State of California—Health and Human Services Agency
Committee for the Protection of Human Subjects

CENTER FOR DATA INSIGHTS AND INNOVATION
CALIFORNIA HEALTH & HUMAN SERVICES AGENCY

GAVIN NEWSOM
Governor

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY (CalHHS)

Friday, June 7, 2024
8:30 a.m.

Zoom:
CPHS June 7, 2024, Full Committee Meeting

Meeting ID: 161 173 2606
Passcode: 793968

Location:
1215 O Street,
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Meeting ID: 160 413 3950

MINUTES

Members
Darci Delgado, PsyD. (Interim Chair)
Larry Dickey, MD, MPH, Vice Chair
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Catherine Hess, PhD
Carrie Kurtural, JD
Laura Lund, MA
Philip Palacio, EdD, MS
John Schaeuble, PhD, MS
Allen Azizian, PhD
Maria Ventura, PhD
Jonni Johnson, PhD

Remote Attendees
Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPH, MPH
Larry Dickey, MD, MPH

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska

Committee Members Present in Person:

Darci Delgado, PsyD.
Catherine Hess, PhD
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD
Maria Dinis, PhD, MSW
Carrie Kurtural, JD
Larry Dickey, MD, MPH
Allen Azizian, PhD

Committee Members Present Remotely:

Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPh, MPH
Maria Dinis, PhD, MSW

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Lucila Martinez
Karima Muhammad
Nicholas Zadrozna

CPHS Staff Present Remotely:

Sussan Atifeh

Center for Data Insights and Innovation Staff Present in Person:

John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

Also, Present (All via ZoomGov) Principal Investigators and Associate Investigators:

Jared Goldman, General Counsel, CalHHS
Maggie Schuster, Attorney, CalHHS
Ann Hamilton, University of Southern California
Denise Modjeski, University of Southern California
Anshu Shrestha, Public Health Institute's/ CRGC
Heather Derry- Vick, Hackensack Meridian Health
Ester M. John, Stanford University

A. Welcome and Chair Updates

a) Welcome

Dr. Delgado informed the committee members that since the April 2024 meeting was long, she would like the committee to consider a 6-month transition. The committee members voted on the two following options:

Option 1 – Continue to meet every other month, full day meetings, 8am-4pm or later.
Option 2 – Meet every month for the next 6-months, meetings will end around 12pm (lunch time).

Dr. Schaeuble sought clarification on whether the protocols would be reviewed during the regular monthly meeting cycle, along with additional meetings for other matters.

Dr. Delgado confirmed that the cadence for projects, submissions, and project reviews would remain unchanged, as many researchers rely on this schedule. The meeting agendas will alternate between project updates and policy discussions, with some flexibility allowed for expedited or special projects.

Dr. Dinis inquired about the time frame for conducting monthly meetings.

Dr. Delgado replied that the committee is scheduled to meet monthly for the rest of the year due to numerous one-time policy issues. The current discussion focuses on the Common Rule and the Information Practices Act (IPA), with subsequent meetings addressing time-sensitive policy matters. The monthly meetings are set to conclude at the year's end.

Dr. Delgado asked for each committee member's preference between option 1 and option 2. Every committee member was in favor of option 2, which involves meeting once a month. Ms. Kurtural questioned whether the policy would be adjusted due to the increased frequency of meetings. Dr. Dickey pointed out that the policy allows a member to miss one-third of the meetings and still retain membership. Ms. Kurtural concurred that this was sufficient, mentioning she might need to miss one meeting a year because of scheduling conflicts.

Dr. Delgado then invited public comments. With no comments forthcoming, Dr. Delgado called for a motion.

Motion: It was moved by Dr. Dickey and seconded by Dr. Hess to adopt meeting once per month for the next 6-months.

Approve: Dr. Dickey, Dr. Hess, Dr. Ruiz, Ms. Kurtural, Dr. Palacio, Dr. Schaeuble, Dr. Azizian, Dr. Johnson, Dr. Ventura
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Ms. Lund

Total= 9 In Favor- 9, Opposed- 0, Abstained-0

Dr. Dinis inquired about the upcoming monthly meeting initially set for Friday, July 5, 2024, which is the day following the July 4th holiday.

Dr. Delgado agreed that meeting on July 5th would not be ideal as it comes after a state holiday. Therefore, the meeting has been rescheduled to the subsequent Friday, July 12, 2024.

B. Presentation and Discussion of Legal Analysis of IPA and Common Rule

Dr. Delgado framed that the Information Practices Act (IPA) and Common Rule presentation was solely for discussion, not decision-making for today. When a project is presented to the Committee under the IPA, deciding whether to review it under the Common Rule and where the statutory guidelines apply has sparked extensive discussion. Both the board members and the public have shown interest. The relevant documents were distributed via email. A group of researchers submitted a letter to the California Health and Human Services Agency on May 6, 2024, regarding the researchers voicing their concerns. Hard copies of the letter were available as well.

Dr. Delgado informed the members that Jared Goldman and Maggie Schuster have examined the documents, assessed the issue, and invited them to will guide the committee and participating public through their analysis.

Jared Goldman, serving as General Counsel for CalHHS, introduced himself and his colleague, Maggie Schuster, an Attorney for CalHHS. Jared Goldman shared he would give a brief

presentation before initiating the discussion and was eager to receive feedback from the Committee for the Protection of Human Subjects committee members.

Jared Goldman began his presentation by stating the Common Rule only applies to research activities in which the institution or State is directly engaged in the research itself. That is one of the simpler aspects of the analysis. The subsequent question is whether the Common Rule can be applied on a discretionary basis to other decisions not mandated by it. The answer is yes. The Information Practices Act (IPA) provides a set of criteria that must be considered in every IPA analysis. This set of criteria is not exclusive, allowing for additional criteria to be included, provided they are not added without careful consideration.

Jared Goldman explained anytime we implement, interpret, or embellishing on a statute, we must do it through regulations in most instances. If CPHS wanted to create a rule or a policy to always apply the Common Rule or to apply the Common Rule in some instances, CPHS would probably need to pass regulation to avoid conflict with the Administrative Procedure Act and its prohibition against underground regulations.

