RESEARCH ADVISORY PANEL OF CALIFORNIA

MEETING MINUTES

JULY 19, 2024

OPEN SESSION

1. Call to Order and Establishment of a Quorum

Panel Members present: Member Martine D'Agostino, Member Jennifer Mitchell, Member James Gasper, Member Boris Heifets, Member Daniele Piomelli, Public Health Officer Designee Erika Pinsker

Panel Members Absent: Member Patrick Finley

A quorum was established and Member D'Agostino opened the meeting with logistical instructions on conducting the meeting under Bagley-Keene Open Meeting Act rules.

2. Introduction of RAPC members

Each Panel member introduced themselves and provided their titles, affiliations and length of time of service with RAPC.

3. Selection of a new RAPC Chairperson

Member D'Agostino opened up the discussion for selection of a Chair. Member Gasper made a motion to nominate Dr. Jennifer Mitchell and Member Heifets seconded that nomination. Member Mitchell accepted the nomination.

Vote:

Boris Heifets - Yes
Daniele Piomelli - Abstain
James Gasper - Yes
Jennifer Mitchell - Yes
Martine D'Agostino - Yes

Member D'Agostino asked how Chair Mitchell would like to proceed and if she would like to lead the rest of the Agenda. Chair Mitchell accepted.

Public Comment

None.

4. Bagley-Keene Open Meeting Act Training by Attorney General's Office

Deputy Attorney General Milad Dalju gave a presentation of a very broad overview of the Bagley-Keene Open Meeting Act aimed at State Boards and Commissions. DAG Dalju discussed teleconference provisions available to RAPC. DAG Dalju also discussed the closed session provisions available to RAPC to discuss, review, and approve research projects containing confidential information.

DAG Dalju opened up the presentation for questions from the Panel. Chair Mitchell asked about the process for adding Agenda items. DAG Dalju explained that Panel members may contact the Executive Officer asking to add an Agenda item to the next Agenda.

Public Comment

Chair Mitchell asked for comments from the public on DAG Dalju's presentation. No comments were received from the public.

5. Discussion of process for preliminary review of research projects

Executive Officer Khan provided a summary of the current RAPC review process. Chair Mitchell opened it up to questions. Daniele Piomelli asked about RAPC's role in reviewing applications already reviewed by FDA, IRBs, or IACUCs. Chair Mitchell said that a process was discussed before and the Panel can now discuss having an expedited review process for studies that already have these other approvals in place, including FDA, IRB, IACUC, DEA, and outside review. She added that the task of the Panel is to review studies for safety, and in the past, studies have reached (RAPC) that had not been fully evaluated for safety and sometimes not for scientific merit.

Member Piomelli expressed that he is new to RAPC, and asked, moving forward, what will be the value added by RAPC to the process. Member Heifets said that it would be difficult to answer that without giving concrete examples that can be publicly shared. Member Piomelli said a major problem is the turnaround time and asked other panel members to agree or disagree that it can be quickly determined whether an application can be expedited. Chair Miichell responded that turnaround was quick in the three years prior to the halting of meetings, so that is not a reason not to review protocols, but that there could be an expedited process for some applicants.

Member Heifets said that expedited approval can be used for animal protocols that have IACUC approval and justification of controlled substance amounts, and human protocols that already have IRB approval/IRB approval pending RAPC review, FDA approval, and a pending DEA application (contingent on RAPC approval). Member Piomelli said he understands now that there was a hiatus due to legal issues which is now over, but he feels that because RAPC review

comes at the end of a long process, an effort should be made to ensure that scientists/ constituents are satisfied with RAPC's work. Chair Mitchell said that RAPC could come up with an expedited review process as Member Heifets was outlining, and she would add outside review to the checklist of items for expedited review.

