RESEARCH ADVISORY PANEL OF CALIFORNIA

MEETING MINUTES

February 13, 2026 - 1:30 PM (Pacific)

OPEN SESSION

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

Panel Members present: Boris Heifets, James Gasper, Jennifer Mitchell, Kelly Lee, Daniele Piomelli, Judy Aoyagi, April Powell-Willingham.

Panel members absent: None.

Quorum established.

RAPC Staff present: Tanveer Khan, Executive Officer

Panel Chair Jennifer Mitchell called the meeting to order and after quorum was established, announced that the RAPC application forms and checklists are available on the website and should be used for new submissions. Chair Mitchell announced next that April Powell-Willingham was sworn in the day before as the new appointee of the California State Attorney General. Panel member Powell-Willingham serves in the seat vacated by former appointee Martine D'Agostino. Chair Mitchell welcomed Panel Member Powell-Willingham and asked her to take a minute to introduce herself. Panel Member Powell-Willingham provided an overview of her experience as an attorney and expressed her enthusiasm to begin the work of the Panel.

2. Approval of Panel Meeting Minutes for December 12, 2025

Panel Chair Mitchell asked for comments or suggestions for changes to the draft of the December 12, 2025 meeting minutes that was sent to Panel Members by the Executive Officer. Hearing none, she asked for a motion to approve the minutes. Panel Member Kelly Lee moved to approve and Panel Member Daniele Piomelli seconded the motion. Chair Mitchell asked for any dissenters. Hearing none, she indicated the unanimous approval of the meeting minutes.

3. Non-Human Studies Using Schedule II Controlled Substances

Chair Mitchell explained that in an effort to be parsimonious, the new State Bill AB 1103 (Ward 2025) states that RAPC will have oversight of all non-human studies using schedule II controlled

substances. However, many institutions and businesses solely use schedule II controlled substances, mainly pentobarbital, to humanely euthanize animals and nothing further. She didn't believe each of these studies should be continuously asking permission of RAPC to do so and introduced the idea of generating a waiver for institutions that are only using schedule II controlled substances for euthanasia. Chair Mitchell thought it would also be possible for larger institutions to ask for waivers for different sites; for example, UCOP could ask for a waiver on behalf of all University of California (UC) sites. Chair Mitchell asked how Panel members felt about enacting a waiver process for each institution using a schedule II controlled substance for the purpose of euthanasia so every group is not continually asking for permission to use schedule II controlled substances specifically for euthanasia.

Panel member Piomelli thought it was a good idea. Panel member Heifets also agreed that it was a good idea because it is already heavily regulated by most IACUC panels.

Chair Mitchell said she believed it is in RAPC's purview to generate a waiver process but asked for a motion to do it officially and to generate a waiver process for the use of schedule II controlled substances for euthanasia. Panel member Piomelli made the motion and Panel member Heifets seconded the motion. Chair Mitchell asked for any dissent, and hearing none, asked for the generation of a waiver to use Schedule II controlled substances for euthanasia.

Panel Member Piomelli asked whether the waiver would apply only to barbiturates, or also anything else (schedule II) used for anesthesia.

Chair Mitchell replied that RAPC could have different waivers for schedule II use in animal models for euthanasia, and for controlled anesthesia, and anything else the Panel feels they are needed for. She explained that CIIs for euthanasia is different than their oversight as part of a behavioral protocol or a health and safety protocol.

Panel Chair Piomelli said he could ask their veterinarians what they are using that is schedule II beyond barbitals.

Chair Mitchell said they should have sixty days to try to disseminate this (information) the best that they can and then see if there are any additional suggestions or comments from the various institutions that are impacted. Chair Mitchell asked if it was reasonable to people and seeing agreement, said RAPC would go ahead with this waiver process so that RAPC does not get several hundred of these applications every cycle.

Public Comment:

None

4. Serious Adverse Effect (SAE) Report Handling

Chair Mitchell provided the background that the Executive Officer had been reviewing the annual progress reports and noted that some of these included SAEs. Chair Mtichell noted that RAPC does not have a clear SOP for reporting or following up on these SAE reports. Chair Mitchell pointed to State language that significant adverse events should be reported to RAPC as they emerge and the reports are appearing on annual reports and in these cases the SAEs appeared on a closure report. This means they come too late for RAPC to take an action on an SAE. However, the question becomes, would RAPC ever take an action on an SAE? With that in mind, she asked whether RAPC would want a clear SOP on what to do in these instances. For example, would RAPC ever consider closing a study if SAEs kept coming up?