Dr. Delgado asked for Jared Goldman to give more clarity on what regulations are. Jared Goldman clarified that regulations are similar to miniature statutes which are promulgated. The public must be notified, allowing them an opportunity to review this notice. The Office of Administrative Law (OAL) then reviews the draft regulations, which are promulgated upon adoption.

Once a regulation is finalized, it carries the weight of law, binding both us and the public. These are not typically for internal procedures but for matters affecting the rights of beneficiaries, the public, or individuals outside the State.

Diving deeper into the details, Jared Goldman shared that the Common Rule must be applied when research is funded by a federal agency, or when the research activity falls under the jurisdiction of a regulating federal agency, and the institution is actively engaged in the research, if the research involves human subjects, and the project is not exempt.
Jared Goldman notes during our last meeting, there was significant discussion about the impact of the Federal Wide Assurance (FWA). The FWA is CalHHS' voluntary commitment to adhere to the Common Rule, regardless of whether we receive federal funding, or the research is regulated by the Federal Government. The FWA is essentially our agreement to comply.

However, this does not mean that the Common Rule applies to all our reviews, as other rules of the Common Rule still apply, specifically the rule requiring the institution itself must be engaged in the research. This means any state research that CalHHS is involved in as a State will be reviewed under the Common Rule. It doesn't mean everything reviewed under IPA will come under Common Rule. Attorney Goldman inquired if there were any questions, either in-person or online, before proceeding. With no questions raised, Jared Goldman proceeded with his presentation.

Jared Goldman highlighted the discretionary application of the Common Rule. Under the IPA, we must approve as a committee any disclosures of personally identifiable information (PII) used for the purpose of research. There are criteria CPHS must apply to approve the release of the data.

Jared Goldman shared that there are two sets of criteria under Civil Code Section 1798.24 subdivision t. The first set, under Civil Code Section 1798.24 (t)(1), is criteria that CPHS always

applies to every disclosure. There's a second set of criteria under Civil Code Section 1798.24 (t)(3), which applies when CPHS reviews the disclosure of information from an agency database. Jared Goldman noted the language right before the enumeration of the criteria says, "shall include" and then lists the criteria to be applied.

Attorney Goldman shared that in cannons of statutory construction, there is a presumption of a non-exclusive "include," meaning that when a statute uses the word 'include' before a list, it is presumed that list is non-exclusive. Attorney Goldman emphasized that this is just a presumption and can be rebutted by other evidence in the statute or other issues. In their analysis, Attorneys Goldman and Schuster did not see anything that would indicate to the contrary that this was supposed to be a non-exclusive list.

In Civil Code Section 1798.24 (t)(3), before it enumerates all the criteria, it uses the language 'at a minimum'. Jared Goldman shared that he thinks that the language is clear and does not need presumption, so when it says, 'at a minimum', the statute means there's these criteria and CPHS can do more. This means CPHS can add to these criteria. However, Attorney Goldman shared that the Administrative Procedures Act governs how criteria can be added to the list. In addition, what criteria can be added are constrained by the purpose and intent of the IPA.

Attorney Goldman shared that at beginning of the IPA, there's a statement by the legislature about the goals and the rights that the IPA is supposed to confer. It is all focused-on information privacy, and security for the individuals whose information CPHS is trying to protect. Because everything under the IPA is aimed at those purposes, Attorney Goldman thinks that any additional criteria that CPHS might decide to add needs to be constrained by the purpose and intent of the IPA.

Dr. Delgado asked whether she understood correctly that the "at a minimum" language means that the list can be added to, but anything that could be added to it has to fall under the scope of the purpose of the IPA, which is for the purpose of information privacy and security. Jared Goldman confirmed that was correct.

Jared Goldman strongly recommended that CPHS add additional criteria through a regulation. Jared Goldman emphasizes that CPHS is not strictly required to do it through a regulation, but if CPHS members decide to apply additional criteria without there being a regulation, there is a material risk that CPHS would run into challenges, including the potential application of the additional criteria on a case-by-case basis in an arbitrary or discriminatory way or the potential of it being considered an underground regulation.

Attorney Goldman noted that while CPHS can apply additional criteria on an ad hoc, case by case basis that is within the constraints of the IPA based on particular facts presented in the research project – such as that the data is so sensitive, or another reason that it would need additional consideration of some other criteria - but Attorney Goldman did not recommend that approach.

Jared Goldman explained that any general rule of application that is interpreting or implementing the statute has to be done as a regulation. If CPHS were to just put it into the CPHS policies and procedures without a regulation it would be considered an underground regulation. Jared Goldman emphasized again that if CPHS decides to create a policy, he strongly recommends they do so through a regulation.

Dr. Dickey asked for clarification that if it is done on an ad hoc basis, the criteria still need to stay within the bounds of data, privacy, and security?

Jared Goldman stated that was correct.

Dr. Schaeuble mentioned that the policy manual seems to have implications for the rights of researchers. He is not clear on the distinctions between needing a regulation and the circumstances being discussed versus information that exists in some form about a whole variety of issues in the policy manual.

Jared Goldman mentioned he did not want to get into the specifics of the CPHS policies and procedures manual since he is not very familiar with it. Jared Goldman noted generally policies and procedures are to govern the internal operations of an organization. Generally, regulations govern the rights of the public or beneficiaries.

Dr. Schaeuble referenced, “that several years ago there was an occasion where they tried to describe situations that might lead to additional factors being considered. What we would have said then may not very well have covered situations we’ve encountered in the past year or so that turned out to be rather contentious. We have the benefit of hindsight now that might cover the situations we have encountered. But again, we won’t be likely to cover some situations we may encounter in the future. So how is this dealt with if you’re suggesting it needs to be organized into a regulation?”