Member Heifets asked the committee for a concrete example of an item that could not be expedited. Member Piomelli said he has some, but cannot share concrete examples. Member Heifets asked if there is any validity to requiring additional review of pharmaceutical company sponsored trials. Member Piomelli suggested focusing the expedited review to studies with funding agencies with very specific timelines such as the NIH or the Department of Cannabis Control. He felt that if they've gone through the process already, RAPC could accept what peers have already said. Executive Officer Khan asked for clarification of what this means for the study types he identified. Member Piomelli explained that it would consist of verifying approval by institutions such as FDA, DEA, and IACUC, and IRBs, and that once RAPC has identified these reviews, it does not have to go through the study with a fine-tooth comb. He would not expedite studies that don't have these in place, or if there is a doubt that one of these boxes has not been checked. In this case he felt it is RAPC's duty to delve into the applications. Member Heifets said that one implication would be that RAPC would be superseding the judgement of the FDA, and that there is a sense that there may be a difference between external and institutional IRBs. Member Piomelli replied that he would agree with treating all applications the same way if all the boxes have been checked, and that the alternative would be to go through a full review of everything. Chair Mitchell added that RAPC members have received some very compelling arguments over the past year from drug companies that were very concerned about the possibility of going out of business while waiting for RAPC to deliver a verdict and so they deserve the same amount of expedience as the institutional protocols RAPC receives.

Chair Mitchell wondered in terms of talking about how to handle an expedited review and if anyone would be interested in approaching it the way some other IRBs do for expedited review. Two Panel members could take a quick look and if they don't see any problems, it can then move forward rather than go to full committee for discussion. Other protocols that don't meet the criteria for expedited review would still get reviewed by two Panel members and would be held for full discussion at one of the closed meetings. Member Gasper liked that approach and said an easy place to start would be non-human studies, which have historically been addressed outside of Panel meetings. Member Piomelli said that colleagues with human studies are also very concerned about the length of time of the review process and suggests that there is a clear checklist so that when a new application comes, RAPC goes through it and it's important to assure uniformity and fairness of the process. Member Piomelli suggested that the checklist doesn't have to be decided today and that RAPC could have another public conversation about

the process. He suggested a checklist is important and that Human and Non-Human studies should be treated equally for potential expedited review. Member Gasper clarified that he was not meaning to leave Human studies out of that, he was only referencing a long-standing process for Non-Human studies that had changed in the past few years. Member D'Agostino expressed that she is a new member of the Panel and in terms of deciding which studies to expedite, it seems to her that RAPC reviewed studies in the chronological order in which they were received, and that handling the backlog in chronological order might be the fairest way to approach it. Chair Mitchell replied that that is a good question and it ties in with the next Agenda item that will be discussed.

Chair Mitchell concluded that in terms of tying this Agenda item up, RAPC had started to generate a list, and next time, the Panel could go over the list and agree if that is appropriate. Boris said he would go one further and you could simply triage where it meets criteria of being academic, human, non-human, and a couple of other categories that may require further review, but that anything meeting those basic criteria doesn't require full committee review. It would be a check box rapid approval. Others, in which it in unclear if the study is under jurisdiction of RAPC where the study is synthesizing things or transferring materials, that is where there may be a need for Panel discussion. He finds it hard to see where two people are needed if it is just a checkbox. Executive Officer Khan asked for clarification on whether the preliminary review would be done by a single person versus a two-person review because it makes a difference in terms of Bagley-Keene. To her understanding a two-person subcommittee cannot make a decision outside of a Panel meeting. Chair Mitchell asked DAG Dalju for clarification. DAG Dalju replied that Executive Officer Khan is right in that it qualifies as a subcommittee if it's more than one member who has been delegated final decision-making authority. The two-person subcommittee would have to agendize their subcommittee meetings. If decision-making authority is delegated to one person, it is fine. Chair Mitchell then reiterated she will agree with Member Heifets that for expedited review, one Panel member would review and render a decision. Member Piomelli said then there would have to be very, very clear instructions. It would have to be a checklist that that person must follow. He pointed out the time lag if someone misses a meeting by just two weeks; that the time lag becomes three months to make a decision for a study that has already been delayed by DEA and FDA, and that this is a significant amount of time.

Executive Officer Khan asked how that ties in to study Amendments because they also can't languish, and what is the most appropriate way to approve those studies in the most efficient way possible. Would a one-person review apply to that as well. Chair Mitchell suggested it would and Member Gasper said it would be adequate.

Member D'Agostino said that before deciding, they need to formally take a vote. Chair Mitchell agreed and said that there are two different things here; part one is going to affect how they review in the private meeting about to happen and part will affect future process. The expedited review they should make a motion and vote on now if everyone feels comfortable, unless they have more to say. Designee Pinsker added that for expedited review, would they be treated the same regardless of funding or institution. It is important to clarify because of the earlier discussion about having a separate process based on that did not have as strong of a justification. Chair Mitchell concurred that this would suggest treating everybody the same. Animal projects, human projects, and maybe in-vitro studies would have a different list.

