

Peer Review Process for CIAPM RFP 2018

Overview

CIAPM Request for Proposals (RFP) 2018 is posted at <u>ciapm.org</u>. The CIAPM peer review process is modeled on the National Institutes of Health (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 three stages. (1) Applicants will submit a letter of intent to submit a concept proposal, (2) applicants will submit a short concept proposal, and (3) selected applicants (finalists) will be invited to submit a detailed full proposal. A Selection Committee will evaluate the concept proposals and full proposals, select finalists, and make recommendations for final awards to the Governor's Office of Planning and Research (OPR). The Selection Committee will be composed of experts in disciplines relevant to this RFP and the submitted proposals. <u>NIH conflict screening rules</u> will apply. The list of Selection Committee members, once established, will be posted to <u>ciapm.org</u>.

The peer review meetings will be announced at <u>http://www.ciapm.org/news-events</u>. Following a public comment session, each scientific review meeting will be closed to the public during the deliberative process, which includes reviewing and ranking proposals and making final selection decisions. Everyone who will have access to proposals or attend the review meetings will be required to maintain confidentiality.

Review of Proposals

CIAPM Request for Proposals 2018 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 preparing critiques and scoring proposals
- 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 <u>CIAPM website</u>

Selection Committee Chair

- Serves as moderator of the discussion of merit of the applications under review
- Serves as a peer reviewer for the meetings

Selection Committee Members (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

- May attend closed review meetings
- 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 2018)
- 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

Reviewers will be asked to consider the selection criteria listed in CIAPM RFP 2018 in the determination of merit. To facilitate consideration of the proposals, the criteria have been grouped into the five categories described below, based on <u>NIH's Scored Review Criteria</u>. Reviewers will be asked to give a separate score for each of these review criteria categories, under which the CIAPM RFP 2018 selection criteria 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?
 - 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 potential for positive economic impact of the proposed intervention or platform, if implemented into clinical practice
 - The potential to scale and leverage multiple electronic health records systems
 - System interoperability
 - The potential to develop the use of tools, measurements, and data, including publicly generated and available data
 - The clinical and commercial potential of the project
- 2. **Investigators.** Are the PIs, 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 approaches, and governance and organizational structures appropriate for the project?
 - The expertise of potential team members

- Diverse expertise and background of team members, including individuals from groups underrepresented in biomedical research such as racial and ethnic groups, persons with disabilities, and women
- 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? Does it seek the refinement, improvement, or new application of existing approaches?
 - The 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 there 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?
 - The feasibility of the project (can the project plan be achieved within the proposed timeline).
 - The prospects for efficient and effective data integration and analysis
 - The quality and extent of patient/participant engagement
 - Methods to increase access and inclusion of populations that experience cancer health disparities
 - Approaches to protect privacy and personal health information
 - Sharing data and/or protocols across institutions
- 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?
 - The depth and breadth of data available in the disease focus areas across applicant institutions
 - The resources available for the project outside of the initiative, including the potential for leveraging non-state funding

Overall Impact

Reviewers will provide a preliminary overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on advancing precision medicine approaches that address cancer health disparities, 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 and 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

selection criterion scores.

Before the peer review meeting, a subset of concept proposals will be provided to each reviewer to ensure that each application is reviewed by multiple reviewers with relevant expertise. Each reviewer assigned to an application will give a separate score for each of the scored review criteria categories. In addition, each reviewer assigned to an application will provide a preliminary overall impact score for that application.

During the first review, to select concept proposal finalists, the preliminary overall impact 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 will be given by each eligible reviewer (without conflicts of interest), including the assigned reviewers. Each reviewer's final impact score will reflect 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 selection criterion scores.

The final overall impact score for each discussed concept proposal will be determined by multiplying the mean overall impact score from all eligible reviewers by 10. Thus, the final overall impact scores will range from 10 (high impact) through 90 (low impact).

This process will be repeated for the scoring of the full applications submitted by finalists whose concept proposals were selected.

E. Decision Process

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

Therefore, at the concept proposal stage, where a subset of concept proposals deemed meritorious will be advanced to the full proposal 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 as necessary, they will 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 four proposals to recommend for funding, based primarily on the rank order of final overall impact scores while also ensuring the inclusion of at least one proposal from a public institution in northern California and one from a public institution in southern California. The Selection Committee will also ensure that no more than one project will be awarded per host institution; an institution may, however, serve as the host institution for an awarded project and the as a partner organization for additional awarded projects. The Selection Committee may additionally adjust the list of recommended proposals to achieve a balanced portfolio as described above.

During the decision-making process, <u>Robert's Rules of Order</u> 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 whose project teams 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 2018. PIs 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 justifying the demonstration project funding decisions and providing a list of the project proposals that were not selected. This report will be posted on the <u>CIAPM website</u>.