Attorney Goldman advised, “this is a problem within the marrow and bones of our statutes and regulations throughout state government, and it is that we create rules. We apply them and we try to capture the most important things, we learn after we adopt statutes and regulations through experience. Then, we amend them to catch the situations that we’ve learned from. It’s imperfect, but it’s flexible. It’s not easy to change, like a policy that can be changed with a simple vote or criteria we can add on an ad hoc basis. It’s the way we operate as a government.”

Dr. Schaeuble asked for clarification for what would happen if a situation is encountered that was not specifically stated in a regulation and yet is very troublesome to the committee.

Attorney Goldman responded that a way to address this hypothetical situation would be to draft a regulation like the way the statute looks. For example, “CPHS will consider criteria that include, but are not limited to…” then CPHS could specify general criteria in the regulation. The regulations would clearly articulate ways CPHS would apply the criteria in a non-discriminatory and non-arbitrary way. But in an emergency, CPHS still might be able to apply an additional criterion. However, Jared Goldman noted that all those same risks would still apply by dropping in some new criteria on top of the regulations.

Dr. Dinis commented that the CPHS committee existed way before the IPA. Then the IPA was implemented at some point in time afterwards. Dr. Dinis mentions in her knowledge the intent of the IPA was to be on top of the committee’s role rather than something separate. The understanding now seems to be that the IPA is something separate. Dr. Dinis raised the issue that the federal regulations are that when there is personally identifiable data, this becomes a human subject if the Personally Identifiable Information (PII) is available to researchers. Dr. Dinis elaborates on that there are researchers taking the state databases and merging them with other databases that also have PII. The question Dr. Dinis was looking for clarification on is regarding data with PII that is not being consented by human subjects - should that data be

available to researchers? Dr. Dinis shared that in these cases, individuals don't consent due to having their information in a mandatory database such as the California Cancer Registry. Then, researchers combine it with, for example, a labor statistics database or another database which collects information that people never consented to. Participants often have no idea that their data is being merged with other data sets.

Dr. Dinis adds, "that if this is allowed under the so-called state regulations, then we have to amend the IPA. I don't see how this is a good idea. Eventually, in this day and age with artificial intelligence (AI) and everything, the State is going to get in big trouble. It's going to happen sooner or later. There will be a major disaster with one of these cases, because it is a lot of data going out there about people, people's lives, very important things, and someone is going to get very upset that their data is being used in the way that it is. That is a concern I have in terms of how we're doing it and possibly our interpretation. If the role of this committee, in which the IPA says it comes back to. They wanted this committee to approve, but you're saying we're not engaged, we only approve the data release. Then why can't the State agencies approve the data releases? Why does it have to come back to an Institutional Review Board (IRB)? To me, it makes no sense, because if it comes back to an IRB, then IRB rules are going to apply. Otherwise, the State agencies could just release their own data sets."

Jared Goldman replied, "I can't read the minds of the Legislature, but I think the reason why the IPA has this information and the decision to make releases come back to you is to have an objective body that is not a department, that has some distance from the decision and can do it in a more removed way and make the decision. I think you (the Committee) play an important role, even when you are not fulfilling the role as an IRB for the purpose of an IPA release."

Dr. Dickey noted that the Department of Social Services (DSS) gave out some data they shouldn't have given out, and it did not go through their internal board, and it was hacked at UC Berkeley. Then, DSS ended up paying $750,000 to notify all the people. This created raised the question of how to prevent this from happening again. To some degree, CPHS was a convenient solution, but CPHS doesn't necessarily have the data security expertise that the IPA implies. That's why CPHS has requested additional resources to help improve the data security part.

Ms. Kurtural added to Dr. Dinis' comments by providing a use case. Ms. Kurtural notes "that there have had a few cases over the past year, where one of them that I reviewed was concerning because it went through expedited review. To give more context, in the expedited review process, it doesn't go through a full board decision. A couple of the board members are assigned to look at it, review it, and ask questions if need be. If it looks good, everything is buttoned up, and it's approved. But, as Dr. Dinis' is concerned, we received data only review project, that is connected with other financial and education data. It gets concerning when you see the connection with not just what we provided, but the other financial and education data. This specific case was under discretion, so I kicked it to full board review, as we needed a conversation before approval to either limit the scope of the project or at least get justification as to what was going on. I feel it's within our discretion, when we get a data review project and feel it needs a full board review, that we can go ahead and do that. The more technical question is if this has to be put in regulations, or if it's more ad hoc to make that decision, or getting consent and going through the Common Rule application. The best middle ground is to move it to full board review to address the controversy of mixing data, which is better than nothing. Then, you get the opinions and idea flows of everyone. How are we going to protect the human subject? In that case, there was another IRB, engaged in the research, that approved the project. What are your thoughts on that?"

Jared Goldman asked for clarification on when reviewing a data only review, and it's human subjects research, in every instance, is there an IRB on the other side, that's dealing with the researcher?

Dr. Dickey provided clarification to Jared Goldman "that the federal rule is that if it is research, then it must have an IRB reviewing it, but it's the institutions that is receiving the data, it their IRB that will review the project. I think a lot of our committee members, including me, think that sometimes, the receiving institution doesn't have motivation to find problems with it. But that's the way the federal law is written."

Dr. Schaeuble asked two follow-up questions:
"One, would you comment on what differences, if any, between trying to have a case-by-case decision on additional criteria versus a more general application of additional criteria? I will state for the public record, I am not advocating, since we have researchers trying to infer things from or what is said at meetings. Would you comment on difference in approach between those two situations. A different question following up on what Dr. Dickey was just observing about our experience with what seems to be happening between researchers and institutions reviewing these kinds of projects. What would be the situation if the Committee wanted to request information in connection with these pre-existing data projects about what kind of consent if any was obtained when the data was originally acquired, before being put into an agency database. And, what review, if any, did the researchers' IRB consider with regard to consent issues, simply for the purpose of the Committee's longer-term education as to what is actually occurring, not for the purpose of intending to apply that information in the evaluation process for the research requests."

Jared Goldman provided a response by answering the second question first, noting, "My sense is there is nothing that would preclude you from asking for someone to submit information in their application if it's voluntary. That's the clear example. 'Please if you are willing, submit information about…'. No problem there. The harder question is, can you require as a condition of approval of the project, information that's not tied specifically to an existing criteria. This is a harder question, and I would want to think about it more before I answer."