Member Gasper voiced concern about removing all conscious assessment of information if they are just following a checklist. Chair Mitchell said that in the past, it seemed like they picked the Panel's expertise and then paired that Panel member with the protocol rather than having one person assigned to do everything because that would be an easy way to miss things. Chair Mitchell asked how do people feel about that process. For example, if things are of a certain ilk and (a certain Panel member) is the best person to review, then (that Panel member) would review. Member Gasper said that there should be some discrimination on Executive Officer Khan's part on triage, which she does now. Chair Mitchell agreed. Member Gasper said that using a checklist does not mean that they go forth without reservations; they may still find some (concerns) within that, and there are examples of that in the past. Chair Mitchell said that is the other thing. If there is something reviewed by that one Panel member that does not, in their opinion, meet expedited review criteria, it would be put on the Agenda for full Panel discussion, yes? All Panel members agreed and member Gasper said that seems like a good use of their time as the majority of studies would fall under that expedited process. Designee Pinsker asked whether those proposals would then be reviewed by two members. Chair Mitchell said that they would have to be at that point. They would be thrown into the pool for full Panel review. Executive Officer Khan asked for clarification whether that means if the single Panel reviewer decides on the full Panel review, is it immediately assigned to a subcommittee that contains the initial reviewer. She said she wants to make sure they remain within the appropriate procedures under Bagley-Keene. Chair Mitchell agreed the subcommittee should contain the initial reviewer.

Member Piomelli said he wants to make sure they briefly discuss the issue of conflict of interest to make sure COI is disclosed prior to going through the process. Because there are so few of them, they should use the COI that comes from the law, which is a financial COI disclosure. What the program could do is have Executive Officer send out a list. Chair Mitchell said that is great and exactly how they have been doing it for years. Executive Officer Khan sends out a list prior to deciding who is going to review, to ensure that there are no conflicts.

Public Comment

Chair Mitchell asked for public comment. A member of the public thanked the Panel for the discussion. He asked to add a fourth thing to consider for the Panel as they think about how to expedite those applications: Would they consider a way of tracking or evaluating whether this expedited review process is accomplishing what is intended, that advocates are watching closely and knows this will help expedite the process. Chair Mitchell said she thinks this is personally a great idea and very much in keeping with some of the records that Executive Officer Khan currently keeps and releases through the Annual Report.

Hearing no more questions, Chair Mitchell asked if anyone would move for expedited approval. Member Heifets moved for expedited approval and Member Piomelli seconded the motion.

Vote:

Boris Heifets - Yes
Daniele Piomelli - Yes
James Gasper - Yes
Jennifer Mitchell - Yes
Martine D'Agostino - Yes

Chair Mitchell said the expedited approval process will stand and believes they can move into closed session with that expedited approval process in place.

6. Discuss backlog of pending applications and prioritization

Chair Mitchell opened up the discussion to addressing the backlog and prioritization and asked the Panel for comment on best how to handle. Member Heifets replied that it should be done quickly and soon. Chair Mitchell suggested non-human protocols go a bit faster, and does the Panel want to start with those, and then human studies, and asked the Panel how they want to handle this. Member Heifets suggested going by the list prepared by Executive Officer Khan, sticking to "first in, first out." Panel members agreed. Chair Mitchell concurred and suggested they use the same process for future meetings.

Public Comment:

Chair Mitchell then asked for public comment. There was no public comment.

CLOSED SESSION

Chair Mitchell, Members Heifets, D'Agostino, Gasper, and Designee Pinsker entered closed session under Government Code Section 11126, subd. (c)(20).

OPEN SESSION

Panel members reentered the open meeting. Roll Call was taken. Members Present: Chair Mitchell, Members Heifets, D'Agostino, Gasper, and Designee Pinsker.

Chair Mitchell concluded that by close of business the following Friday July 26, the Panel aims to notify applicants, and she referred everyone to the website for details on the next meeting and the Agenda. For new applications, RAPC will add a new review process, which will be outlined at the next Public Meeting in August.

Chair Mitchell thanked the Panel and adjourned the meeting.