

RESEARCH ADVISORY PANEL OF CALIFORNIA

MEETING MINUTES

August 16, 2024

**OPEN SESSION**

**1. Call to Order and Establishment of a Quorum**

Panel Chair Mitchell call to order 1:02 pm

Welcome, roll call, and establishment of a quorum

Panel members present: Chair Jennifer Mitchell, Member Boris Heifets, Member Daniele Piomelli, Member James Gasper, Member Martine D'Agostino, Public Health Officer Member Designee Cyrus Rangan.

Panel members absent: None.

**2. Introduction of RAPC members**

Brief introductions by Panel members who each stated their names and academic and/or professional affiliations.

**3. Discussion of process for expedited review of studies**

Chair Mitchell opened this agenda item, stating that this discussion was started at the July 19<sup>th</sup> meeting, then summarized a few points to see what was missing: (a) How to potentially begin a process for expedited review of study amendments. (b) Moving forward, a single Panel member can be assigned to review an amended study. (c) That single Panel member may unilaterally approve the amended study without going to a full Panel meeting IF certain criteria are met. (d) For human studies, the study would have pre-existing IRB approval, DEA and FDA approvals if required, and the schedule I drug was in keeping with the aims of the study, and there were no significant changes to the aims of the study. Likewise, for non-human studies, if all approvals are in place, the requested quantities are in keeping with the aims of the study, and there are no major changes to the aims of the study, the amendments could be considered for expedited approval. (f) However, if a single reviewer were not comfortable with approving an amendment, whether human or animal or otherwise, the single reviewer could request to discuss the amendment within a subcommittee, or at a full Panel meeting prior to approval. It would be at the discretion of the Panel member to decide whether to move the amendment into subcommittee/full Panel review. (g) The success of this process will depend on expeditious

review by the Panel member. Chair Mitchell opened it up for comment and discussion by the Panel.

Member Heifets recommended “as soon as possible” for the turnover period instead of a specific, set period of time. Chair Mitchell asked if it would be reasonable for the amended study to be reassigned by the Executive Officer if the Panel member could not turn it over in a reasonable period of time. Member Heifets agreed that this was reasonable. Member Heifets also suggested that a reasonable standard would be that, based on a checklist of items to check for, including if the amendment is IRB-approved, there should be very good reason to add another layer of review.

Member Gasper asked the Executive Officer whether amended studies have gone through other approval processes such as the internal IRB. Executive Officer Khan replied that some studies wait until receiving Panel comments to incorporate the changes prior to sending the amendments to their IRB. Member Gasper said he would be okay getting ahead of the IRB and leaving it to the discretion of the Panel member to decide. Member Heifets added that the primary determination (of approval) should be with the local IRB, and the Panel should have a very good reason to conflict with the local IRB. Member Gasper suggested having the amendment approval contingent upon approval by the IRB. Member Piomelli agrees that RAPC should rely heavily on other institutional approvals. Member Piomelli also suggested the possibility of having two Panel members review and then discuss at the next Panel meeting. Member Heifets reminded the members that amended studies have already been approved by RAPC, the IRB, and other agencies. He suggested the only thing RAPC should be determining for amendments is checking the boxes (of requirements) and while still having the purview to hold up the process, allowing the amended studies to move forward. Member Piomelli supports this process in the specific case of amendments.

Chair Mitchell asked if RAPC could do something conditional based on other approvals, and some other members agreed with the condition of the study sending a copy of the approvals. Chair Mitchell said that it sounds like everyone is on the same page for an expedited process for amendments. Member D’Agostino asked if one Panel member will approve without consulting the rest of the Panel. Member D’Agostino stated that it would be delegating approval to one Panel member, and Member Heifets responded that it would be a clerical process because it is a checklist, and Chair Mitchell concurred that it would be an administrative process. Member D’Agostino said that it would allow the previous approval to stand, but it would still be exercising some authority, and she would need to think about that some more. Chair Mitchell said that the expedited process is to ensure a way forward without a full Panel meeting, with only an administrative process. Member Piomelli said he would support having two people for

such a review would be best. Executive Officer Khan pointed out that two members reviewing the amendment would form a subcommittee. Member D'Agostino said administrative functions generally don't need to be conducted in an open meeting, but she wants to confirm with the Bagley-Keene expert at DOJ because it was her understanding this had been handled by the whole panel in the past. Chair Mitchell explained that some years ago the process was different and not handled by the whole Panel. Several members commented on the necessity of a formal approval and the need to streamline the process.

Chair Mitchell confirmed with Member D'Agostino that she could ask for a motion, and Member D'Agostino could let us know if something was not appropriate. Chair Mitchell asked if someone would be willing to move to consider an expedited process for both human and non-human amendments to use a checklist and allow it to move forward. Multiple members gave assent to vote for a one person expedited review process for human and non-human study amendments.

Vote:

Boris Heifets - Yes

Daniele Piomelli - Yes

James Gasper - Yes

Jennifer Mitchell - Yes

Martine D'Agostino - Abstain

Cyrus Rangan - Yes

Chair Mitchell concluded that the Panel has an approved process for expedited review of amendments, pending Member D'Agostino's review to ensure that it meets the standards of Bagley-Keene.

Chair Mitchell opened the discussion to the expedited review of new studies. Member Piomelli thanked the Chair and suggested picking up the conversation at the next public meeting and creating a subcommittee to put together ideas for that discussion. Chair Mitchell said that the Executive Officer has started creating checklists for quickly evaluating studies, and that as a starting point, requested the Executive Officer to send Panel members these checklists for quickly evaluating human, non-human, benchtop, and institutional and commercial protocols.

Public Comment

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

**CLOSED SESSION**

Chair Mitchell, Member Heifets, Member Piomelli, Member Gasper, Member D'Agostino, and Public Health Officer Member Designee Rangan entered closed session under Government Code Section 11126, subd. (c)(20).

**OPEN SESSION and ADJOURNMENT**

Roll call was taken. Members Present: Member Boris Heifets, Member Daniele Piomelli, member James Gasper, Chair Jennifer Mitchell, Member Martine D'Agostino, Member Cyrus Rangan.

Member D'Agostino asked for the date and time of the next meeting, which was established to be on October 18, 2024. Time TBD.

Hearing no additional comment, Chair Mitchell thanked everyone for their time and adjourned the meeting.