Jared Goldman asked for Dr. Schaeuble to elaborate more on the first question.
Dr. Schaeuble elaborated: "I was not sure whether there were nuances or not, in your responses about what the committee should do, what's legally obligated to do in the situation of wanting to have the option to, on a case-by-case basis, apply some kind of additional criteria versus the Committee wanting to more generally applying additional criteria."

Jared Goldman replied: "I don't think the Committee, as a body should adopt an invisible approach to how you're going to apply additional criteria. There shouldn't be some implicit policy that you're applying. You could potentially end up sideways with the underground regulation. I think that any ad hoc application of an additional criterion really needs to be driven by the specific facts that are presented to you and the specific risks you're seeing in the particular project. The criteria needs to be narrowly tailored to apply to the facts as you see them in front of you. My recommendation as your lawyer is that you minimize that approach, just because the more you take that approach, the more you get into that territory I'm worried about, of people making claims that you are applying these criteria in arbitrary and discriminatory ways. That makes me nervous, my preference is that we ultimately engage in a rulemaking process, if this is the thing we ultimately need to do."

Dr. Dickey returned to Dr. Schaeuble's second question by noting CPHS could probably require researchers to submit a copy of their approval from their IRB because that is required in law. It would ensure that they have another IRB reviewing the protocol, but often the approval letter just says, 'exempt'.

Ms. Kurtural commented, "Another thought is that departments contract directly with Agency. For example, my department, Department of Developmental Services (DDS) utilizes CPHS as its IRB, or privacy board. There's a small amount of money that's exchanged between the departments and asks for us to review. Back to what Dr. Schaeuble pointed out, is the consumer on notice. It depends. If you're a HIPAA covered entity and you're the department of health care services (DHCS) or DDS, they are getting a privacy notice on the front end. When they sign up for services that says their data could be used for purposes, because we're HIPAA covered and required to do that under the law. But there are other departments like Department of Social Services (DSS), that might not have that notice being provided. If you're worried about some kind of notice being provided, there are other departments like the Department of Rehabilitation that might not have that. I don't know if they have a similar kind of privacy notice. But one of the things we could do is address it in the contract that there has to be a privacy notice."

Jared Goldman asks for more information about the contract.

Dr. Delgado noted that Ms. Kurtural is referring to the contract between the department and Agency.

Ms. Kurtural explained that there is a basic contract between all the departments and Agency consenting for this board to be the IRB or privacy board for HIPAA covered entities.

Dr. Delgado added to what Ms. Kurtural was saying that HIPAA covered entities have privacy notices. It would be good to explore the DSS privacy process.

Ms. Kurtural replied that it's possible the counties provide privacy notices when people sign up for social service benefits and are eligible. Dr. Delgado advised this was a good question and something for the Committee and Counsel to explore.

Dr. Dinis added that some projects request a HIPAA waiver or a waiver of informed consent. This creates difficulty because if CPHS is just doing an IPA review, as then it goes back to having to use Common Rule. She noted that the two cannot separated and that is where it becomes confusing.

Jared Goldman agreed with Dr. Dinis that CPHS cannot approve a HIPAA wavier as an IRB for an entity for which CalHHS is not engaged in the research. The HIPAA wavier is for the IRB that is overseeing the researchers, not for the organization that's overseeing the data-only disclosure under the IPA.

Dr. Dickey commented this would need to change in IRBManager because everybody who applies for data has the option of applying for HIPAA waiver, regardless of whether CPHS is actually serving as their IRB. Either that, or CPHS declares itself as the privacy board for the entire state of California government.

Dr. Dinis asked about the wavier of informed consent. Jared Goldman responded that he thinks the wavier of informed consent should come from the IRB of the institution that is overseeing the

researcher. Dr. Dinis asked how can an outside entity, like Berkeley, do a waiver of informed consent for the data from the State of California?

Jared Goldman replied that the researchers would obtain the wavier of informed consent from their institution, but it wouldn't bind us or compel us to disclose the information.

Dr. Hess asked Jared Goldman what to do in an instance where CPHS disagrees with another IRB's decision to waive informed consent when dealing with state data. She noted that some CPHS members don't think other IRBs are granting it with all the facts.

Jared Goldman replied to look at the criteria available under the IPA and make a determination if members feel the concerns which are able to be taken into consideration are met. There may be some crossover and authority can be asserted based on the criteria CPHS is able to take into consideration.

Dr. Delgado noted that it is also a department decision to disclose the data. Jared Goldman agreed, a department can just decide not to disclose the information.

Dr. Dinis added that the IPA does not deal with the issues of consent, just data and privacy issues. It's very outdated and doesn't include what's happening with data issues and computers, etc. When it was initially written, everything was done on paper with paper protocols. It doesn't even address the data online and issues with data being hacked.

Dr. Dickey mentioned "the Federal Government offers protection that the IRB should be reviewing databases as they're established and part of the review can be informed consent procedures so that the informed consent can be reviewed up front, but not reviewing every release. Even though the IRB is not engaged in the research, they are engaged in establishing the registry which is considered research. Part of establishing that registry is informed consent issues."

Dr. Delgado open the floor up for public comment.

