RESEARCH ADVISORY PANEL OF CALIFORNIA

PUBLIC MEETING MINUTES

August 15, 2025 at 1:00 pm (Pacific)

OPEN SESSION

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

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

Panel Members absent: None

A quorum was established.

Staff present: Tanveer Khan, Executive Officer

Panel Chair Jennifer Mitchell announced that the RAPC annual report was posted to the RAPC website at the end of June and was available for download.

2. Annual Nomination of the Panel Chair

Chair Mitchell opened the nomination for a vote for a new Panel Chair or for her to continue. She asked for motions for nominations.

Panel Member Boris Heifets moved to nominate Dr. Jennifer Mitchell to continue as Chair, and Panel Member James Gasper seconded that nomination. Chair Mitchell accepted the nomination.

Vote for Jennifer Mitchell as Panel Chair:
Boris Heifets - Yes
Cyrus Rangan - Yes
Daniele Piomelli - Yes
James Gasper - Yes
Jennifer Mitchell – accepted nomination
Kelly Lee - Yes
Martine D'Agostino - Yes

Public Comment:

None

3. Approval of Panel Meeting Minutes for April 18, 2025 and Amended Meeting Minutes for February 14, 2025.

Panel Chair Mitchell offered Panel Members a chance to take another look at the meeting minutes for April, and the amendments to the February meeting minutes in which the date was inadvertently noted as 2024 and some of the agenda items were out of order. She then entertained a motion to approve or for members to note any corrections. Panel Member Boris Heifets moved to approve the minutes to both of the meetings and Panel Member Kelly Lee seconded the motion.

Vote to approve Meeting Minutes:

Boris Heifets - Yes
Cyrus Rangan - Yes
Daniele Piomelli - Yes
James Gasper - Yes
Jennifer Mitchell – Yes
Kelly Lee - Yes
Martine D'Agostino – Yes

Chair Mitchell noted that there was a long list of approvals to get through in closed session, and to ensure the Panel retained quorum to complete those reviews, the Panel would move into closed session next and then come back to open session to discuss RAPC as an authorized entity and the genetic consent form. She requested comments from the Panel and then from the public.

Public Comment
Public participant Agnes Balla from University of California, Office of the President, asked about making comments on the two agenda items remaining and in general. Chair Mitchell reiterated that the Panel would move into closed session then come back to discuss the remaining agenda items. The public participant made arrangements to be notified once the Panel came back to the open session.

CLOSED SESSION

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

OPEN SESSION

Panel members reentered the open session and roll call was taken. Panel Members present: Jennifer Mitchell, Boris Heifets, Martine D'Agostino, James Gasper, Kelly Lee and Daniele Piomelli and PHO Designee Cyrus Rangan.

A quorum was established.

4. RAPC as an Authorized Entity

Chair Mitchell opened the discussion for the language regarding RAPC as an authorized entity in the consent form checklist, which was an item requested by public participant Agnes Balla from the University of California Office of the President. Chair Mitchell asked for public comment.

Public Comment:

Public participant Balla had questions about the informed consent checklist that RAPC has posted as a resource for researchers submitting proposals. She referenced section 15 of the RAPC informed consent checklist that says a statement be included in the consent form and the HIPAA form, advising potential research subjects that their records may be inspected by RAPC. She asked under what circumstances RAPC reviews PHI and what technical safeguards does it have in place to be able to receive it.

Chair Mitchell explained that any investigation that occurred was before her time, and she didn't know of a case where RAPC had ever gone in and looked specifically at PHI as much as it could potentially be contained within study records RAPC may receive. In the course of doing an investigation, she felt that the Panel wanted to make absolutely clear ahead of time on the HIPAA form that that could happen.

Public participant Balla asked again about any technical safeguards to protect the information that RAPC receives.

Chair Mitchell responded that it hadn't happened in the last few years, and that technical safeguards would have to be reconsidered if RAPC was beholden to conduct an investigation. Chair Mitchell explained that for confidential information, the DOJ has a secure platform for conveying information to others. She said that would probably be the context that would be

used if RAPC were ever to conduct a full investigation, but those were technical issues that have never come up before.

