Getting Your PCORI Grant Funded: Advice from Insiders
Conference Call Meeting Minutes
Tuesday, 7/16, 2:00 – 3:00 pm PDT

Mike Steinman, MD: Intro, Agenda & Housekeeping. Archive of this and all other Comparative Effectiveness Research (CER) resources posted at http://accelerate.ucsf.edu/research/cer

A. Expert Panel

1. Larry Fisher, PhD (PCORI Reviewer):

Suggests attendees visit PCORI 101 for overview of application process, goals & especially the eight criteria.

a. Simplify and clarify your application: PCORI review process is diverse, includes reps from many perspectives, including delivery systems, NGO's, and other stakeholders. Within the scientific review area, Larry reviewed diverse applications, among which quality and content area varied greatly. Since each reviewer is allotted equal voice, be sure to make your application as clear and specific as possible to reach as many as possible.
b. Include as many stakeholders as possible and engage the stakeholder at *each* stage of research: Show specifically how stakeholder input will be seamlessly and systematically integrated. Document and emphasize how you'll use the stakeholder input.
c. Focus on patient intervention group (especially in scientific focus area): Be sure to include two (experimental *and* control) patient groups in comparative effectiveness research (CER) work. Use caution when proposing usual care groups, for example if the intervention involves a lot of hands-on patient contact and usual care does not (in which case it is difficult to distinguish the specific effects of the intervention from the generally beneficial effects of paying close attention to patients).
d. Ensure your study design is concise and robust: Limit the number of study aims. Review committee most appreciates a clear study design.
e. Generalizability of patient size: Include as diverse and large a patient group as possible given your study aims, and highlight the applicability and scalability of your design.
f. Patient applicability: Consider including moderator analysis to identify whether the intervention has differential impacts across different populations (i.e. some types of patients receive substantial benefits, other types of patients little if any benefit).
g. Outcome measurement: Use relevant specific, measurable outcome. Consider including a methodologist on the investigator roster.

2. Dean Schillinger, MD (PCORI Reviewer):

Review panel was comprised equally of scientists and of patients and stakeholders (PCORI parlance is that patients are distinguished from stakeholders, which may include patient advocacy groups, health systems, and so on).

a. Know Your Audience: Don't cut/paste from NIH R01, since goals of and approach to PCORI grants are very different from the focus of NIH. On review panel on which Dean served, he saw examples of this.

b. Pay adequate attention to and involve stakeholders' groups as early in process as possible. One applicant listed "stakeholder TBD". The patient reviewer rejected that application on sight.
c. Include a comparative or control group. As Larry suggested, the comparative effectiveness aspect is crucial.
d. Generalizability: clearly show dissemination plan, especially if your application is not in the Communication and Dissemination Research focus area. Whether or not it's already part of the research question, highlight how you will disseminate your findings.
e. Choose correct focus area to reach the most appropriate reviewers. Dean's review panel encountered some misdirected proposals.
f. Show how the question is relevant to public health and patient-centered care: with diverse panel (2 scientists, 1 stakeholder & 1 patient reviewer) the important question is: "Is this disease an important problem?"

3. David Thom, MD, PhD, MPH (Funded Applicant):
David's funded pilot project: Health Team Support for Patient Informed Decision Making. These funded pilot projects (from 2012) were more fundamental and broad in methodology and approach than the current proposals being solicited.

a. Current PCORI Funding Announcements (PFA)'s and patient involvement: The criteria for David's pilot studies were very different from those in current PFA's. Updated PFA's and review process include *much more* patient involvement. David doesn't think his specifications for patient involvement would have met the current criteria for involvement.
b. PCORI vs. NIH: Greater involvement by & accountability to PCORI: PCORI awards "contracts," not "grants"; and as such PCORI focuses more than traditional grants on meeting milestones and showing accountability throughout the implementation of the grant.
c. Patient involvement "can't be faked": Patient doesn't need to be a co-investigator, but does need to be involved from an early point in formulation of study question and all later stages of the grant process. Patient advocacy groups, community groups are as appropriate to "patient involvement" as are individual patients.
d. Examples of types of [funded] studies: See also PCORI website for funded study abstracts.