Evan White from the California Policy Lab commented, "thank you, Darci. Thank you, Jared and Maggie, for your work on the memo. I appreciate your attention to the topic. I also want to thank the Committee for it's obvious and considered engagement with these topics, which are important to me as a researcher and to a lot of research that is done in this state. One point that bears repeating is that the IPAs review under subsection t is focused on data security. I don't think that the CPHS could adopt regulations that mimic the Common Rule. In this case, the Common Rule covers more topics than just data security. I heard some concerns from committee members about data linkage. I am curious to hear what Jared thinks about another piece of the IPA, which was a change made more recently, was the IPA was amendment recently to allow the Cradle-to-Career dataset. This is a data set that links together several state administrative datasets, including the higher education data, K-12 data, workforce data, and also in the future, data from Health and Human Services. I'll give Jared a chance to respond, but I'll say my view is that the adoption of the Cradle-to-Career dataset and its integration into the IPA shows that the legislature is eager to allow data linkage between different administrative datasets and has in fact done so in a pretty dramatic fashion recently. It may well be the folks on the Committee may have a different policy judgement about whether or not that should be the case. Policy judgements are entirely reasonable. But I don't think it allows this Committee to substitute their policy judgements for the legislatures. If the Committee does not like the IPA, then they can advocate to get the law changed. I don't think the Committee has the ability to

basically take their own opinions and place them into the IPA and make decisions on that basis. So, I hope that is something that is taken away from the memo which I thought was well done. And I'll say one more thing. Which is just from my experience and honestly, I've been submitting projects to this Committee for several years and I often hear from both the researchers side that the committee members think of themselves as the State IRB. In fact, this entity is not the State IRB, it is the CalHHS IRB. It has authority over CalHHS departments and the research in which they're engaged. I think it's a good reminder for the board that you're not empowered to rule over all state research, as frustrating as that might be there are other entities in place you may think less of those entities. That's perfectly fine, but I don't think you have the ability to then overrule them, just because you think that your opinion is better."

Dr. Delgado thanked Dr. White for his comment and advised during the public comment section to avoid have a back-and-forth conversation between public comment and Committee response. But Jared Goldman had a response to the one-pointed question Evan White had. Dr. Delgado reminded attendees that if they had specific questions they needed answered, they could email the board, herself, or Jared Goldman.

Jared Goldman thanked Evan White for his participation and contribution to the discussion, expressing his appreciation for the memo and recognized the time spent to submitting it, advising it was insightful to read.

Jared Goldman clarified on whether or not CPHS is the State's IRB: "I would clarify, we are the State of California's IRB, but we are not the entire States' IRB, if that's what Evan White was implying. I think that the authority to act as an IRB extends beyond CalHHS. I'm seeing a no head shake from Dr. Dickey so I will have to hit the books on that one."

Dr. Dickey advised that it's only the departments that are signed into our FWA, for which we act as an IRB. Dr. Delgado advised that other agencies do ask us to act as their IRB. Dr. Dickey advised we do act as an IRB out of the goodness of our heart. Jared Goldman thanked Dr. Dickey for the clarification and expressed appreciation for his expertise.

Jared Goldman continued the discussion on whether there could be an additional criteria added to an IPA review related to consent. Jared Goldman does not think the IPA is limited to information security only. When looking at the very beginning of the IPA, there's a statement by the Legislature on the rights conferred by the IPA. It's a statement of the value judgement that the legislature is making in the IPA, and it discusses both individuals' privacy and security. Jared Goldman suggested working together on any criteria CPHS might add, either through regulations or an ad hoc basis. He did not think the issues of consent are off the table as consent is an important part of privacy. It looms large in the HIPAA rule, as privacy rule consent is a very large issue there.

Dr. Dickey asked for clarification on how we would go about creating regulations.

Dr. Delgado advised that any piece of regulation that's passed across the State is a complicated process that involves both Agency as well as the Office of Administrative Law (OAL).

Dr. Delgado opened the floor back up for public comment.

Sidra Goldman-Muller, a professor of Public Health at University Merced provided a public comment, "Thank you for allowing me to comment. I appreciate the work you all are doing here today. I'm Sidra Goldman-Mellor. I am Professor of Public Health at the University of California,

Merced in the valley. I've worked with Dr. White at California Policy Lab for a while. He and CPL stores data that I've requested from you guys and gotten approval for on for several occasions. I just want to comment from a researchers' perspective as someone who has spent the last 10-years working with de-identified administrative data, including linked data from a variety of sources at the state. There is no world I want to downplay the importance of consent, privacy, and data security in any way as they obviously take precedence over everything. But there is a great deal of important research that can only be done by using large scale administrative linked data of the kind which you oversee. So, as you know having that individual level of consent is sort of a foreign concept for researchers that are using these kinds of de-identified data sets. Which would be completely prohibitive to these kinds of projects. I do research on suicidal behavior and drug overdose among pregnant and postpartum women in this state. This kind of research needs very large data because those outcomes are rare. I really need to work with the sort of entire datasets and it's just not possible to get informed consent. I've had concerns about this or worries that changing the regulations in this way on an across-the-board premise, could be prohibitive and shut down the work of researchers doing important work in the state. But thank you all for your careful attention to all these issues. I know that it is contentious and very complicated."

Dr. Delgado thanked Sidra Goldman-Muller for her comments and for the important research work that she does. Dr. Delgado echoed Sidra Goldman-Muller's acknowledgement that any suicide research requires huge data sets because of the low base rate, and she understands where she is coming from. Dr. Delgado appreciated Sidra Goldman-Muller's comments and expressed gratitude that she called in. In response to Evan White's letter that was cosigned by several researchers, Dr. Delgado commented "one thing that stood out to her was that the letter insinuated the Board was pushing for written informed consent for all administrative data sets, which to me was generalizing the topic and issue in a way that was not representative of the nuanced discussion that we're having. So, Sidra I am happy you are here and hearing first-hand, the very narrow scope that we're trying to operate in a way would be better reflective of the thoughts of the board members, than what was written in the letter."

Dr. Delgado opened it up to other public comments. No other public comments were made. Dr. Delgado advised that CPHS is a volunteer board and if you are interested in joining, we are always taking applications for research members to join the committee and contribute their expertise.

Dr. Delgado wanted to remind the board that no decisions are being made on this item today. The goal for today was met, which was to have Jared Goldman and Maggie Schuster provide their analysis and have the public have a chance to weigh in on this topic. The goal is to come back to this topic the next time we meet, and have a motion in place, should it be appropriate. The motion would be that CPHS continue to operate as is with no regulation change or, an option to pursue the regulations process with what Jared Goldman described today.

Dr. Johnson requested to get extra information on what regulations would actually look like.

Dr. Delgado advised they could provide a background on what regulations are and what the regulations process is.

