California Initiative to Advance Precision Medicine

CIAPM Recommendation to Selection Committee: Peer Review Process for CIAPM RFP 2016

Overview

CIAPM Request for Proposals (RFP) 2 is posted at ciapm.org. The CIAPM peer review process is modeled on the NIH peer review process, and is designed to ensure that applications to this RFP are evaluated in a manner that is fair, equitable, timely and free of bias.

The application process consists of two stages. (1) Applicants will submit a short concept proposal, and (2) selected applicants (finalists) will be invited to submit a detailed full proposal. A Selection Committee will evaluate the concept proposals and full proposals and will select finalists (stage 1) and make recommendations for final awards (stage 2) to the Governor's Office of Planning and Research (OPR). The Selection Committee is composed of experts who have expertise in disciplines relevant to this RFP and the proposals. The list of Selection Committee members, once established, can be viewed at ciapm.org.

The peer review meetings are announced at http://www.ciapm.org/news-events. Following a public comment session, the scientific review meetings are closed to the public during the deliberative process as it relates to reviewing and ranking proposals and making final decisions. Everyone who will have access to proposals or who will attend the review meetings will be required to maintain confidentiality and NIH conflict screening rules will apply.

Triage Process

Depending on the volume of responses, the Selection Committee may limit the number of concept proposals from each institution that will be accepted into the review process. The Selection Committee will consider the information provided in the Institutional Cover Letter (e.g. institutional commitment and ranking) when deciding which applications will be reviewed from each institution. Institutions are highly recommended to include no more than two proposals. If a high volume of proposals are submitted, and, if a ranking is provided by an institution submitting more than two concept proposals, at least the two highest ranked proposals will be reviewed.

Review of Proposals (concept and full proposals)

CIAPM Request for Proposals 2016 specifies the review criteria and other considerations that will be used in the evaluation and selection of proposals.

A. Peer Review Roles

The Selection Committee process is overseen by a Scientific Review Officer (SRO). The SRO is responsible for ensuring that each application receives an objective and fair peer review, and that the process described herein is followed.

Scientific Review Officer:

- Analyzes the content of each application, and checks for completeness.
- Documents and manages conflicts of interest.
- Assigns applications to reviewers for critique preparation and assignment of individual criterion scores.

- Attends and oversees administrative aspects of peer review meetings.
- Keeps detailed minutes of all the meetings
- Works with the Selection Committee to report on the justification for selecting the demonstration projects that are awarded funding and provide a list of the demonstration projects that were not selected. This report shall be posted on the CIAPM website.

Selection Committee Members

Chair:

- Serves as moderator of the discussion of merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest with specific applications according to NIH conflict screening rules.
- Receive access to the grant applications prior to the peer review meeting.
- Prepare a brief written critique for each application assigned, based on review criteria and judgment of merit.
- Assign a numerical score to each scored review criterion.
- Make recommendations concerning the scientific and technical merit and the potential impact on advancing precision medicine, in the form of final numerical scores.
- Work with the CIAPM SRO to report on the justification for selecting the demonstration projects that are awarded funding.
- Make recommendations concerning appropriateness of budget requests.

Other CIAPM affiliated individuals:

- CIAPM affiliated individuals are permitted to attend closed review meetings.
- These individuals may provide administrative and programmatic input during the review meeting.

B. Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see CIAPM RFP 2016).
- Assigned reviewers summarize their prepared brief written critiques for the group.
- A discussion with Selection Committee members follows.
- Final scoring of overall impact scores is conducted by private ballot.

C. Peer Review Criteria

Review Criteria

Concept proposals and full proposals are submitted to CIAPM and are evaluated for their scientific and technical merit and their potential impact on advancing precision medicine.

Scored Review Criteria. Reviewers will be asked to consider the selection criteria listed in CIAPM RFP 2016 in the determination of merit. To facilitate consideration of the proposals, the criteria have been grouped into the five categories described below. Reviewers will be asked to give a separate score for each of the five main review criteria categories under which they are listed.

1. **Significance.** Does the project address an important problem or a critical barrier to progress in precision medicine? Is there a strong rationale for the project? If the aims of the project are achieved, how will precision medicine be advanced?
    - Potential for tangible benefit to patients within two to five years, including the likelihood that the study will have an immediate impact on patients;
    - Potential to reduce health disparities;
    - The potential for positive economic impact of the proposed intervention or platform, if implemented into clinical practice.

- Potential to scale and leverage multiple electronic health records systems;
- Potential to develop the use of tools, measurements, and data, including publically generated and available data;
- Clinical and commercial potential of the project.