Panel member Heifets said reflexively he wanted to say 'not our business,' however, RAPC's actual mandate is to protect the public and this is very consistent with that. Panel member Heifets said the process would be that the study reports to the IRB and to the Sponsor and FDA collects these things. He said RAPC never finds out about it because we don't have a mechanism to find out about it, so how would RAPC protect the people of California? He felt that FDA is surely doing its job. He said RAPC's protection is that it should not be approving these studies. He said if no corrective action were taken, there should be some consequence. He asked whether the only consequence RAPC has is to not approve future work and whether RAPC would investigate these studies. He said he felt it was FDA's job to shut down a study.

Panel Member Piomelli asked whether they have power to terminate an approval.

Panel Chair Mitchell said she thought Panel Member Heifets' point is that RAPC would not know to do so if RAPC doesn't hear about SAEs until the closing report, and this would be too late in a deleterious situation.

Panel Member Piomelli said if something happens and RAPC cannot do anything about it, what use it is to the Public.

Chair Mitchell said she thought RAPC had teeth in two ways. One is to terminate the study approval because that's allowed. The other is that RAPC would talk to the FDA to ask them why they have allowed a study to proceed, given the side effect profile.

Executive Officer Khan pointed out that the general conditions of panel approval document states that the panel requires that it receive email, electronic notification within 7 days of any study drug-related serious adverse event that may emerge during the conduct of the study.

Chair Mitchell asked what do we do if they don't? She pointed out that RAPC sometimes deals with the Sponsor and sometimes with the actual group (conducting the study) in the State of California.

Panel Member Heifets asked what FDA would do if you failed to report an SAE in a timely fashion and if anyone has encountered this?

Chair Mitchell replied that she has only hear about it, but what she has heard is that if it is life-threatening, a hospitalization, potential death, they actually halt the study for a period of time for review, which closes the study to recruitment, which takes a lot of time and money, so it is taken very seriously.

Panel Member Heifets asked how RAPC would do that and enforce it, and what happens if there is some discordant decision-making (between RAPC and FDA). Can RAPC shut the study down when the FDA says no, that is fine.

Chair Mitchell said that as she understands it, RAPC has final purview for the state of California.

Panel member Heifets agreed that it is a possible outcome that RAPC could exercise.

Panel Member Lee thought that RAPC at the very least needs to get clarification from the investigators about whether it was reported to FDA in a timely manner and what the FDA said.

Executive Officer Khan pointed out that the Panel meets every other month so there's that huge delay, and if they receive something, would they call a special meeting of the Panel, or what would it require?

Chair Mitchell said that according to her understanding of the language in AB 1103, RAPC could form a subcommittee immediately. They can call together whomever had the time to discuss an urgent issue.

Panel Member Piomelli raised the possibility that the FDA doesn't have the resources or the interest in doing its job. He said he would naturally say this is none of our business, but given the circumstances, RAPC probably ought to do it or consider it. He said investigators couldn't breach the terms of the agreement, and if RAPC reminds them that they need to do it and AEs appear, he felt that after consulting with the FDA, the next step would be necessarily to stop the study.

Chair Mitchell agreed and said it sounded right to her. She hoped it would never happen, but RAPC has had a instance where the FDA approved a study, and RAPC was shocked to see the protocol come to RAPC. She felt it was political for FDA to have approved it, and they thought RAPC would shut it down, and was it relying on RAPC to do so? Chair Mitchell also wondered if FDA didn't or won't always see these reports when they are submitted. She felt RAPC should

not discuss the details of the study in open Panel. She felt that, if anything, RAPC should have a clear SOP in place so that RAPC knows what it would do if it ever happened and it is not scrambling to figure it out. The first thing is, if they have seven days to report to RAPC, and there are people who do not, perhaps RAPC should generate some sort of a letter of notification to PIs that it has come to RAPC's attention that these were not filed in the appropriate time frame, and that an additional infraction of this nature would incur a penalty, and be ambiguous of the penalty. Chair Mitchell said it's possible that PIs report to another system, but this way PIs know they are responsible for directly reporting to the state.

Executive Officer Khan asked whether multi-site studies should do the same for reports outside of California or just inside of it.

Chair Mitchell said that as she understands it, RAPC doesn't have any purview over what happens outside of California, but she thinks the question becomes, if they report to a sponsor, does RAPC want that sponsor interacting with RAPC and telling us, or does RAPC want the California sites to do it. In this case she can imagine the California site is going to say they told the sponsor and thought the sponsor was going to talk to RAPC. Chair Mitchell said it seems worthwhile to explain to the investigators that they are in California and are the ones that are supposed to make sure, ultimately, that reporting gets done to the State.

Executive Office Khan indicated that when she communicates with the multi-site studies, she never communicates directly with the site-specific studies; it is just the central study.