Public participant Balla asked where the right to audit comes from. Chair Mitchell said that it was in the original language and it was ascertained by the former Chair so it wouldn't be unclear to participants that it could happen. Public participant Balla said her statement was coming from the UC perspective because the California requirement says that a HIPAA authorization form has to be distinct from the research consent form.

Chair Mitchell said she believed the language was just trying to do due diligence in case part of the medical record was somehow imbedded in a study file, and so there wouldn't be a surprise to the participant.

Public participant Balla said that the way that HIPAA governs health information, once PHI is disclosed for research purposes, it's no longer HIPAA protected information. She said it becomes research data and is governed separately. She asked if the Panel could take out inclusion in the HIPAA authorization form and just keep a statement in the consent form.

Chair Mitchell asked for comments from the Panel members. Hearing none, Chair Mitchell said that she agreed that if something is taken out of the medical record and put in the research record, RAPC would not need HIPAA authorization to review it in the case of an audit and shouldn't need to go back to the original medical record. However, Chair Mitchell felt that participants may not understand that.

Public participant Balla replied that it is not PHI anymore and they would be talking about research records. Chair Mitchell said that she agrees with that, and she thought that it was there just to make sure the participant understood, but that legally speaking, it should not be necessary. Chair Mitchell asked Panel Member D'Agostino whether she sees any need for it to be included in the HIPAA form. Panel Member D'Agostino replied that she didn't feel prepared to opine on the topic without having done some research on it and she does not usually offer legal advice on the fly. Chair Mitchell asked whether it would be possible to revisit the discussion at the next Panel meeting, and if Member D'Agostino had comments, she could make them then. Hearing agreement, Chair Mitchell tabled the conversation on agenda item four until the next meeting.

5. Genetic Consent

Chair Mitchell noted that public participant Agnes Balla of University of California, Office of the President brought this topic to RAPC. Chair Mitchell said that the genetic consent guidance document was put on the RAPC website approximately four or five years ago, but that genetic

consent was part of the RAPC process for over 20 years so that people would be told that they need a genetic consent form. Chair Mitchell explained that former Chair Enid Camps had made a boilerplate of a possible consent form that people could start with because so many people had questions about what a genetic consent form would actually entail. Chair Mitchell then asked for public comment.

Public Comment

Public participant Balla said the gist of her question was what does a DNA consent form have to do with controlled substances and the use of that DNA consent form for the oversight over controlled substance research? She questioned the use of that form for the review of controlled substances, and her ask for the Panel was whether it could stop being used because she felt it confused information between it and the regular consent form that's already being used. She explained that the HIPAA authorization form is also being used and then separately for controlled substance research the DNA consent form has to be signed by participants as well. Public participant Balla said a lot of the information that's in the DNA consent form was already covered in the research main consent form and asked why the separate DNA consent form could not no longer be required.

Chair Mitchell requested input from Panel Member D'Agostino again, not to answer on the fly, but because the need for a genetic consent form was in keeping with California State law, and because the process was put in place many years ago.

Panel Member D'Agostino said she was asked specifically about SB41 because it was raised at a prior meeting, and whether SB41 applied to RAPC. Panel Member D'Agostino said she researched that and didn't think it did. She pointed to SB41 regulating direct to consumer genetic testing companies. She said that is how it was defined under the statute. Panel Member D'Agostino then read: "*Direct to consumer genetic testing company means an entity that does any of the following sells markets, interprets, or otherwise offers consumer initiated genetic testing products or services directly to consumers, analyzes genetic data obtained from a consumer, except to the extent that the analysis is performed by a person licensed in the healing arts for diagnosis or treatment of a medical condition, or collects, uses, maintains, or discloses genetic data collected or derived from a direct to consumer genetic testing process or service or is directly provided by a consumer*." Panel Member D'Agostino concluded that this was the answer, or, the question back would be whether any of the studies fell under any of those categories.

Public participant Balla wanted to refer back to a specific section at the very end of SB41. Panel Member D'Agostino pointed to an exception for research by universities and asked whether that

is what public participant Balla was going to refer to. Panel Member D'Agostiono thought that was for dissemination to a third party. Public participant Balla and Panel Member D'Agostino searched for wording from SB41 about what would qualify as direct to consumer genetic testing.

Chair Mitchell asked what would happen in cases where investigators tried to partner with companies such as 23andMe to obtain data for specific study-related activities.

