RESEARCH ADVISORY PANEL OF CALIFORNIA
Meeting Minutes
February 14, 2025

## OPEN SESSION

1. **Call to Order, Establishment of a Quorum, and General Announcements**

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

Panel members absent: None.

Quorum is established.

Chair Mitchell in her general announcements asked (1) Panel members to complete Form 700's and complete ethics and tribal trainings and send the certificates to the designated emails by their deadlines; (2) Let the executive officer know as early as possible if Panel members cannot make a Panel meeting so that we can ensure there are enough members to make quorum or make adjustments to make quorum.

Chair Mitchell asked for public comment.

Public Comment:
None

**2. Approval of Panel Meeting Minutes**

Chair Mitchell asked if there are any comments or changes to the meeting minutes of the December 6, 2024 Panel meeting. No comments or requests for changes were provided, and Chair Mitchell asked for a move to approve the minutes. Member Heifets moved to approve the minutes and Member Gasper seconded the motion. All Panel members voted to approve the December 6, 2024 meeting minutes.

Public Comment
None

**3. Panel Meeting Frequency**

Chair Mitchell asked Panel member Piomelli if he would like to start the discussion on Panel meeting frequency. Member Piomelli suggested that having meetings at a little greater frequency would allow for reviewing fewer studies and accelerate the approval process for the scientific community. Chair Mitchell commented that RAPC has had discussions several times in the past about meeting more often, and that the Executive Officer had put together a list of those previous points that had been made and the issues that we had previously faced, including legislative language and the budget. Member Heifets said that increasing the frequency of meetings would be a challenging scheduling task, but that the alternative is to reduce the number of applications for full Panel review by having single reviewer authority for some straightforward applications. As an alternative, he pointed to the expedited process for study amendments and potentially decreasing the number of studies that must be discussed at the Panel meetings by using a similar expedited process for new studies. A single Panel member could have the authority to say (a study) does not need to go to full Panel review because it is a straightforward study that checks the appropriate boxes. Chair Mitchell reminded everyone that an expedited review process is also on the agenda for today. Member Piomelli suggested having an "exceptional meeting" if there are suddenly a whole bunch of applications at one time. The Executive Officer responded to Panel Member Piomelli's question on the timing of increased applications that it tends to be unpredictable.

Chair Mitchell brought up (1) the difficulty of meeting quorum if there are an increased number of meetings and people are less able to attend all of them. She referred back to Member Heifets' suggestion for some sort of an expedited review process to review and approve studies outside of a normal meeting cycle. On chair Mitchell's request, the Executive Officer listed some additional issues previously discussed –(2) that meeting quorum is an ongoing challenge, (3) the unfilled seat on the Panel (4) Panel member recruitment and retention difficulties due to the heavy workload and time commitment to attend meetings, and (5) the Panel would also have to consider what changes to make to the review cycle if meeting frequency were increased. Chair Mitchell pointed out other considerations are (6) the workload for the Executive Officer and (7) the budget/costs for increased meetings and additional staff to handle the increased workload of more frequent meetings. Member Piomelli said at two different levels the Panel could increase their ability to work under the current regulations or try to lobby for change to those regulations to serve the scientific community. He suggested making the number of meetings more flexible. The Executive Officer pointed to the expedited review process approved for amended studies that has resulted in a turnover time of an average of five days once the application reaches the Panel, and the positive feedback from this process.

Chair Mitchell reminded everyone that the Panel is ready to adopt an expedited review process for new applications. Chair Mitchell said she has done her best to explain to the State Legislature the issues facing RAPC and what could be improved. But it's not easy because changes would require writing a bill and someone to author that bill. She said she's not a politician, but she was advised not to ask for more money in the budget because we're not going to get it, so that would make hiring new staff a challenge, or paying Panel members anything for their time, given that RAPC is a Panel, not a commission, and so there is no payment or reimbursement for their time. Member Piomelli said he didn't want reimbursement and was against reimbursement, but reiterated his suggestion for ad hoc meetings if the Panel is flooded with applications, and allowing the Executive Officer to gauge. Member Heifets agreed and suggested the Executive Officer gate-keep when things get back-logged and meetings should happen sooner. per. Chair Mitchell said that if we are suddenly flooded with applications, there is nothing that says RAPC cannot (look into) meeting quorum and having an ad hoc meeting; that is totally acceptable according to the legislative language. Member Piomelli reiterated about being more flexible and suggested codifying it by putting a sentence on the website explaining that this (increasing meeting frequency) is possible so that people know we are doing our best. Member Piomelli also suggested making multiple small changes instead of one large change. Member Heifets said he feels we can do our best by a fast turnaround of studies that are fundamentally safe, and maximizing our flexibility. Chair Mitchell suggested thinking more about incorporating the expedited review process where a small handful of studies are reviewed at a full Panel meeting and the rest are expedited because that would address a lot of the problems.