Dr. Dickey advised there are other laws other than the IPA that have been written that specify the CPHS has to review and approve.

C. Follow-Up Presentation and Discussion on the Department of Health Care Access and

Information (HCAI)'s Health Care Payment Data (HPD)

Dr. Delgado advised agenda item C was scratched from the June meeting and will come back to this agenda item in the July 2024 meeting.

D. Review and Approval of Meeting Minutes

Dr. Delgado requested a review and approval of the meeting minutes from March 1st and April 5th, 2024.
Dr. Schaeuble brought up to the attention that the March 1, 2024, meeting minutes were not distributed for committee member review and thus, the committee would not be voting to approve those minutes today.

The April 5, 2024, meeting minutes, had edits that were received by Dr. Schaeuble and implemented in the final version of the meeting minutes.

Motion: It was moved by Dr. Dickey and seconded by Dr. Ventura to approve the April 5, 2024, meeting minutes.

Approve: Dr. Dickey, Dr. Ventura, Dr. Ruiz, Dr. Dinis, Dr. Hess, Ms. Lund, Dr. Palacio, Dr. Schaeuble, Dr. Azizian, Dr. Johnson
Oppose: None
Abstain: Ms. Kurtural
Absent: Dr. Bazzano, Ms. Lund

Total= 11 In Favor- 10, Opposed- 0, Abstained-1

E. Projects with Reported Adverse Events and/or Deviations

None.

F. New Projects – Full Committee Review Required

1. Project # 2024-094 (Hess)
   Title: Tracking Health and Responses to Living with Cancer (THRIVE Study)
   PI: Arnold Potosky, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:

Dr. Anshu Shrestha, a research scientist at the Cancer Registry of Greater California and the Co-Principal investigator for the protocol, Tracking Health, and responses to living with cancer (THRIVE study) explains the protocol. Conducting a longitudinal a survey study of individuals living with advance colorectal cancer. This study involves recruitment for up to 900 cancer survivors from 48 counties in California. There will be four surveys that will be sent out. First the baseline survey followed by three follow-up surveys, four months apart. If the participant agrees to participate, there will be a twelve-month follow up period.

The overall Principal Investigator (PI) of the study is Dr. Arnold Potosky from Georgetown University. The sample selection, recruitments, and data collection will happen within the registry. Initial contact of patients will be conducted through the mail. The package the

participants will receive in the mail will include an information sheet that has elements of informed consent, a cover letter introducing the team, information about the study, study ID, and return postage included with an envelope. The participants will receive additional information about California Cancer Registry. The cover letter will provide information about how to fill the survey out online. The return postage and survey provided will not have any identifiable information. This is to ensure that confidentiality is protected for all the individuals who choose to participate. Participants are informed in the information sheet they can choose to participate in part of the four surveys. As well as participants can choose to not answer any question that they do not feel comfortable with.

The participants will receive a $40 gift card for their time in the baseline survey, the researchers anticipate the baseline survey to be a longer survey. The follow up surveys are going to be conducted by monitoring, the participant will be provided a $15 gift card since this survey is shorter survey. At the end of baseline survey, participants will be asked if they would be interested in participating in another component of the study which involves use of their medical record regarding their cancer treatment. If participants agree the will receive a $15 gift card.

Dr. Hess asked for clarification that all the recruiting and data collection includes patient medical records, if they authorize them and are being undertaken by the Cancer Registry of the State of California and the Researchers at Georgetown are only receiving a de-identified analytical dataset. Dr. Anshu Shrestha confirmed that no identifiable information will leave the California Cancer Registry (CCR).

Dr. Hess noted the protocol states, the survey included is the draft survey and not the final survey. Dr. Anshu Shrestha clarified they are in the works of finalizing the survey in English and will submit an amendment for the Spanish version.

Dr. Hess clarified they can approve the draft survey, but nothing can be changed from the draft survey without an amendment. The researchers can test the draft survey but are required to come back to CPHS by submitting an amendment if any changes are made to the survey.

Dr. Hess clarified if this project will be requesting data from VSAC. Dr. Anshu Shrestha confirmed they will be utilizing CDPH/ VSAC data in the protocol and have already applied for it.

Dr. Hess noted she flagged the reading level of the information sheet and cover letter. Dr. Hess showed her gratitude to the researchers for making those changes prior to the board meeting. The researchers were able to get the reading level down to around a 10th grade level on the information sheet and the cover letter.

Dr. Ventura inquired clarification about the information sheet. In the information sheet, regarding the recruitment and consenting of participants completing the baseline survey. Are they any information for participants to ask clarifying question about the consent?

Dr. Anshu Shrestha noted they do provide contact information in information sheet if participants have any questions or concerns to contact them. If the research team does not receive any response for two to three weeks after the information is mailed to them. The researchers will call the participants and reach out to see if they want to participate in the survey, providing another opportunity to ask questions.

Dr. Ventura's asked for the subset of individuals who completed the baseline survey, did the project specify how many participants they plan on asking for access to their medical records. Dr. Ventura wanted to clarify if it's a small subset of individuals that could potentially be identifiable.

Dr. Anshu Shrestha responded that the goal is receive medical record access from up to 400 participants. Dr. Anshu Shrestha noted that they are not sure if we will be able to reach that many people, but plan to send out the request to the 900 participants of this study. This study will be focusing on the under 65-year age group so that they can obtain their additional treatment related information. That information is often unavailable for participants over the age of 65. The recruitment plan is to recruit individuals who are diagnosed with cancer between two to thirteen months.

Dr. Ventura's last question relating to the protection of small cell sizes. The California de-identification guidelines require cells under less than eleven. Dr. Ventura asked to have the number from the project be changed from five to eleven being consistent with the California de-identification guidelines.

Motion: It was moved by Dr. Hess and seconded by Dr. Schaeuble to grant the project a deferred approval for one year with minimal risk pending the following minor revisions, which require expedited review and approval.

