CIAPM RFP 2018 - Full Proposal Submission Process

Updated on September 28, 2018

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 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 and 0.5 inch margins, and submit as a single PDF to ciapm@ucsf.edu by 5:00 pm PT on November 2, 2018**. The proposal must be submitted by a primary contact PI.

1. **Cover Page**: 1-page maximum
    a. Title of the proposal
    b. Name of all PI(s) and co-PIs, the host institution, and email address(es) for all PIs and co-PIs. Indicate which PI(s) will be the primary contact(s). The primary contact(s) must be affiliated with the host institute. Project team members and roles do not need to be identical to those specified in the concept proposal submitted by your team (e.g., you may add new team members and institutions).
    c. For the host institution only, the Vice Chancellor of Research (VCR), Chief Executive Officer (CEO), or other equivalent or designated authorized institutional official's name, email address, and signature.
    d. Key team members/collaborators not included in item a, listed by institution/organization, including external partners
    e. For any participating institution that was not included in your concept proposal submission, one sentence describing the role of the institution and a signature from the institution. Signatures can be from PIs and do not need to be from VCRs, CEOs, or other authorized institutional officials.

    Note: The signature specified in item c indicates that the host institution agrees to administer an award resulting from this proposal, and acknowledges that any award will not cover indirect costs. No signatures other than the ones specified in items c and e are needed on the Cover Page.

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 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-i below), taking into consideration Selection Committee feedback. Please include the headings for these items in your proposal.
    a. Impact on precision medicine cancer care for populations that experience cancer health disparities: Describe how the proposed project will improve understanding in providing

precision medicine approaches to populations that experience cancer health disparities.[1] Be as concrete as possible (e.g., cite numbers, references) about the population(s) you will be serving, the nature of the cancer 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 genomic data to EHR; access to existing biobanks, databases, medical records; an engaged participant community; established mechanisms for responsible data sharing).

b. Project plan: Describe the components of your proposed project–i.e., your specific aims and research strategy.
c. Patient data/other data: Briefly describe the data set(s) you propose to use or create, the rationale for integrating this data, and how this integration may contribute to better outcomes by improving preventative, diagnostic, or treatment approaches. Please include the integration of "omic" data (e.g., genomics, exposomics, proteomics, pharmacogenomics, and behavior/lifestyle). Please provide rationale for use of designated standards that are already recognized, for example by the College of Pathologists.
d. Precision medicine capabilities: Describe the precision medicine capabilities that will be developed as a result of this project (e.g., infrastructure and tools that will be built as a result of this project including new consortia, collaborations, personnel competencies, databases, datasets, applications or software or computational development, intellectual property, patient cohorts, participant communities and networks, models for responsible data sharing).
e. Participant engagement: Describe strategies to engage patients and/or healthy participants (e.g., opportunities to build trust, approaches to ensuring consent, approaches to data sharing, privacy, security). For example, integrating a patient advisory board, having patient navigators, hosting focus groups to understand patient issues, etc. Describe efforts to allow patients access to their medical data and/or opportunities for patients 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 disease areas.
g. Economic impact/value analysis: Describe the anticipated utility of your project and how you will perform an economic impact analysis (i.e., impact on healthcare spending) of your proposed intervention. Address the following questions: Who will you partner with to do the analysis, what data will you analyze, and what analysis method(s) will be used?
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), and describe potential solutions to these challenges.
i. Project team: Provide a brief description of the PIs, team, and key collaborators. Describe

[1] See https://www.cancer.gov/about-cancer/understanding/disparities

collaborations with any California organizations that are part of your proposal. Describe 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).

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. 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.

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

7. **Project Team Biographical Sketches**: No limit to number of biosketches
   Provide NIH format biographical sketches for project team members.

8. **Budget Narrative**: 1-page maximum
   a. Propose a budget of up to $3.5 million.

      Note: No indirect costs will be provided with CIAPM funds. Your budget can differ from the budget proposed in your submitted 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, including DNA, RNA, and genomic sequencing; computational platforms, including genome 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. 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.

9. **Budget**: 1-page maximum
   Provide a detailed budget breakdown to support the narrative.

10. **Alternate Budget**: 1-page maximum
    Explain how your proposal would change if your project team receives an award of $2.33 million, referring to
    a. Specific project plan items (a-i).
    b. Specific budget narrative items (a-b).

    Note: The inclusion of this alternate budget component is intended to facilitate the possibility of the Selection Committee selecting three demonstration projects to award within the overall budget provided for the CIAPM Request for Proposals 2018.

11. **Changes from Concept Proposal**: 1-page maximum
    Summarize any significant changes made to your concept proposal, including 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 limit to number of support letters

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 Kate.Nolan@ucsf.edu (mention CIAPM RFP 2018)

You will need to know whether your research needs IRB review in the case that 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 and does not require IRB review.

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