Public participant Balla replied that if UC were the ones conducting the research, the exemption would apply, based on the way UC's lawyers have understood that requirement, although they understood that companies like 23andMe might have certain obligations that they need to uphold, and in that instance UC wouldn't prevent those companies from being able to uphold their requirements under the State law. She said the State law was not applicable to them, but that if those companies have language that they want UC to use because of their requirement to meet the law, UC would help them with that. However, Public participant Balla said she believed that information took place when they're collecting information and at that point consent should have already taken place, and the information that they were working with was already consented information. Public participant Balla said that from what she understood, that would not necessarily come into play for them unless they needed to do something to help their partner hold up their requirements.

Chair Mitchell referred to an item discussed at a previous meeting about using the terms genetics versus DNA and said RAPC could clean up that language. Chair Mitchell then asked public participant Balla whether the addition of a genetic consent form, in her opinion, was doing anything to deter study participants from entering research.

Public participant Balla said she knew that question was asked last time, and she thought so from her discussion with the IRB director, and she thought they had some concerns that the information in the DNA consent form overlapped with what is in the traditional consent form. She said sometimes when too much information is presented to the participants, it could become overwhelming and confusing. Public participant Balla asked what the benefit is of having the form because it may or may not be necessary, and she didn't know for sure if it deterred participation. She felt it could be overwhelming to be able to digest all the information. She asked what made the requirement applicable for controlled substances and what made controlled substances unique where this had to happen for that type of research, unlike other types of research conducted within the State.

Chair Mitchell referenced a past study on drug abuse and addiction in a particularly vulnerable population that was beholden to NIDA to take and bank a genetic sample, but that it wasn't

initially made clear to the participants the type of information they were providing and how it was being shared. Chair Mitchell was also unclear what NIDA does with that information and whether those individuals are then branded as drug addicted or drug-abusing. She felt RAPC was reassured that it had always required a separate genetic document to make certain individuals understood how their genetic data might be used.

Panel Member D'Agostino said she didn't know that RAPC necessarily had to have a checklist, but that it was a decision for the Panel as a whole whether to include the checklist or not. She didn't think there was any argument about RAPC's authority to require a checklist. Panel Member D'Agostino pointed to RAPC's mission to ensure the safety and protection of the public, so including the checklist was to further that mission and which is how it has been operating for many, many years. Panel Member D'Agostino requested clarification on public participant Balla's question and whether it was about RAPC's jurisdiction or authority, or whether, practically speaking, it made sense.

Public participant Balla explained that there were many types of research being done, but only a subset of research comes to RAPC, and that subset requires the form, but no other research, potentially doing very similar things except without the use of controlled substances, required it.

Panel Member Piomelli felt RAPC was requesting substance abuse investigators to go over yet another obstacle after going through many more obstacles than any other group of investigators because in the case of substances use, there are also DEA and other requirements. Panel Member Piomelli explained he didn't know about the law, and this was not his area of expertise, but his preference was for whatever made things easier. He felt that research subjects had a lot of paperwork to read, and that the major strength of the argument for him was the fact that RAPC was singling out substance use investigators by doing this. He said he would also be surprised if NIDA was the only NIH institute that required depositing DNA information in a general database; he didn't know personally for a fact that others did, but he would be surprised if NIDA was the only one.

Chair Mitchell replied that it was not. She thought it also included NIMH and NIAAA. She said she couldn't speak for others but thought that at some point there was a federal mandate that those data be stored in a repository.

Panel Member D'Agostino said she didn't find any requirements in law that RAPC had to have a checklist and said that if the Panel decided to keep it or get rid of it, it would be based on what the Panel decided was best practices.

Chair Mitchell asked public participant Balla whether it would be comfortable to her if requests for clarity on how genetic data would be used were in the main consent form.

Public participant Balla responded yes.

Chair Mitchell requested confirmation that they would still be part of the checklist for the main consent form; in other words, that there would be a separate section on genetics in the main consent form.

Public participant Balla confirmed that genetic consent would be in the main consent form.

Chair Mitchell summarized that in the standard ICF that every study uses there would be a genetics section like there is now at UCSF that says how genetic data will be used. She said this would be the new boilerplate. Chair Mitchell then asked the Panel Members whether they had any other comments.

