CIAPM RFP 2016 - Full Proposals

Principal investigators (PIs) of concept proposals, selected through a peer review process to advance to the second stage of review, will be invited to submit a full proposal. The recommended CIAPM review process is posted on the CIAPM website.

CIAPM asks applicants to prepare a full proposal as listed below. **Use minimum Arial 11 font; 0.5 inch margins, and submit as a single PDF to ciapm@ucsf.edu by 5:00 pm PT on September 30, 2016**.

1. Cover Page: 1 page maximum
    a. Title of the proposal
    b. Lead PI's name, institution, email address
    c. Vice Chancellor of Research or other Authorized Institutional Official's name and email address
    d. Key team members / collaborators, listed by institution/organization (including external partners)

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 advancement of precision medicine. This Public Abstract will become public information and will be available online; therefore, do not include proprietary or confidential information or information that could identify the PI and applicant institution.

3. Cover Letter: 1 page maximum, addressed to the review committee, summarizing your response to their feedback. Brief comments and suggestions from the review committee will be provided to PIs selected to submit full proposals on or before Sep 9, 2016.

4. Project Plan: 5 page maximum; expand on the information provided in the concept proposal (items a-k below), taking into consideration reviewer feedback.
    a. Impact on precision medicine: Describe how the proposed project will address a knowledge gap or need in a specific disease area(s), health issue, technology or fundamental biological process and, in doing so, demonstrate the promise of precision medicine. Provide rationale for the project by outlining existing strengths, resources and opportunities available (e.g., ability to obtain molecular measurements, remotely collect behavioral or other data, subtype the disease, link genomic data to EHR; access to existing biobanks; databases, medical records; an engaged participant community, established mechanisms for responsible data sharing, etc.).
    b. Focus area: Describe which relevant focus areas(s) the project will address (see RFP section IV,B, 2). Provide rationale for the selected focus area(s) by outlining the current associated challenges to and opportunities for the advancement of precision medicine.
    c. Project plan: Describe the components of your proposed project (specific aims

and research strategy).

d. Patient data: Each proposal should demonstrate its commitment to the use of robust data. For example, your proposal could make use of patient data from at least two data sources, such as eligible institutions, health care providers, or other sources of health-related data. Use of additional data sets is encouraged. Briefly describe the data set(s) you propose to use and the rationale for their choice.
e. Precision medicine capabilities: Describe the precision medicine capabilities that will be developed as a result of this project (i.e., infrastructure and tools that will be built as a result of this project including physical capacity, new consortia, collaborations, personnel competencies, databases, software or computational development, startup company opportunities, intellectual property, patient cohorts, participant communities and networks, models for responsible data sharing, etc.).
f. Participant engagement: Describe strategies to engage patients (e.g. opportunities to build trust, approaches to ensuring consent, approaches to data sharing, privacy, security, etc.).
g. Impact for patients: To the extent it is applicable to the project, describe opportunities to improve patient outcomes within the 18-month project timeframe—and beyond.
h. Economic impact / value analysis: As appropriate for your project, describe the anticipated clinical utility and the economic impact (impact on healthcare spending) of your proposed intervention or platform, if implemented into clinical practice (see e.g., http://meetinglibrary.asco.org/content/152750-156 and Lamond et al., Expert Rev Pharmacoecon Outcomes Res. 2013, 243-50).
i. Health disparities: Describe the impact the project will have on reducing health disparities.
j. Anticipated challenges and proposed solutions: Describe potential barriers to the project's success, especially those that could delay the launch, progress or completion (e.g., human subjects), and describe potential solutions to these challenges.
k. Project Team: Provide a brief description of the PI, team, and key collaborators. Partnership is highly valued. Describe collaborations with at least two additional California non-profit or for-profit organizations as part of your proposal. Additional partners are highly encouraged. Describe the nature and strength of any existing collaborations.

5. References: List references cited in the project plan. No page limitation.

6. 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. Continued funding of awarded

projects is not guaranteed. It is, instead, contingent on meeting agreed upon milestones and demonstrating measurable progress towards these milestones as evidenced through quarterly progress reports and possibly site visits as determined by the CIAPM management team.

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. 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.

7. Protection of human subjects: no page limitations
   Applications must designate if human subject research is proposed. **Please see Appendix A for**
   - **"Protection of human subjects" form (append filled out form after section 7)**
   - **"IRB review tool" (append filled out tool after section 7)**
   - **Details for the narrative for this section 7.**

8. Project Team Biographical Sketches - no limit to number of biosketches; provide NIH format biographical sketches for project team members.

