), considered the primary institution. The lead PI will serve as the main contact throughout the proposal process, demonstration project, and post-award evaluation. Up to 10 additional PIs may also be designated. At least one PI must be from a nonprofit community-based organization, patient advocacy group, community clinic, or a public or tribal entity that provides support to people with or at risk for depression.
- 2. By the full proposal stage, projects must also have 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 will not be allocated to support salaries of private sector collaborators. In-kind contributions may include, but are not limited to:
 - Experts' time
 - Molecular/genetic characterization
 - Access to computational platforms, including data visualization, innovative databases, data sharing, data privacy and security, or high-performance computing
 - Mobile platforms to reach patients between medical encounters and/or track their health outcomes
- 3. Additional matching funds and in-kind contributions are highly encouraged and will be considered during the selection process. Additional collaborations with other nonprofit organizations and private sector collaborators are encouraged.
- 4. Current and former CIAPM lead PIs are ineligible to act as a lead PI on a proposal, but they may serve other roles within the project team. Team members who are not current or former lead PIs but have served other roles on a CIAPM-funded project, are eligible to apply as a lead PI.
- 5. Only one proposal per team will be accepted. An individual may serve as lead PI for one proposal but may contribute to multiple proposals.
- 6. There will not be more than one award per primary institution, but several lead PIs may apply from one primary institution (i.e., this is not a limited submission).
- 7. Demonstration projects must take place in California. Partners may be located outside of California if they provide their own funding.
- 8. Research teams may only use awarded funds for direct costs. Indirect costs will not be supported except via subawards to nonprofit community partners.

Concept Proposals

Proposed projects should not significantly overlap with CIAPM's current and former project portfolio. Information about projects funded by CIAPM can be found here: https://opr.ca.gov/ciapm/activity/research/index.html

Concept proposals must address all topics listed below, in maximum three pages total, PDF format, minimum Arial 11 font, minimum 0.5-inch margins. Include the headings for each topic area in your proposal. Tables and figure legends may use a minimum 10 Arial font. Figures may use a minimum 8 Arial font. Tables and figures count toward the three-page limit. There is no

page limit on the list of references, and references do not count towards the three-page limit. Except for references, do not add to the three-page concept proposal additional pages or attachments, including press releases, manuscripts, etc.

Required Sections for the Concept Proposal

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 heath history, and any combination of these populations.

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.

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 and data sharing plan. We will consider the extent to which community members are engaged, in part, by considering how data is shared and/or owned by community partners. Please also consider a communication plan for sharing resources, outreach materials, data, etc. for non-technical audiences.

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.

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.

Impact for patients and other participants

Describe opportunities to improve patient outcomes within two to five years—and beyond. Describe how research participants and/or communities will benefit from this project.

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.

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.

Project team

Describe collaborations between at least two California-based institutions/organizations:

- At least one non-profit academic research institution (including tribal institutions), one of which is designated as the primary institution
- At least one nonprofit community-based organization, patient advocacy group, community clinic, or public or tribal entity that provides support to people with or at risk for depression

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 will not be allocated to support salaries of private sector collaborators. The concept proposal need not include details on the private sector partner but should include a plan for engagement with the private sector to ensure that there will be a private sector team member by the full proposal submission deadline.

Additional collaborations with other nonprofit organizations and private sector collaborators are encouraged. Describe the nature and strength of any existing collaborations or plans for new collaborations.

Biosketches and resumes for each team member must be uploaded in a separate document, described in the "Biosketches and Resumes" section.

Budget overview

Briefly outline how project funds (\$1.8 million to \$3 million per project) will be used.

- A minimum 15% of the budget must be allocated to a nonprofit community-based organization, patient advocacy group, community clinic, or public or tribal entity that provides support to people with or at risk for depression. We highly recommend that project teams strive for budget equity and that projects include a budget for research coordination at these organizations if these activities are not already supported.
- Include information about any additional matching funds or in-kind contributions.
- Include \$1,500 per year (\$4,500 in total) to cover costs associated with annual site visits and travel to CIAPM events, such as an annual Depression Research Symposium and All-Teams Meeting in Sacramento.
- Comment on why CIAPM funds are needed as opposed to other funding sources, such as federal or philanthropic grants.

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 would leave the state. The amount of funds that can leave the state will be subject to the final award agreement.

Aim Development Process

CIAPM's goal is to fund projects that are co-designed by researchers and the communities the project seeks to benefit. Communities and/or participants must be engaged throughout the project, including developing the concept and full proposals, planning and participating in the project, and evaluating and sharing project results.