1. **Change the small cell size to 11 per the DHCS guidelines.**
2. **Upload the most current version of the draft survey.**
3. **Point out that any subsequent follow up survey will need to come back to CPHS.**

Approve: Dr. Hess, Dr. Schaeuble, Dr. Dickey, Dr. Ruiz, Dr. Azizian, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Ms. Lund

Total= 9 In Favor- 9, Opposed- 0, Abstained-0

2. Project # 2024-095 (Schaeuble)
   Title: Northern California Breast Cancer Family Registry
   PI: Esther John, PhD
   Board Decision: Approved Pending Conditions - Designee Review

Discussion:
The Breast Cancer Family Registry (BCFR) study is a Multi-Institution Study which was established by the National Cancer Institute (NCI) in 1995 at 6 sites in the U.S., Canada, and Australia. This request is for the Northern California Breast Cancer Family Registry, which is one of 6 international sites that are participating in this study. Starting in 1996, the BCFR has enrolled and followed over 15,000 families affected with breast cancer, including individuals diagnosed with breast cancer, and relatives and population controls never diagnosed with breast cancer. With the extended funding from the National Cancer Institute (NCI), Over the next 4 years, the six BCFR sites will recruit 950 women diagnosed with breast cancer under age 45 years and 950 first- or second-degree relatives who have never been diagnosed with breast cancer; 200 families will be recruited in the San Francisco Bay Area by the Northern California BCFR site at Stanford University.
The study has two parts. Part one involves recruiting 200 young women with breast cancer to collect baseline data via specimens, and additional data through future follow-ups. The second part involves data sharing as required by the National Institutes of Health (NIH). These datasets include data collected from the women through questionnaires and data from the Greater Bay Area Cancer Registry (GBACR).

For part one, researchers plan to request case listings from the GBACR to invite young women with breast cancer to join the study. They submitted related documents including invitation letters, a screening questionnaire, the consent form, and baseline epidemiology and family history questionnaires. Researchers extensively edited the application based on comments from Dr. Schaeuble.

Reducing the reading level of the consent form has been challenging because researchers are required by the Stanford University IRB to include some paragraphs into the consent form verbatim. Additionally, concepts related to data sharing from the BCFR consent form template must be included. Researchers are working hard to decrease the reading level of the sections that can be modified.

Regarding part two, data sharing, the Breast Cancer Family Registry (BCFR) has been funded by the National Cancer Institute (NCI) since 1995, always including funding for a central database. The central database maintains all coded data collected at the six study sites, which are assembled and cleaned for joint statistical analysis and collaborative research.
Researchers were advised to expand the research team to include all Co-Principal Investigators (Co-PIs) from the other family registry sites to share coded California Cancer Registry (CCR) data and vital status variables with the central database.
Each Co-PI at each site submitted the CCR appendix 3 confidentiality agreement for disclosure of CCR data and the Information Privacy and Security Requirements (IPSR) agreement with institutional signatures. Any researchers at the six family registry sites who will analyze select coded CCR and vital status variables will be asked to sign the CCR Appendix 2 form. The research team will also collect appendix 3, the IPSR agreement, and appendix 2 forms from investigators external to the Breast Cancer Family Registry who wish to analyze the coded data.

Per National Institutes of Health (NIH) requirements, researchers must share data with an NIH database such as the database of Genotypes and Phenotypes (dbGaP), which the BFCR has selected for data submission. This data sharing requirement will also apply to new families.
Dr. Schaeuble acknowledged the challenges with the reading level of the consent form, noting it is currently at a 14th grade level, including the summary which is at a 13th grade level. He appreciated the researchers' efforts to lower the reading level where possible. Dr. Schaeuble mentioned that some mandated paragraphs in the consent form from other IRBs contain considerable redundancy. He suggested that the research team look for ways to reduce this redundancy while also working to lower the reading level.
Regarding the interviewer version of the screening questionnaire, Dr. Schaeuble found it logical that respondents who clearly do not meet eligibility criteria are directed to a section at the end of the form stating their ineligibility. However, he noted that the self-administered version lacks this approach, allowing respondents to indicate they are ineligible early on, yet still directing them to the end of the questionnaire where it says, “Our study staff will review your responses to determine your eligibility.” Dr. Schaeuble recommended that ineligible respondents should receive a message saying, “Based on your responses, it appears you're not eligible for the study. Please mail back this questionnaire so we can confirm your ineligibility in our records, and we won’t contact you again.”
Dr. John, the Principal Investigator (PI), mentioned that they would review and edit the questionnaires to address Dr. Schaeuble’s comments.
Dr. Schaeuble explained that the project is a complex study involving approximately 400 new female participants. Information about their recruitment and participation has been uploaded in the application. The study also includes data from women who participated in the past, going back several decades, though it is not possible to reach out to them directly. The application

includes a request for a waiver of consent for the ongoing and future sharing of data. Additionally, data may be collected and used from Stanford, where it can be accessed by researchers there or by others who apply. There is also a consortium of six sites contributing to a central database, which researchers can apply to access. Dr. Schaeuble then invited questions from the committee members.
Dr. Hess asked for clarity about the section in the consent form that refers to contacting participants when potentially clinically useful results are found in their biospecimen samples. She wanted to ensure participants receive enough information and support, and inquired about how the contact process works and what researchers offer when reaching out to subjects.
Dr. John explained that the language was coined by the physicians in the breast cancer family registry. They frequently find genetic alterations without clear links to breast cancer risk. Researchers cannot send the actual results to participants due to the possibility of sample and laboratory errors. Instead, they send a letter informing participants that potentially clinically useful information was found. They recommend discussing this with their healthcare provider and provide a brochure with contact information for multiple genetic testing centers, including the Genetics clinic at Stanford University. Several women who received this notification contacted the Stanford genetics clinic and underwent evaluations, which typically involved providing another blood or saliva sample for testing. Genetic counseling is also offered before clinical testing to ensure participants understand the implications for themselves and their family members. Additionally, participants can opt out of being contacted with clinically useful results.
Dr. Hess recommended adding a definition in the consent form to clarify what is meant by "clinically useful results."
Dr. Dickey inquired if the database is monitored for new clinically relevant genetic findings and if patients are notified accordingly. Dr. John confirmed that the genetic data from collaborative research is centralized and that they can identify and report new clinically useful genetic alterations. She emphasized that their team includes informed oncologists and doctors who are involved in national committees for clinical testing guidelines, ensuring they stay updated on the latest clinically relevant findings. Additionally, the team has multiple members who can provide clinical perspectives to researchers who are not clinicians.
Ms. Kurtural asked for clarification on the protection against small cell data by using statistical aggregates in publications and the methodology for de-identification.
Dr. John explained that their extensive dataset, which includes over 15,000 families and 40,000 participants, ensures that they do not encounter issues with small sample sizes. Participants are assigned a 10-digit study ID number upon enrollment, and no personal health identifiers (PHI) are disclosed. Only select staff have access to the protected database at Stanford University. Data shared with the central database or collaborators are further de-identified with new IDs, preventing linkage across datasets.
Ms. Kurtural requested assurance that counts under 11 will be masked in publications.
Dr. John suggested discussing this with the central database to include this condition in the data use agreements between the central database at Columbia University and