4. Tung Nguyen, MD (Funded Applicant):
Tung's proposal funded within Addressing Disparities focus area: A Patient-Centered Intervention to Increase Screening of Hepatitis B and C Among Asian-Americans

a. Submission logistics: Use the PCORI template biosketch (the instructions said it was OK to use either the PCORI or NIH templates, but reviewers seem to prefer the PCORI template).
b. Coordinate w/your grant manager especially re: proposed budget: Respond to PCORI's questions re: budgets; they have a different process from NIH, and are very hands-on.
c. Know your deliverables: Per legislation establishing PCORI funding, investigators are required to release research findings w/in 90 days of the end of grant funding. Even if you don't publish anything, you will be expected to release findings, in some way, within 90 days.

d. Tung's biggest challenge: Defining clear outcomes while incorporating patient-centered outcomes research (PCOR) and interventions. How best to address a significant health problem, through proven, persuasive interventions, while still focusing on PCOR? E.g., Tung's study included both hepatitis B *and C* testing to allow for more patient input and preference.
e. Emphasize the patient input aspects, to reach the patient reviewer: Tung's review scores were 2, 2, 2, and 5. Tung believes the patient reviewer on his panel issued the 5, based on the reviewer's comments to effect that Tung hadn't incorporated enough patient input into study design. This was despite the limitations of his study design, which precluded further involvement (e.g., randomized controlled design vs. lay-person protocol experience).
f. Include the community advocate or alternative type of patient perspective as early as possible: Tung's design included (and budgeted for) a patient advocacy organization as an active, engaged consultant, *in addition* to including advisors. However, his reviewers seemed to have missed this higher profile consultant role for the advocacy organization. Suggestion: Establish relationships with the patient advocate(s) early on. Ensure his/her role is clearly emphasized in the proposal.
g. The Patient & Stakeholder Section: where to include patient and stakeholder activity in research plan? Even if it's already outlined in your research plan, emphasize how well integrated into the design the patient and stakeholder activity will be.

B. Question and Answer Section

Leslee Subak/UCSF: How much preliminary data is needed to demonstrate efficacy for each of the interventions/arms proposed? Is it OK to have a new experimental arm alongside another arm where the intervention has proven efficacy?
Dean: The latter is OK, so long as you provide justification.
Larry: Agreed; PCORI application not like an NIH application.

Ian Kobner/UC Davis: Is "usual care" an appropriate comparator?
Larry: OK to include "usual care" arm as long as there's parity in attention paid to each group.

Rena Pasick/UCSF: In PCORI's view, is there a difference between a "patient" and "stakeholder"?
Dean: Yes. "Patients" are distinct from "stakeholders." The "patient reviewer" in his panel reviewed only grants related to his/her condition, and was intimately familiar with that disease condition.
M. Margaret "Peggy" Knudsen, MD, FACSS (PCORI Reviewer): In her experience as a reviewer, Peggy understood that "stakeholders" could be clinicians, researchers, policy workers or industry. "Patients" were defined as patients, their caretakers or surrogates for patients. Arthritis foundations, lung society, or similar groups might be considered policy workers, in contrast.

Peggy suggested not emphasizing cost effectiveness, which PCORI *will not* fund.
Merit Review Criteria #2, 4, and #7 = most important
Dean agreed about omitting mention of cost effectiveness.

Jacqueline Leung/UCSF: How best to select "patients" as part of patient/stakeholder engagement?
Tung: In his proposal, he recruited patient advisors from his target population (Asian Americans via SFGH, UCSF, etc.). Tung thinks including both individuals *and* groups would be most effective.

Peggy agreed.

Yan Leykin/UCSF: Would PCORI fund a postdoc in personnel?
Dean: Yes, he saw postdoc applicants (funded).
Larry: Yes, but justify, especially if postdoc will serve as an investigator and at what percentage supported.
David: Agrees, and suggested applications define postdoc's role in terms of how they'll serve the study. The key idea is that whoever is involved should have his/her work clearly defined. Grants are judged based on the quality of the work, not labels / position of the investigators. Also, David's insight into direct cost: current PFA *implies that* clerical and administrative staff time seem be included, however David called PCORI representative for clarification and learned "No" (as for previous PFA's).

Mike asked reviewer panelists: Most effective way to communicate with PCORI?
David: PCORI does not entertain phone calls, but have been responsive via email. However, there is not a single staff person assigned to each proposal.
Tung agreed.

Mike: Are resubmissions submitted to the same panel?
Dean: His panel reviewed 2 applications that were actually resubmissions. However, he hadn't been alerted to this status until afterwards. None of his fellow panelists (who were also, all new to the applications) were given access to the original submissions. PCORI review panels are dynamic, not a sitting study section.
David: Consider adding a section (in beginning of resubmission) with previous reviewers' criticisms and how you've responded, as in an NIH resubmission. Applicants who are resubmitting should loop in "new" reviewers, and assume that those reviewers will be brand new.

Noel Lessing?/UCDavis: Would PCORI fund junior faculty?.
Dean: Applications from assistant professors absolutely acceptable. The review panel paid more attention to the [overall] quality of the study's research team. However, Larry, David, and Dean had not seen any grants with asst. professors listed as "co-investigators".

Mike: Thanks to the five presenters (including Peggy Knudsen). Friendly reminder that audiolinks for this webinar will be posted (along with the other, archived resources) at the UCSF CTSI CER website. Thanks for attending.