Panel Member Heifets asked whether a study with a schedule I controlled substance would need to explicitly say whether or not it was collecting genetic samples in the consent, and whether RAPC needed to keep it in the checklist if it wasn't required by California law, and the IRB should be enforcing it.

Chair Mitchell responded that was what Panel Member D'Agostino confirmed. Panel member Heifets said if DNA was not being collected, then nothing should be said about DNA. Chair Mitchell agreed but said if the section was removed that says a separate DNA informed consent is required, the purpose of the DNA test should still be included in the ICF, and whether it was mandatory or optional.

Public participant Balla agreed to that.

Chair Mitchell entertained a motion from the Panel to vote on removing the requirement for a separate DNA consent form and moving those requirements into the standard informed consent form.

Panel Member Piomelli provided the motion and Panel Member Heifets seconded the motion. Chair Mitchell requested a vote for all those in favor of removing the requirement for a separate genetic consent form and using those bullets in the primary consent form.

<u>Vote to remove the requirement for a separate genetic consent form and include those bullets in the primary consent form</u>:

Boris Heifets - Yes
Cyrus Rangan - Yes

Daniele Piomelli - Yes
James Gasper - Yes
Jennifer Mitchell – Yes
Kelly Lee - Yes
Martine D'Agostino – Yes

4. RAPC as an Authorized Entity (cont'd)

Chair Jennifer Mitchell summarized that RAPC would table the discussion on RAPC as an authorized entity until Panel Member D'Agostino had more time to weigh in properly.

Public Comment:

Public participant Balla clarified that her request was just for RAPC as an authorized entity for the HIPAA form.

Panel Member D'Agostino asked for further clarification on whether the question was whether RAPC is an authorized entity under HIPAA to receive PHI.

Public participant Balla answered that the consent form checklist includes a statement that RAPC has to be listed in the research form and the HIPAA form advising potential research subjects that their records may be inspected by RAPC. She said the way that she knew it, on UC's form, it was set up so that they list those individuals who have an obligation to oversee the research and therefore might need to receive PHI. She questioned whether RAPC really needs to receive it separately from research data and requested its removal. She requested that RAPC only be included in the consent form and not included in the HIPAA form.

Chair Mitchell referenced a section in the UC consent form that included government entities, and asked public participant Balla whether she would take as much issue if it said "US and California government entities." She questioned whether if there was an investigation and a federal entity wanted to look at the PHI, wouldn't the state want to look at it as well. Chair Mitchell added that she didn't know whether the reviewer would be DOJ or DPH.

Public participant Balla responded that the University of California form was different from other institutions and that everyone had their own way of doing things, but that UC pushes back very hard against making any changes to their form or else they would get sponsors coming to them saying they can receive data and to be added. But what it currently would list are those on the research team described in the consent form, those at UC authorized to oversee the research and those required by law to review the quality and safety of the research,

including US government agencies, such as the FDA, OHRP and the research sponsor. She guessed in theory that could include RAPC, but she would rather not specifically list out RAPC as one of those entities.

Chair Jennifer Mitchell suggested a compromise to say 'US government and State agencies.'

Public participant Balla responded that she would need to think about that.

Panel Member D'Agostino pointed out that the form says "Government agencies and government agencies in other countries," but it didn't seem to say anything about State agencies.

Chair Mitchell agreed with Panel Member D'Agostino's statement and that it didn't include California if there was something that happened for safety and need for oversight.

Public participant Balla asked what agency reviews research or PHI.

Panel member D'Agostino noted that public participant Balla had two separate questions.

Public participant Balla thought the reason they write them out is because there are requirements that they have when conducting research. For investigatory purposes, certain agencies would need to have access to information, like the FDA. They are required to have access to that information, but she didn't know of other state agencies that were required to have or were mandated to have that info.

Panel member D'Agostino clarified out that public participant Balla had two questions. One question was about whether RAPC is one of those agencies and then the other question was how can they change the form. Public participant Balla agreed. Panel member D'Agostino said the first question was for Chair Mitchell and the rest of the Panel, and she didn't know whether RAPC needed access to PHI.

Chair Mitchell clarified that as she understood it, it hadn't come up for many, many years, so the question was for the Panel: How would it come up and if so, would RAPC need access? Chair Mitchell said she didn't know that RAPC would need it over another California Institutions, but she could imagine, especially in this day and age, if the Federal Government was looking for PHI for some reason, then the California government would also want the chance to do the same. She didn't know if it would be through RAPC.