Motion: It was moved by Dr. Schaeuble and seconded by Ms. Kurtural to grant the project a deferred approval for one year, classifying it as minimal risk, pending the following specified revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Schaeuble.

1. Work on reducing the reading level and redundancy in the consent forms and resubmit those revisions.
2. Change the paper version of the screening questionnaire to handle the ineligible participants in a way similar to the online version.

3. Consider alternative words for the phrase "clinically useful" when asking participants about contacting them with genetic information.
4. Consult with the central database about including a requirement in data use agreements that cell sizes smaller than 11 will not be reported.
5. Complete making other changes noted by reviewer's comments that you've already started to address.

Approve: Dr. Schaeuble, Ms. Kurtural, Dr. Hess, Dr. Dickey, Dr. Ruiz, Dr. Azizian, Dr. Johnson, Dr. Palacio, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Ms. Lund

Total= 9 In Favor- 9, Opposed- 0, Abstained-0

G. Full Board Continuing Review

None.

H. Amendments – Full Committee Review Required

1. Project # 2023-123 (Dickey)
   Title: Risk Stratified Survivorship Care Pathways for Early-Onset Colorectal Cancer (the Survive-CRC Study)
   PI: Ann Hamilton, PhD
   Board Decision: Approved

Discussion:

Dr. Hamilton, the subcontract Principal Investigator is explaining this protocol has two aims. The first aim did not involve any patient contact and involved the review of path reports. This aim is primarily focused on younger patients (patients under the age of 50) with colorectal cancer. The review of path reports was used to identify instance of metastatic disease from a population-based perspective.

The amendment submitted for the protocol is for the second aim which does involve patient contact. Aim two will have a survey sample of roughly a thousand cases from the Los Angeles County who were diagnosed under the age of 50, between 2019 and 2023. The primary protocol is that they will be sent a survey in the mail to fill out if they choose to, $20 dollars up front with and information sheet which has the elements of the informed consent, a cover letter, and paid postage to return the survey. The survey can also be done online. The survey primary includes information about the treatment that these patients (age younger than 50) with colorectal cancer cases have received. The information consists of how they have been screened for the recurrence they have had, how their medical care has been coordinated, side effects from the treatment, how it is affecting them and questions regarding if they have or have not had genetic testing.

Dr. Dickey reviewed the protocol in advance to the meeting and had questions regarding how they were handling missing data, brought to light some inconsistencies in the information sheet and survey. The patients can skip any question they do not want to answer and will just leave

that question blank. Dr. Hamilton noted they have removed the instructions to write skip and go to the next question to leaving that section blank. This doesn't apply to the online survey since there are not restrictions on going to the next question and can skip any question they do not want to answer. In some cases, for the paper surveys, if there is a whole page left blank, we assume that the pages stuck together. In the past for that situation, we have reached out to see participant to see if they would be willing to answer the questions and have the participant answer those question either on the phone or mail the blank pages back to the participant in an envelope and ask them to complete them if they wish.

Dr. Dickey briefly noted to the committee members that the survey did not have the language out at the start, that the participant doesn't have to answer any questions. Dr. Hamilton has amended the survey to the wording in the information sheet. Dr. Dickey also addressed a question relating to the call backs. Dr. Dickey suggested that for questions that were skipped that have to do with sensitive information such as income, sexual orientation, and gender identity questions the researchers will not call on those questions if they were skipped in the survey. Dr. Dickey requested a call back script and Dr. Hamilton provided the callback script and it has been shared with the other committee members.

Dr. Delgado expressed gratitude to Dr. Hamilton on the communication with Dr. Dickey and the willingness to walk back the callbacks specific for the Sexual Orientation and Gender Identity (SOGI) data.

Motion: It was moved by Dr. Dickey and seconded by Dr. Ruiz to approve the amendment as submitted which includes the call back script.

Approve: Dr. Dickey, Dr. Ruiz, Dr. Azizian, Dr. Hess, Dr. Johnson, Ms. Kurtural, Dr. Palacio, Dr. Schaeuble, Dr. Ventura.
Oppose: None.
Abstain: None.
Absent: Dr. Bazzano, Dr. Dinis, Ms. Lund

Total= 9 In Favor- 9, Opposed- 0, Abstained-0

I. Second Review Calendar

None.

J. New Projects – Expedited Review Requested

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (22)

K. Projects Requiring Continuing Review- Administrative Action Taken

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (34)

K1. Projects Requiring Continuing Review

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (209)

L. Amendments – Projects with Revisions Approves through Expedited Review

Some projects listed may have been approved by expedited review prior to this meeting and were not reviewed by the full committee.
Total Project Count (31)

M. Projects with Request for CPHS to Rely on Another IRB

None.

N. Exemption/Not Research Approvals

Total Project Count (32)

O. Final Reports

Total Project Count (13)

P. Public Comments

None.

Q. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, July 12, 2024.

R. Adjournment

This meeting was adjourned at 11:52 AM on June 7, 2024.