9. Budget Narrative: 1 page maximum
   a. Propose a budget of up to $1.2 million. Note: no indirect costs will be provided with CIAPM funds.
   b. Budget overview: Briefly outline how CIAPM funds will be used and how other resources will be leveraged. Comment on why CIAPM funds are needed as opposed to other funding sources such as federal or philanthropic grants. Examples of other resources that may be leveraged include: experts' time; molecular characterization, including DNA, RNA and genomic sequencing; computational platforms, including genome analysis, data visualization, innovative databases, data sharing, data privacy and security, or high-performance computing; mobile platforms to reach patients between medical encounters, to track their health and outcomes, etc. Please see existing CIAPM demonstration projects for examples of leveraged resources.

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

10. Budget - 1 page maximum; provide a detailed budget breakdown to support the narrative

11. Letters of Support - no maximum

For questions about the full proposal, please contact ciapm@ucsf.edu

Appendix A

Protection of Human Subjects Form – please fill out and append this form after section 7

Replace boxes "□" with an "X" to choose answers to questions 1-4, as appropriate.

1. Does your proposed work involve Human Subject Research? Yes □ No □

Please use the "IRB Review tool" (next page) to answer this question, and append the tool page after this form.

If you answered "yes" to question 1:

- your project requires IRB review
- please answer questions 2-4

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

To answer this question, consider the four categories listed at http://irb.ucsf.edu/levels-review#exempt under "Exempt Certification". If the entire scope of your proposed research falls into one or more of the four categories, your research qualifies as "exempt".

2a. If you answered Yes to question 2: your project requires IRB review, but gets *acknowledged* rather than *approved*

- 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. Are you proposing a NIH-defined phase III clinical trial? Yes □ No □

- For definitions of "human subjects" go to http://irb.ucsf.edu/research-needing-irb-review
- For definition of "clinical trial" go to http://grants.nih.gov/grants/glossary.htm
- In addition to IRB requirements at your institution, awards made by CIAPM will require UCSF IRB review or approval if Human Subject Research will be conducted under the award.

Appendix A continued - IRB Review Tool

Please fill out and append this tool after the "Protection of Human Subjects" Form

If you have any questions about this form, please contact Kate Nolan, Regulatory Knowledge and Support, UCSF, at 415 476 3067 (mention CIAPM RFP 2016)

In order to be able to expedite the necessary IRB review at UCSF in case your proposal is awarded CIAPM funding, please use this IRB screening tool to determine whether your proposed research is Human Subjects Research.

"Identifiable" information includes the following:

- Names
- All geographical subdivisions smaller than a State, including street address, city, county, precinct, zip code
- Dates directly related to an individual including birth date, admission date, discharge date
- Phone numbers, fax numbers, email addresses
- Social Security numbers, medical record numbers, account numbers, Certificate/license numbers, vehicle identifiers and serial numbers, license plate numbers
- Device identifiers and serial numbers, Web Universal Resource Locators (URLs), Internet Protocol (IP) address numbers
- Biometric identifiers, finger and voice prints, identifiable photographic images

IRB Pre-Screening

1. Does your project involve the initial collection of identifiable tissue specimens for research purposes?

☐ Yes ☐ No

2. Are you interacting with research subjects? Interaction includes communication (e.g., phone call or email) or interpersonal contact between the researcher and subject.

☐ Yes ☐ No

3. Does the research involve human stem cells?

☐ Yes ☐ No

4. Does the research involve drugs, biologics, or devices regulated by the Food and Drug Administration?

☐ Yes ☐ No

5. Will anyone on the research team have access to any identifiable information about the subjects at any point?

☐ Yes ☐ No

- If the answer to ANY of the above questions is "Yes," your project requires IRB review.
- If the answer to ALL of the above questions is "No," your project does not constitute Human Subjects Research.

Appendix A continued

Instructions for section 7 "Protection of human subjects" in full proposal

Questions 1-4 refer to questions on "Protection of Human Subjects" Form

1. If your work does not involve human subject research, the "Protection of Human Subjects" section is not required. Please enter "N/A" in section 7 of your full proposal.

Please provide the following narratives in section 7 of your full proposal, if questions 2a, 2b, 3, and / or 4 apply to your proposed work

2a. If your work involves human subject research and qualifies as "exempt", indicate which "exempt category" it falls under (see four categories listed at http://irb.ucsf.edu/levels-review#exempt under "Exempt Certification")

2b. If your work involves human subject research and does not fall into one of the four "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 & 4. If you are proposing a clinical trial:

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

- For information on Data Safety and Monitoring Plans, go to https://www.nlm.nih.gov/ep/dsm.html and https://humansubjects.nih.gov/data_safety