Panel Member Heifets said it is the sponsor who is filing all of the multisite studies. The PIs will have gotten it through their IRB and will hold the DEA license, but they're not actually responsible to apply to RAPC because they are not the IND holder.

Chair Mitchell agreed.

Panel member Heifets said it's the sponsor that RAPC has to communicate with and who they have to hold to account, not the PI.

Chair Mitchell asked whether that is what they want to do or do they want to let the PIs know that they should be reporting to RAPC if there is an SAE, and only for an SAE.

Panel member Heifets reiterated that it is on the sponsor and it is the sponsor who commits to do those things by submitting the RAPC application.

Chair Mitchell's concern was about what they can do to hold the sponsors - a lot of them international - accountable within the state of California. She suggested RAPC could determine they couldn't use any more California sites.

Panel Member Gasper said RAPC's existence is throwing them off, and RAPC could send them a reminder and that RAPC is a part of monitoring research in California, and to please let us know if bad things happen. He felt that is as far as RAPC can go and applying a penalty is beyond RAPC's control.

Chair Mitchell asked whether he would suggest sending the letter to the sites within California or to the sponsors.

Panel Member Gasper answered that the sponsor is the RAPC chain of command for communication with them and the sites are kind of out of the loop. He suggested RAPC needs to be friendly and say please and thank you. He felt their failure to inform RAPC is not an intentional cover-up and not done willfully. They just forget that RAPC is a part of the process, so it's an educational component. Panel Member Gasper said the other part is about privacy and conducting investigations. He reminded the Panel that RAPC decided not to have that level of access.

Chair Mitchell asked if it was the Agnes (Balla of UCOP) question about whether or not RAPC could. She thought RAPC never completely closed that door because Agnes Balla didn't come back to finish the discussion with RAPC. Since the new Administration, she has been very, very busy.

Panel Member Gasper reiterated that they seem to be related components. His question is, if it's reported to RAPC, what does RAPC do with the information. This is another part of what does RAPC do if it's not reported to RAPC, so it is kind of a general question of how does RAPC handle these. He felt that there needs to be some resolution on that.

Chair Mitchell said one of the things RAPC could do, as Panel Member Piomelli pointed out, is at least confirm with FDA that they know about this themselves, and that this wasn't an oversight. And, in the cases where it is not, RAPC could make sure that the FDA knows about it as well.

Panel Member Gasper said he would hope that the IRB and the Data Safety Monitoring Board would be informed, and there are others.

Panel Chair Mitchell said that when a sponsor reports an SAE, and it is reported late, they can request the sponsor demonstrate that it was reported properly to the FDA and IRB. She felt this as an easy ask and allows RAPC to know if there might be collusion or something more nefarious going on if they didn't do those things. And if they did, RAPC is done. She said it doesn't account for the possibility that the FDA has not had a chance to review something, and that is something that came up when the government was closed. Chair Mitchell concluded that RAPC might have to revisit this topic in the future.

Panel Member Heifets felt that RAPC meets often enough that if they are getting word that the FDA is not returning correspondence, RAPC has not closed any doors in what it is discussing to the future possibility of taking over FDA's regulatory responsibility.

Chair Mitchell responded that it was fair enough and for right now, RAPC would follow up. RAPC will follow up with a letter to the sponsor requesting that they supply RAPC with information demonstrating that they properly reported to FDA and IRB. She then asked for further comment and then a motion for that to become RAPC's SOP.

Panel Member April Powell-Willingham said that she wants to go on record to say she has some reservations about the plan because there are other considerations that perhaps should be considered, but she would not elaborate at the time.

Panel Chair asked for further Panel comment and then asked for public comment. Hearing none, she asked if anyone would want to move to create an SOP regarding this process, if it occurs again, for SAEs.

Panel Member Piomelli moved to create an SOP. Panel Member Heifets seconded the motion.

Chair Mitchell asked for any dissenters, and hearing none, said RAPC would move forward. She asked again for any public comment, and hearing none, announced that Panel Members would remove themselves from the public Zoom meeting to go into closed session.

Public Comment:

None

CLOSED SESSION

Panel members entered closed session pursuant to Government Code section 11126, subd. (c)(20), as amended by California AB 1103 (Ward) (2025)

OPEN SESSION

5. Adjournment

After completion of the closed session Panel members returned to open session.

Panel Members present: Boris Heifets, James Gasper, Jennifer Mitchell, Kelly Lee, Daniele Piomelli, Judy Aoyagi, April Powell-Willingham.

Panel members absent: None.

Quorum established.

The next Panel meeting was confirmed to be on Friday April 10, 2026, and the meeting was adjourned.