Chair Mitchell asked for public comment.

Public Comment

A member of the public introduced herself as Agnes Balla from the Research Policy Office of the University of California Office of the President. She said she is hearing from the Panel Members that there is an interest in making improvements and efficiencies, which will be very appreciated by the research community. She agrees with Member Piomelli about making multiple small improvements along the way and she fully supports the expedited review process. She said she is also lending her assistance from the UC Office of the President and appreciates the effort to make improvements to the review process.

**3. Expedited Review Process/ Review Process**

Chair Mitchell said that because there is concern that legislative language is open to interpretation, talking to the Legislature and codifying the process for expedited review would help with consistency over time and to prevent backsliding when there is a change in the Chair.

Chair Mitchell asked Panel members to refer to the draft checklists for expedited review that they have seen and discussed before and suggested having two different paths for approval (expedited review and regular review). Member Heifets said it is important not to penalize Pharma or to favor academic studies or impugn private IRBs over institutional IRBs. Chair Mitchell suggested it might be easier to get approval from a commercial IRB which is paid to approve studies. Member Piomelli said he has reviewed excellent applications from both academic institutions and from (commercial) companies. Chair Mitchell said using vetted IRBs could be a criteria for expedited review. Member Lee asked about the difference between substance use disorder (SUD) studies and other study types and whether a study can be multiple study types. The Executive Officer responded that SUD studies refer to the population studied and studies are categorized as a single study type. Member Piomelli asked whether studies involving substance use disorder are tasked to RAPC by legislation. Chair Mitchell responded that they are, but questioned whether this may be something RAPC needs to do anymore because there is so much NIH (National Institutes of Health) oversight of at-risk populations. Member Piomelli pointed out that things may change on a federal level. Chair Mitchell agreed that we don't know if the same level of protections will exist for vulnerable populations in two years, and on some level this needs to be considered.

Chair Mitchell asked if she could get an approval of the expedited review process and visit it again after trying it for a couple of review cycles. The Executive Officer requested clarifying some questions about how the process would work. Chair Mitchell agreed and asked about distributing the workload with the expedited review process. Member Heifets suggested doing an anonymous poll asking members how long they spend on the expedited review to gauge the workload. Chair Mitchell suggested assigning expedited review to the three (experienced) members who have been on the Panel for multiple years for these off-cycle reviews and then letting them off the hook for other reviews. Member Piomelli said he thinks using a checklist document is a simple Standard Operating Procedure and any of the Panel members could follow the process for expedited review. Chair Mitchell said she doesn't know that all members feel comfortable with that and suggested a soft opening with beta-test testing. Member Piomelli suggested the Executive Officer determine the complexity of the study and assign it to a Panel Member based on that. Member Heifets suggested practicing in a closed Panel meeting with two people having gone through the expedited criteria and ensuring that there is concordance between the two at the meeting before doing it on their own. Member Piomelli agreed with this plan.

Chair Mitchell suggested a time-limit on returning an expedited review. Members Piomell and Gasper recommended seven days. The Executive Officer clarified whether this would be after a conflicts of interest check is conducted and Panel members agreed. The Executive Officer asked how to handle studies that have the required documents but still have obvious issues and asked whether the Panel member reviewing has the option of making the final determination of whether the study qualifies for expedited approval or to send the application to full Panel review. Member Gasper suggested that if a study that is being considered for expedited review has a problem (as determined by the reviewer), the study can be brought to the Panel meeting and discussed with the entire Panel.

Chair Mitchell said that something can be posted on the website about the expedited review process after it is completed. The Executive Offer clarified that an expedited review can only be conducted by a single Panel member (under Bagley-Keene). The Executive Officer asked Panel Members if there is any additional information that they would like her to collect as part of the application process. Chair Mitchell again suggested beta-testing the studies first. Member Piomelli said the most important step is to have clear guidelines.