2. **Investigators.** Are the PI, collaborators, and other team members well suited to the project? If investigators are in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? Do the collaborators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?
    - Expertise of potential team members.
3. **Innovation.** Does the application challenge and seek to shift current research, clinical practice or other relevant paradigms? Does the project's innovation apply to one field of research or is it novel in a broad sense? Is it seeking the refinement, improvement, or new application of existing approaches?
    - Innovative concepts, approaches or methodologies, instrumentation, or interventions to advance precision medicine
4. **Approach.** Are the overall strategy, methodology, and analyses well reasoned and appropriate to accomplish the aims of the project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems and alternative strategies presented? Are the proposed milestones, timeline and success metrics well thought out and achievable? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in human subjects? If the project involves human subjects and/or clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?
    - Feasibility of the project (can the project plan be achieved within the proposed timeline);
    - Prospects for efficient and effective data integration and analysis;
    - Quality and extent of patient engagement.
5. **Environment.** Will the professional environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the professional environment, subject populations, or collaborative arrangements?
    - Depth and breadth of data available in the disease focus areas across applicant institutions
    - Resources available for the project outside of the initiative, including the potential for leveraging non-state funding.

Overall Impact. Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on advancing precision medicine, in consideration of the above review criteria. A proposal does not need to be strong in all categories to be judged likely to have a major impact.

D. Scoring

Scores will be used to guide the review process, they will not be provided to the applicants. CIAPM will use the NIH scoring system, which utilizes a 9-point rating scale (1 = exceptional; 9 = poor) for overall impact scores. (NOT-OD-09-024). A modified system, using letters (a= exceptional; e=poor), will be used for criterion scores.

- Before the peer review meeting, each reviewer assigned to an application gives a separate score for each of the scored review criteria categories.
- In addition, each reviewer assigned to an application gives a preliminary overall impact score for that application.
- During the first review, to select the concept proposal finalists, the preliminary scores may be used to determine which applications will be discussed in full at the meeting. Reviewers may, however, bring concept proposals designated as "not discussed" up for discussion.
- For each proposal that is discussed at the meeting, a final impact score is given by each eligible reviewer (without conflicts of interest) including the assigned reviewers.
- Each reviewer's score reflects his/her evaluation of the overall impact that the project is likely to have on advancing precision medicine, rather than being a calculation of the reviewer's scores for each criterion.
- The final overall impact score for each discussed application is determined by calculating the mean score from all the eligible reviewers' impact scores, and multiplying the average by 10. Thus, the final overall impact scores range from 10 (high impact) through 90 (low impact).

E. Decision Process

Merit as determined by the final overall impact scores will be the main determinant of concept proposal selection and final award recommendations. However, OPR aims to fund a balanced portfolio that represents diversity in several areas, including but not limited to, approaches, disease areas, focus areas, types of partners, and types of patient populations. Furthermore, statute requires that public institutions in both northern and southern California are included.

Therefore, at the concept proposal stage, where approximately 10-15 proposals deemed meritorious will be advanced to the second stage, CIAPM will ask the Selection Committee to draw a concept proposal selection line based on rank order of final overall impact scores. Subsequently, the Selection Committee may move additional proposals into the "select" category, based on considerations of OPR's goals to achieve a balanced portfolio as described above. Using this process if necessary, they have to ensure that proposals from public institutions in both northern and southern California advance to the full proposal stage.

At the full proposal stage, the Selection Committee will be asked to select up to 6 proposals to recommend for funding, based primarily on rank order while also ensuring that at least one proposal each from a public institution in northern and in southern California is included. The Selection Committee may also choose to adjust the list of recommended proposals to achieve a balanced portfolio as described above.

During the decision making process, Robert's Rules of Order will be used to take actions.

F. Review Results

Scores will be used to guide the review process, they will not be provided to the applicants.

Based on the review discussions for the concept proposals, the PIs who are selected to submit a full proposal will be provided with brief feedback that describes opportunities for improvement, for their consideration when preparing full proposals. The feedback will be provided in the context of one or more of the five main review criteria and the selection criteria listed in section C and in CIAPM RFP 2016. They will not receive written comments for their full proposals. PIs of concept proposals not selected for submission of a full application will not receive written comments.

CIAPM will work with the Selection Committee to prepare a report on the justification for selecting the demonstration projects that are awarded funding and provide a list of the demonstration projects that were not selected. This report shall be posted on the CIAPM website.