In a separate document from the three-page concept proposal, explain who developed each of the proposal's specific aims, and how each of the aims were developed. The Aim Development Process document must be a one-page PDF, Arial 11 font, minimum 0.5-inch margins.

Biosketches and Resumes

Provide biosketches, in <u>NIH format</u>, for each scientific team member. Provide resumes for non-scientific team members. Include a cover page that lists the name, title, organization, and project role for each of the team members. A template for this cover page is given in the table below. Individual biosketches and resumes for a particular team member must not exceed five pages. The cover letter, biosketches, and resumes must be combined into one PDF (no page limit for the entire PDF).

Project Team Biosketch and Resume Cover Page Table

(Add more rows as needed.)

Name	Title	Organization	Role in Project

Submission

Concept proposals must be submitted electronically through the online CIAPM submission portal on or before 12/1/2023 at Noon (12:00 p.m. Pacific Time) at https://opr.ca.gov/ciapm/activity/research/depression/rfp.html.

Full Proposals

An out-of-state expert selection committee will identify a subset of submitted concept proposals to move on to the full proposal stage. CIAPM will then provide instructions for electronic submission of full proposals, which will be due 02/15/2024 by Noon (12:00 p.m. Pacific Time). 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 will not be allocated to support salaries of private sector collaborators. Within the full proposal, applicants should also describe how the addition of the private sector collaborator changes the data sharing and ownership plan, if at all.

VI. Selection

Selection committee

A selection committee will be comprised of out-of-state individuals and include subject matter experts representing the breadth of topics included in the submitted proposals. Nominations for the selection committee will be considered from the legislature, public, and research communities. Selection committee members shall be deemed to be free of conflicts of interest in any proposal and will be screened according to 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.

Selection criteria

Section 65057 of the Government Code sets forth the following selection criteria:²⁴

- 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.

²⁴ AB 1602, Chapter 24, Statutes of 2016, which establishes Article 6. California Initiative to Advance Precision medicine under Chapter 1.5 of Division 1 of Title 7 of the Government Code

The selection committee will also consider the following additional factors in reviewing the proposals:

- The innovative concepts, approaches, methodologies, instrumentation, or interventions to advance precision medicine.
- The feasibility of the project, within the proposed timeframe.
- The quality and extent of patient/participant engagement.
- The quality and extent of partnerships with community-based organizations, including budget equity, how data are shared and/or owned by community partners, and sustainability of the partnership beyond the funding period.
- The project team's experience and expertise with the proposed study population or community.
- The quality and extent of the collaboration with a private sector collaborator (by full proposal stage only).
- Approaches to protect privacy and personal health information.
- Methods to increase access and inclusion of populations that experience inequities.
- System interoperability.
- The quality and extent of training and educational contributions to improve the integration of precision medicine approaches in mental health settings.
- Sharing data and/or protocols across institutions.
- Communication plan for sharing resources, outreach and other materials, data, etc. for nontechnical audiences, such as community-based organizations and stakeholders, including community members, patients, families, and caregivers.
- Where the project is located in California to balance geographic equity of awards and diversity of awarded institutions.
- Diverse expertise and background of team members, including those underrepresented in research, such as underrepresented racial and ethnic groups, persons with disabilities, and women.
- Overall impact to advance precision medicine.
- The extent to which the project differs from current and former CIAPM-funded projects.
 Information about CIAPM's project portfolio can be found here:
 https://opr.ca.gov/ciapm/activity/research/index.html

Results

The selection committee will report on the justification for selecting the demonstration projects that are awarded funding and will provide a list of titles of the demonstration projects that were not selected on the CIAPM website, as required by statute. Therefore, do not include in the project title any proprietary or confidential information or details that could identify the PI and primary institution, unless there are no reservations against being identified.

VII. Resources

Precision Medicine Asset Inventory

To facilitate cross-sector partnerships, CIAPM created the <u>California Precision Medicine Asset Inventory</u>, an online, searchable, interactive mapping tool that includes private, public, and nonprofit entities working within areas relevant to precision medicine and community health. Researchers, patient advocacy and community organizations, health care providers, companies, and others are invited to submit their basic information to be included in the

inventory using the <u>Asset Inventory Entry Form</u>, and use the inventory to search for potential collaborators.

Guidance on Authentic Research-Community Partnerships

CIAPM has developed guidance and a list of resources (see appendix) for researchers, communities, clinicians, and other project partners to encourage high-quality, interactive, and proactive collaborative models, where patients are represented in the governance, design, conduct, dissemination, and evaluation of CIAPM-funded research demonstration projects. We encourage applicants to review this guidance before, during, and after the development of their proposals.