Chair Mitchell asked for public comment about the expedited review process before making a motion.

Public Comment

Agnes Balla from the University of California Research Policy Office said that she appreciates what the Panel is doing to increase efficiency and to have in place an expedited review process, and feels like that would be really, really, important and she likes the directing the Panel is headed in. They have a policy that builds in certain mechanisms of what needs to happen in order to work with (outside) vendors, and they have a list of vetted vendors. She said she could share that list of vetted vendors. She also said she likes the direction that RAPC is headed in to increase efficiency by having in place an expedited review process, and that would be really, really important.

Agnes Balla said it is not clear to her what RAPC's role is in comparison to the other IRB's role, because it seems there's a desire to protect human subjects who participate in research, but that is the designated role of an IRB to do. Another thing Agnes Balla noted is that the DNA checklist can be confusing for why that is included in applications for RAPC review because there are many types of research that might use DNA and why is it controlled substance research that gets picked on to have to include this separate informed consent language. And to mention that NIH has very complicated rules about genetic sharing of genetic data and sometimes it could be very confusing to have added language that can conflict with other parts of the consent form or other rules or requirements that might be in place. Agnes Balla said if

there is an opportunity to reevaluate kind of what's in the scope of these types of studies, she would appreciate that conversation and maybe the consideration of taking out the DNA checklist because she doesn't think it serves quite the role that it was intended to.

Chair Jennifer Mitchel said that she thinks that is a separate agenda item, technically, and RAPC would happily put that on the agenda perhaps for the next open meeting and asked the Executive Officer to entertain Agnes [Balla's motion to add that to the agenda.

Chair Mitchell said the issue is a historical one because the previous chair had a vested interest in genetic data accumulation within the state of California. And she was quick to acknowledge that if you have some of these genetic data on hand, there is nothing anonymous about it, and knowing some of the NIH repositories were lumping together data from a number of studies without participants really understanding what that meant. So in other words, if you were in a drug abuse study because you had a cocaine addiction and a genetic sample was being taken and then it was being dumped into a NIDA repository for a whole bunch of people to use in perpetuity, that didn't always historically work out well, and therefore there needed to be a separate consent form so that people understood specifically within the State of California if they were giving a genetic sample that could be used in perpetuity. But why just controlled substance research in that case? But yes she fully agrees because she is absolutely right.

Executive Officer Khan asked to correct her if she is wrong that a separate genetic consent is required in California? Public participant Agnes Balla responded that separate genetic consent is required for direct to consumer genetic testing companies, but is not required for researchers.

<u>Vote to approve an expedited review process with beta-testing prior to going live</u>:

Chair Mitchell asked for a motion to approve the expedited review process, with beta-testing in the beginning. Beta testing would involve two Panel members applying the expedited criteria to assigned studies and then discussing the studies and checking each other's work. Member Heifets made a motion to approve, and Member Gasper seconded the motion. The Panel unanimously approved the expedited review process with initial beta-testing:

Member Heifets - Yes
Member Gasper - Yes
Member Piomelli - Yes
Chair Mitchell - Yes
Member Lee - Yes
Member Rangan - Yes
Member D'Agostino - Yes

**3. Future Agenda Items**

Chair Jennifer Mitchel noted that the Panel had already covered Agnes Balla's request, and said to her that if she wishes to join the Panel for the next Panel meeting as a public member she if free to do so.

Chair Mitchell then invited any other comments.

Public Comment

(Public comment on future Agenda items from Agnes Balla appears in the prior section on Expedited Review)

## CLOSED SESSION

Chair Mitchell, Member Heifets, Member Gasper, Member Piomelli, Member Lee, Member D'Agostino, and Public Health Officer Designee Rangan entered closed session to discuss Agenda items number 4, 5, 6, and 7 under Government Code Section 11126, subd. (c)(20).

## OPEN SESSION

**8. Meeting Adjournment**

Panel members present: Chair Mitchell, Member Heifets, Member Gasper, Member Lee, Member D'Agostino, and Public Health Officer Designee Rangan.

Panel members absent: Member Piomelli

Chair Mitchell provided a reminder that the next Panel Meeting is scheduled for April 18, 2025 at 1:00 pm and then adjourned the meeting.