Colorado Department of Public Health and Environment

Meeting Minutes

Medical Marijuana Scientific Advisory Council

Date: October 24, 2014
Time: 9:00am
Place: TELECONFERENCE (may also attend in-person at CDPHE)

Acting Chair: Dr. Ken Gershman, CDPHE

Members present on teleconference: Tim Byers, Alan Shackelford, Kenon Heard, Edward Maynard, Joseph Frank, Stacy Livingwell, Ken Finn, Teri Robnett, Mike Van Dyke, Alan Feiger, Judy Shlay, and Tony Capello.

Note Taker Elyse Contreras

	Topics:	Presenter
9:00 am	**Welcome and Updates;** • **New and improved link to Google Drive emailed to all reviewers on 10/23. Reviewers need to contact Elyse immediately if problems accessing applications persist.** • **Reminder for reviewers to sign, scan and email Reviewer Confidentiality form to Elyse.** • **November's meeting will be held at the Colorado Department of Transportation (CDOT), 4201 E. Arkansas Ave. Denver. Meeting is all-day, 8:00 am to 5:00 pm and is mandatory for all SAC Members. Elyse will send out updated calendar appointments.**	Ken Gershman and Elyse Contreras
	Q & A: Grant Review Guidance (for reviewers only) • **Applications will be divided up for review among 18 reviewers. Out of 14 SAC members, 12 will conduct primary reviews. The SAC chairman Larry Wolk and SAC member Terri Robnett will not take part in primary review.** • **Added six ad hoc reviewers, names listed; Tista Ghosh, Mike Van Dyke, Bernadette Albanese, Alan Feiger, Judy**	Ken Gershman

Shlay, and Tony Capello.

- **Addendum to guidance explained.**
- **Guidance document reviewed in detail, through each section.**

Questions from reviewers;

1. **Does the RFA specify that projects must start within 6-9 months of funding approval?**
   Answer: No. The funding period technically started July 1, 2014 and projects need to be completed before the end of the five year time period authorized by the state legislature. When reviewing applications, think about the likelihood of that project getting any necessary federal and IRB approvals, and being successfully completed before funds expire. This will also be considered during November 21 SAC deliberations and final scoring.

2. **Regarding double-blind randomized trials, have researchers been told it will be very difficult to get approval and do they realize time might become an issue?**
   Answer: Not specifically. However, page 5 of the RFA lists the various federal approvals necessary for university-affiliated researchers to conduct different types of studies.

3. **If we review a good double-blind, randomized trial grant that doesn't get funded now, will there be opportunity later?**
   Answer: Not that we can say now. These are one-time funds. We do not currently have, or know about, additional funding at this time.

4. **Were there areas of focus for applications or was it open for all topics?**
   Answer: Per the August SAC meeting, it was decided to leave the focus open. There is some study-design focus and preference specified in RFA (see page 6). Use your knowledge and expertise to decide how well a proposed study will add to the knowledge of efficacy of medical marijuana (or component parts) to that condition, and the importance of that condition in terms of burden (i.e.,

numbers affected) and importance to patients/advocates .

5. **In reference to page 5 of the RFA, regarding human observational studies, does this mean subjects are obtaining their own marijuana for research, not the researcher supplying?**
   Answer: Yes, this circumvents the need for federal approvals to conduct these studies, since they do not include researcher interventions – just researcher "observation" (which can include specimen collection and data collection).

6. **What is the intent for providing written feedback to applicants and are the reviewers comments going to be giving to applicants?**
   Answer: Yes, please provide your comments on the scoring sheet as feedback for applicants (strengths, weaknesses and summary comments). Please type your answers for submission, no hand-written comments please.

7. **Do we use decimals or whole numbers?**
   Answer: Use whole numbers only per page 2 (third bullet down) of the grant review guidance. You will not be awarding preference points at this time – these will be added on November 21 by the full SAC discussion and scoring of the finalist grants.

8. **In reference to the list of detailed "Research Plan" items that applicants were supposed to address in their grant (p. 7 of review guidance; p.7-8 of RFA), are each of these bullets to be addressed in your grant review?**
   Answer: Some of these bullets might not apply to all study designs (e.g., randomization) and, therefore, may not be applicable. It is most important to comment on what you feel are the most notable strengths and weaknesses (especially omissions) in the applicant's discussion of these items. A panel of statisticians will be conducting review of the statistical aspects of the finalist grants, and their comments will be shared with the full SAC on November 21.

9. **How many people are reviewing each application?**
   <u>Answer</u>: Three reviewers have been assigned to each application. Each person has 7-8 applications to review.

Update on Submitted Applications and the Intake Process

- **Received 86 letters of intent (LOI's) ,one LOI was withdrawn, 57 grant applications submitted. After technical intake review, 10 applications were disqualified for not meeting timeliness/completeness requirements, leaving 47 total grants for review.** Ken Gershman

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Adjourn