Precision Medicine Primer

Precision medicine (sometimes referred to as personalized medicine) places humans at the center of health care. With modern technology and big data, precision medicine integrates all information about an individual to create a clearer picture of one's health status. This can include everything from the mechanisms that drive disease, to the social and built environments that affect our physical and mental well-being. More information about precision medicine can be found in CIAPM's Precision Medicine Primer.

VIII. Terms and Conditions of Funding Awards

Research teams that are selected for funding will be asked to enter into an agreement with OPR. Terms and conditions will be based on University Terms and Conditions (<u>UTC-220</u>) for UC/CSU/CSU auxiliary institutions. All agreements will include the following terms:

- Indirect Costs Indirect Costs will not be supported except for nonprofit community partner
 subawardees. Indirect Costs are defined by the NIH as "Facilities and Administrative Costs"
 and include accounting and legal expenses, administrative salaries, office expenses, rent,
 utilities, and similar expenses that are incurred for common or joint objectives and cannot be
 identified readily and specifically with a particular project. Salaries for members of the
 project team, such as Study Coordinators, Patient Navigators, Counselors, and Research
 Assistants, and any expense for nonprofit community partners related to the project would
 be supported as Direct Costs.
- **Intellectual Property Agreement** Agree to terms of patent and copyright agreements that balance the State's interests with the needs of the research team.
- Funds Funds will be disbursed monthly.
- Start Date Initiate work within 30 days of agreement execution.
- **Reporting** Submit biannual progress reports using a CIAPM-provided template. Submit interim status updates for inclusion in CIAPM's annual report to the legislature. Submit a final report at the end of the project period, using a CIAPM-provided template.
- **Monthly Meetings** Meet at least monthly with a CIAPM Program Officer to assess progress toward milestones, budget status, and other pertinent topics.
- **Kickoff Meeting and Site Visits** Coordinate with the CIAPM Program Officer for a project kickoff meeting and an annual site visit.
- Annual Symposium Attend an annual research symposium with other CIAPM awardees.
- **Use of Data** Share data and research findings in a manner consistent with academic and state open-access standards.

• **Protection of Privacy and Health Information** Investigators and demonstration project teams are expected to follow state and federal law to protect privacy, personal health information, and rights of human subjects.

IX. RFP Administration and Contact Information

During the solicitation process, questions may be directed to:

The California Initiative to Advance Precision Medicine Governor's Office of Planning & Research 1400 Tenth Street, Sacramento, CA 95814

Email: ciapm@opr.ca.gov (Use subject line "Depression RFP")

Applicants may submit questions via email or mail. All questions regarding the letter of intent must be received by 10/27/2023 at 12:00 p.m. (Pacific Time). Questions regarding the concept proposal must be received by 11/29/2023 by 12:00 p.m. (Pacific Time). On a weekly basis, or as necessary, CIAPM staff will update a list of Frequently Asked Questions on the CIAPM website.

Any oral 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 must 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 of the solicitation. CIAPM, 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, CIAPM 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.

X. Appendix

Appendix A: CIAPM Guidance on Authentic Research-Community Partnerships

A significant mission of CIAPM is to reduce health inequities, in part by orienting the vast health research infrastructure and the emerging field of precision medicine toward addressing inequitable medical and health outcomes. In order to foster research outcomes that address the needs and concerns of patients, family members, and health care providers, authentic research community partnerships are critical.

According to the Institute of Medicine of the National Academies of Sciences, authentic researcher-community partnerships enhance community members' understanding of the issues under study and improves researchers' ability to understand community priorities, the importance of addressing community priorities, and the need for culturally sensitive approaches and outreach²⁵. Part of ensuring the success of CIAPM in demonstrating the promise of precision medicine is ensuring vital research results are informed by and shared with those who need it most and in ways that are timely, relevant, and meaningful.

This guidance aims to provide resources for researchers, communities, clinicians, and other project partners to encourage high quality, interactive, and proactive collaborative models,

²⁵ Rosenstock L, Hernandez L, Gebbie K, eds. *Who Will Keep the Public Healthy? Educating Public Health Professionals for the 21st Century.* Washington, DC: National Academies Press; 2003.

where patients and families are represented in the governance, design, conduct, dissemination, and evaluation of CIAPM-funded research demonstration projects.

