CIAPM RFP 2019 - Full Proposal Submission Process

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. Recent updates are marked in yellow.

I. Timeline

CIAPM Provides Select Committee's Feedback	9/14/2020
Due: Full Proposals	**1/14/2021 by 11:59 PM**
Awardees Announced	March 2020
Anticipated Project Start	5/1/2021 – 5/31/2021
Duration of Projects	36 months

All times listed are in Pacific Time.

II. Application Instructions

All application materials must be submitted electronically as a single PDF document via the CIAPM online submission portal, which will open for Full Proposal submission on or before September 14, 2020. Use minimum Arial 11 font and 0.5-inch margins. Frequently Asked Questions will be regularly updated on the CIAPM website.

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.

2. **Overview**: 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, "Addressing Health Impacts of Adverse Childhood Experiences Through a Collaborative Precision Medicine Approach." 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, confidential, or could identify PIs and applicant institutions.

3. **Project Plan**: 5-page maximum

Expand on the information provided in the Concept Proposal (items a.-j. below), taking into consideration Selection Committee feedback (delivered by CIAPM on or before September 14, 2020). Please include the headings for these items in your proposal.

a. Impact on health outcomes and health disparities: Describe how the proposed project will improve health outcomes and reduce disparities among populations affected by ACEs. Be as concrete as possible (e.g., cite numbers, references) about the population(s) you will be serving, the nature of the health disparities you seek to address, and your theory of change–i.e., what underlying factors contribute to the disparities you seek to impact and how your project will influence those factors. Provide additional 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 data to EHR; access to existing databases, medical records, or study group; an engaged participant community; established mechanisms for responsible data sharing).

b. Project plan: Describe the components of your proposed project, including specific aims and research strategy.

c. Data: Each proposal should demonstrate its commitment to the use of robust data. Use of multiple data sets is encouraged (e.g., electronic medical records, mobile health device data, registries, 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 preventative, diagnostic, measurement, and/or treatment approaches. Please provide a rationale for use of designated standards that are already recognized, for example, by the American Academy of Pediatrics.

d. Precision Medicine capabilities: Describe the Precision Medicine capabilities that will be developed as a result of this project, such as infrastructure and tools that will be built, including new consortia, collaborations, personnel competencies, databases, datasets, applications, software, intellectual property, patient cohorts, participant communities and networks, and models for responsible data sharing.

e. Participant 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. For example, projects may integrate a community advisory board, 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 opportunities to contribute data from this demonstration project to other research studies.

f. Impact for patients: To the extent it is applicable to the project, describe opportunities

to improve patient outcomes within the 36-month project timeframe. What is your vision for how the project will impact patients and contribute to precision medicine beyond the project timeframe? Please indicate which elements of your project might be scalable or generalizable to other patient populations and/or other health issues.

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 clinical care, 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 ACEs 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, the COVID-10 pandemic, health literacy barriers, or mobile patient populations), and describe potential solutions to these challenges.

i. Project team: Provide a brief description of the PIs, team, and key collaborators. Describe collaborations that are part of your proposal, including the nature and strength of existing collaborations. Highlight the expertise, background, experience, and perspectives of project team members, including those from diverse sectors, disciplines, and populations underrepresented in biomedical research (e.g., underrepresented racial and ethnic groups, persons with disabilities, and women).

j. Data-Sharing Work Group: Teams must express a willingness to attend coordination meetings with fellow grantees, share lessons learned, discuss the use of designated data standards, and agree to examine and potentially select and use a common data-sharing platform.

4. **References**: No page limitation

   List references cited in the project plan.

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

   In order 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, listing each deliverable, the metric that indicates its successful achievement, and the anticipated start and end date for associated work, assuming a start date in May 2021. This draft will be part of the assessment by the Selection Committee and will serve as a basis for negotiation with CIAPM to finalize the milestones for the project, if funded.

6. **Project Team Biographical Sketches**: No limit to the number of biosketches

Provide NIH-format biographical sketches for all scientific project team members. Any community member of the project team may instead provide a resume.

7. **State Law Compliance**: 1-page form limitation

   Please provide the completed form in **Appendix A**.

8. **Protection of Human Subjects**: No page limitation

   Applications must designate if 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 subject research, the "Protection of Human Subjects" section is not required, please enter "N/A" in section 8 of your Full Proposal.

9. **Budget Narrative**: 1-page maximum

   a. Propose a budget between $1.8 and $3.0 million.

      Note: Indirect costs will not be supported by CIAPM funds. 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 outside entities. Comment on why CIAPM funds are needed as opposed to other funding sources, such as federal or philanthropic grants. Examples of other resources that may be leveraged include experts' time; molecular characterization; 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.

      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, consultant, or contractor 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 (max. 1 additional page allowed).

10. **Budget**: 2-page maximum

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

    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**: 2-page 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 limitation

III. Administration

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

Julianne McCall, PhD
Governor's Office of Planning & Research
1400 Tenth Street, Sacramento, CA 95814
Telephone: (916) 323 – 9912
Email: ciapm@opr.ca.gov

Applicants may submit written questions via email or mail. All technical questions must be received by January 7, 2021. Non-technical questions (e.g., questions concerning format requirements or submission instructions) may be submitted to CIAPM staff at any time prior to the January 14, 2021 deadline for Full Proposals. On a weekly basis, or 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

Complete this form by replacing each box "☐" with an "X" to indicate your response, as appropriate.

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]

Replace boxes "☐" with an "X" to select responses to prompts 1-4, as appropriate.

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, and you may enter "N/A" in Section 8 of the Full Proposal.

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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, but requires an acknowledgment, rather than an approval.

- Has IRB acknowledgment been obtained from your institution? Yes ☐ No ☐
  - If yes: IRB acknowledgement date:
  - If no: have you submitted an application to your IRB? Yes ☐ No ☐

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

- Has IRB approval been obtained from your institution? Yes ☐ No ☐
  - If yes: IRB approval date:
  - If no: have you submitted an application to your IRB? Yes ☐ No ☐

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

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

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

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

Appendix B (Continued)
Section 8 Narrative Instructions

Please provide the following narratives in Section 8 of 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

[Download the Budget Template as an Excel Spreadsheet]

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

Lead Principal Investigator:	
Period (Start - End Dates): 02/01/21 -01/31/24	

Lead 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 & CONTRACTORS				
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 & Contractors 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**
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**

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**
TOTAL COSTS (Site 1 Only)	**$0**	**$0**	**$0**	**$0**

Partner Site 2 - 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**
TOTAL COSTS (Site 2 Only)	**$0**	**$0**	**$0**	**$0**

Partner Site 3 - 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**
TOTAL COSTS (Site 3 Only)	**$0**	**$0**	**$0**	**$0**

PERSONNEL BREAKDOWN BY SITE

Lead Site - PERSONNEL	Full-Time Equivalency Y1 (%)	Y2 (%)	Y3 (%)	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
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**

Site 1- PERSONNEL	Full-Time Equivalency Y1 (%)	Y2 (%)	Y3 (%)	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
Individual 11- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 12- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
TOTAL:						**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**

Site 2- PERSONNEL	Full-Time Equivalency Y1 (%)	Y2 (%)	Y3 (%)	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
Individual 13- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 14- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
TOTAL:						**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**

Site 3- PERSONNEL	Full-Time Equivalency Y1 (%)	Y2 (%)	Y3 (%)	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
Individual 15- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 16- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 17- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
Individual 18- Role/Affiliation	0%	0%	0%	0.00%	$0	$0	$0	$0	$0	$0	$0	$0
TOTAL:						**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**