Panel member Heifets asked whether it could be DOJ. Several Panel Members clarified that the question was whether the California DOJ could under a subpoena. Panel Member D'Agostino said that would be pursuant to the AG subpoena authority or a government code section for investigations.

Public participant Balla agreed that in that case they would be mandated to share. Chair Mitchell mentioned safety. Panel Member Heifets gave an example of a complaint coming up through the Medical Board of California and asked who would investigate the claim and how, and under what hypothetical the medical board would have a right to subpoena. He questioned how else it would even come up because of the illegality to administer a schedule I drug outside of a research study.

Panel Member D'Agostino replied that she didn't think this form would affect the subpoena authority of any other state agency that is separate, and whether the consent form says state agencies on it or not, they still had that subpoena authority, so that included DOJ and the medical boards. Many other state agencies have subpoena authority, investigative subpoena authority, but the question was really does RAPC need to access that information. She thought the form should refer to State agencies if RAPC thought it needed access to that information.

Chair Mitchell said if a research subject lodged a complaint with the State and there needed to be an investigation, her understanding was that RAPC would be beholden to conduct that investigation. Panel Member D'Agostino did not understand how that complaint would come up and whether it would be a complaint to RAPC or to the Department of Justice. Chair Mitchell replied that she assumed it would be a complaint to RAPC, but she didn't know, and asked Panel Member D'Agostino whether it would be easier on a legal level to have California Government Entities called out in the HIPAA form or should RAPC rely on a subpoena process if it came to that.

Panel Member D'Agostino didn't think there was anything in the form that could subrogate the supreme subpoena process because that would be a separate process, and it was a question of whether that was part of informed consent. She said that if looking only at the HIPAA form, the question was whether the patient's consent was needed to use their PHI under HIPAA, and the question was still, does RAPC need to access PHI, and the Panel didn't seem to have a firm answer, yes or no. She didn't know why, given it already said oversight by US Government Agencies, the UC form wouldn't include State Agencies as well.

Public participant Balla said that's the UC's form, but not everyone's form, and said they didn't want to promise that they are doing something that they are not doing. So, if no PHI was going to state agencies, why call them out. Panel Member D'Agostino said it didn't look like a promise to her and she requested to look at the information again.

Panel Chair Mitchell's view was that one doesn't know what they don't know, and the subject could come up in few years in a way that they haven't considered here. She felt this would just

assure that it could happen. Panel Member D'Agostino agreed and emphasized that the form says "may be shared."

Panel Chair Mitchell asked for any further comment from Panel members. Hearing none, she summarized that Panel Member D'Agostino would look into it some more, and the Panel would still table the topic and move on for now, if that was comfortable for everyone. Seeing agreement, she thanked everyone and concluded the discussion.

Next Meeting Date and Adjournment

Panel Chair Mitchell summarized that meeting dates are run by everybody many, many months ahead of time to ensure RAPC can post them to the website and get the meeting administrator involved because she has to administer the meeting, and then publicly post them with the Agenda. This is why, because of the Bagley-Keene issues, RAPC doesn't have the wiggle room to quickly reschedule a meeting, and they have to worry a lot about meeting quorum. She summarized the unanticipated events that led to RAPC not being able to meet quorum in June. She hoped that would never happen again and that an expedited review process could make meetings far less arduous than they were several years ago and RAPC would not have any more all-day meetings, but it would also require RAPC to continue to meet quorum. She asked the Panel for suggestions on how to better disseminate meeting dates, or for a better way to do it.

Panel members discussed potential alternatives to Friday afternoon to hold Panel meetings, and about the challenges to scheduling meetings a year in advance.

The Executive Officer reminded Panel Members they would be selecting Panel meeting dates for 2026 at the October Panel meeting and that although Panel meeting dates have always been subject to change, they are posted a year in advance to help researchers plan ahead.

Chair Mitchell explained the Panel had been trying to be thoughtful about how to arrange the Agenda to get the important work done before quorum is lost. She asked for Public comment. Hearing none, the next meeting date was announced as Friday, October 10, 2025, and Chair Mitchell adjourned the meeting.

Public Comment

None.