Resources for authentic research-community partnerships

Successful CIAPM demonstration project proposals will exemplify a thoughtful strategy to developing and facilitating authentic cross-sector partnerships. The following resources are freely available and recommended:

- "Community Partnership Guide for Engaging with Academic Researchers", Written by Amal Saleh, Brian Saelens, Maxine Hayes, the Health Equity Community Advisory Committee, and Tumaini R. Coker, published in May 2022 in the *Progress on Community Health* Partnerships, 2022;16(1):129-134. <u>Download</u>
- Community Partnered Participatory Research: Learnings from an Interview with Ms. Andrea Jones and Dr. Kenneth Wells, Evidence for Action. (2022, April 26). Download
- "Community-Based Participatory Research During the COVID-19 Crisis: Lessons for Partnership Resiliency," Written by Elaine K. Donnelly, Robin Toof, and Linda Silka; published September 2021 in the *Journal of Higher Education Outreach and Engagement*, 25(3): 91-106; <u>Download</u>
- The Practical Playbook II: Building Multisector Partnerships That Work, Edited by J. Lloyd Michener, Brian C. Castrucci, Don W. Bradley, Edward L. Hunter, Craig W. Thomas, Catherine Patterson, and Elizabeth Corcoran; published May 21, 2019 by Oxford University Press; Download
- "Patient and Public Involvement in Research: Enabling Meaningful Contributions," Written by Sarah Ball, Amelia Harshfield, Asha Carpenter, Adam Bertscher, and Sonja Marjanovic; published in 2019 by RAND Corporation; <u>Download</u>
- "Applying a community-based participatory research framework to patient and family
 engagement in the development of patient-centered outcomes research and practice,"
 Written by Simona C. Kwon, Shiv Darius Tandon, Nadia Islam, Lindsey Riley, and Chau
 Trinh-Shevrin; published October 2018 in *Translational Behavioral Medicine*, 8;8(5):683691; Download
- "Precision Medicine Initiative Cohort Program Building a Research Foundation for 21st Century Medicine Report," published September 17, 2015, p. 38-44. <u>Download</u>
- Principles of Community Engagement, Second Edition, Written by the Clinical and Translational Science Awards Consortium Community Engagement Key Function Committee Task Force on the Principles of Community Engagement; published June 2011 by the National Institutes of Health; Download
- "Community Engagement in Research: Frameworks for Education and Peer Review,"
 Written by Syed M. Ahmed and Ann-Gel S. Palermo, published August 2010 in the American Journal of Public Health, 100(8): 1380-1387; Download
- "Chapter 1. The vision, valley, and victory of community engagement." Written by Loretta Jones, Kenneth Wells, Keith Norris, Barbara Meade, and Paul Koegel; published Autumn 2009; *Ethnicity & Disease*, *19*(4 Suppl 6), S6–7. Download

Health inequity research resources

Applicants for CIAPM funds are encouraged to learn about health inequities and establish new collaborations through the <u>California Precision Medicine Asset Inventory</u>. Additional resources are available via the following links:

 National Institute on Minority Health and Health Disparities Community-Based Participatory Research Initiative, https://www.nimhd.nih.gov/programs/extramural/community-based-participatory.html

- Health Resources and Services Administration (HSRA) Office of Minority Health: Search for health disparity programs at https://www.hrsa.gov/index.html.
- U.S. Centers for Disease Control and Prevention Office of Minority Health and Health Equity, https://www.cdc.gov/healthequity/index.html.
- National Institutes of Health (NIH) Research Portfolio Online Reporting Tool (NIH RePORTER): Search for NIH awards at https://projectreporter.nih.gov/reporter.cfm.
- National Library of Medicine, NIH, PubMed: Search for investigators publishing studies on health disparities at https://www.ncbi.nlm.nih.gov/pubmed.
- Patient-Centered Outcomes Research Institute: https://www.pcori.org/
- U.S. Department of Education: Search for institutions that may have increased access to disproportionately affected populations at https://www2.ed.gov/about/offices/list/ocr/edlite-minorityinst.html
- National Coalition for LGBT Health: For more information on programs focused on lesbian, gay, bisexual, and transgender (LGBT) research, policy, education, and training, search http://www.healthlgbt.org.
- Indian Health Services, https://www.ihs.gov/.
- Native American Research Centers for Health (NARCH): https://nigms.nih.gov/capacity-building/native-american-research-centers-for-health-(narch)
- National Alliance for Hispanic Health, https://www.healthyamericas.org/.
- National Medical Association, https://www.nmanet.org/.
- National Rural Health Association, https://www.ruralhealthweb.org/.
- California Department of Public Health Office of Health Equity, https://www.cdph.ca.gov/Programs/OHE/Pages/OfficeHealthEquity.aspx