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, August 2, 2024
8:30 a.m.

Zoom:
CPHS August 2, 2024, Full Committee Meeting

Meeting ID:160 144 2415
Passcode: 345196

Location:
1215 O Street,
Allenby Building,
2nd Floor,
Meeting Room 212,
Sacramento, CA 95814

Phone:
+1 669 254 5252 US (San Jose)
+1 669 216 1590 US (San Jose)
+1 646 828 7666 US (New York)

Meeting ID:160 144 2415

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
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Laura Lund, MA

Alternate Member
Millard Murphy, JD
Lois Lowe, PhD

CDII
John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director

CPHS Administrator
Agnieszka Rykaczewska, PhD.

Committee Members Present in Person:

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

Committee Members Present Remotely:

Philip Palacio, EdD, MS
Juan Ruiz, MD, DrPH, MPH
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Laura Lund, MA

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Center for Data Insights and Innovation Staff Present in Person:

John Ohanian, Director
Agnieszka Rykaczewska, Deputy Director
Maggie Schuster, Attorney for CalHHS

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

Loretta Erhunmwunsee, City of Hope (COH)
Aamna Akhtar, City of Hope (COH)
Danielle Shores, City of Hope (COH)
Justin Harty, Arizona State University
Wendy Cozen, University of California, Irvine (UCI)
Mallory Bernstein, University of California, Irvine (UCI)

Members of the Public Present in the Meeting

Satish Kumar

A. Welcome

a) Chair Updates

Dr. Delgado, serving as interim Chair, reminded the group that the Chair position is open for others to serve. According to CPHS policies and procedures, the Chair must be a current employee of the California Health and Human Services Agency (CalHHS) or one of its departments (such as the Department of Public Health or State Hospitals) and must have served on the Committee for the Protection of Human Subjects (CPHS) for at least two years. The Vice Chair must have been a CPHS member for at least one year; however, current employment with CalHHS is not required.

Dr. Delgado expressed her intention to discuss the Chair role in January 2025, aiming to transition to a new permanent Chair. She also emphasized the importance of reviewing the document sent by CalHHS General Counsel, Attorneys Jared Goldman and Maggie Schuster, which includes a description of the Bagley-Keene Act. She stressed the need for members to understand the Act, particularly the complexities of serial communication, and urged them to revisit the document's relevant sections.

Ms. Lund inquired about the process for selecting a Chair and Vice Chair, noting that the qualifications were clear, but the selection process was not.

Dr. Delgado explained that the Chair is nominated by the Center for Data Insights and Innovation (CDII)'s Director, John Ohanian, voted on by the CPHS Board, and then approved by the Secretary, involving three steps. For the Vice Chair, the selection does not go through a nomination process with the Director; instead, the Vice Chair is chosen by the CPHS Chair and then approved by the Secretary. She acknowledged that the policies and procedures are more detailed regarding the Chair's selection, service, tenure, and duties compared to those of the Vice Chair.

Dr. Dickey added that CPHS Vice Chairs and members who are CalHHS employees will have 10% of their work duties designated for CPHS activities, while the CPHS Chair will have 20% designated for such activities.

Dr. Delgado requested the administrative staff to review the current members' lengths of service to determine eligibility for the CPHS Chair position, without singling out any individual.

B. Administrator Updates

a) Orientation to draft regulations for proposed CPHS fees

Dr. Rykaczewska, CPHS Administrator, presented the committee with proposed draft regulations concerning CPHS charging fees. The statutory authority comes from the California Health and Safety Code. Specifically, Division 109, Section 130207(f) of the code states, "The center may collect fee-for-service payments from a non-state entity for services provided to the non-state entity by the State Committee for the Protection of Human Subjects."

This issue has been longstanding since CPHS offers services to non-state entities, such as study reviews. The statute grants CPHS the authority to charge for these services, similar to other Institutional Review Boards (IRBs). However, the statute does not specify the fees or their structure.
Dr. Delgado reminded the committee about the Interagency agreements between CalHHS departments and CPHS. Departments within CalHHS pay an annual fee to CPHS to cover administrative costs, staff time, and resources, which is based on the volume of applications reviewed by CPHS for those departments. Introducing fees for non-state entities will impact external researchers who are not affiliated with CalHHS departments but wish to use CPHS IRB for their studies, along with the associated services. These fees would be waived for any state department.

Dr. Rykaczewska referred to the previous committee meeting where Attorney Goldman explained the regulatory process to the members. She noted that CPHS enacts regulations to either interpret statutes or to provide more specificity. Since the statute does not set the fee schedule or delve into such specifics, CPHS must enact regulations to establish these fees, including when and whom to charge. These particulars are determined through the regulatory process. Currently, CPHS is engaged in the initial stage of this process, known as Preliminary Rulemaking Activities, during which it conducts research, analysis, and drafts potential options before publishing notices of these proposed actions.

Some of the Preliminary Rulemaking Activities CPHS has done include initial market research, reviewing what other IRBs are charging, and have received Preliminary feedback from the chairs. The feedback from the CPHS full committee is the step of the Preliminary Rulemaking Activities CPHS is currently at for the proposed regulations for CPHS to charge fees. Dr. Rykaczewska emphasized refinements will be made based on the feedback from the committee and CPHS will not move forward to the next stop of the regulations process until the post regulations have been endorsed by the committee.

The market research that was conducted focused two things:

- The categorical structure of the types of things the IRB’s charge for.
- The fee amounts, the total charge for the types of reviews.

There was also a goal to pull information from public, private, California-based, and non-California based IRB’s.

Review types were divided as follows with the average fee across the ten listed IRB's:

Proposed Fees:
Initial Submission, Full Board Review - $3,500.00
Initial Submission, Expedited Review** - $2,100.00
Initial Submission, Not Research/Exempt Review - $500.00
Continuing Review, Full Board - $1,200.00
Continuing Review, Expedited Review** - $1,000.00
Amendment, Full Board Review - $1,400.00
Amendment, Major Change Expedited Review - $1,200.00
Amendment, Minor Change Expedited Review - $0.00
Closure Report - $0.00
Adverse Event - $0.00

The most expensive and most intensive application would be the initial review of a study that requires a full board review. Continuing reviews requiring a full board review tend to be rare. Sometimes, a study initially submitted for expedited review may be determined to be for full board review. CPHS would charge for the expedited review, then charge for the difference once the study is up for Full Board Review, so the requester is not double charged.

Dr. Delgado asked about the proposed fees being the average of the ten IRB's researched. Dr. Rykaczewska advised the variation was minimal.

Based on the proposed fees, the following revenue would be generated for CPHS as a result based on the number of research requests in 2023, and the Power Point read:

Projected Revenue by Review Type Based on Proposed Fee Schedule and Number of Research Requests in 2023:

Full Board Reviews – 20 ($3,500.00) = $70.000.00
Expedited Reviews – 103 ($2,100.00) = $216,300.00
Exempt Review – 19 ($500.00) = $9,500.00
Continuing Review Applications – 746 ($1,000.00) = $746,000.00
Full-Board Amendments – 2 ($1,400.00) = $2,800.00
Amendments, Major Change – 41 ($1,200.00) = $49,200.00

2023 TOTALS

- 931 submissions from non-state entities
- $1,093,800.00 in generated revenue

Dr. Rykaczewska noted the current IRB Manager System does not differentiate between state and non-state entities, so the dollar amount is likely an overestimate since state entities are not subject to fees.
Dr. Rykaczewska also conducted a workload analysis to account for the costs associated with the processing fees. The analysis included financial tracking staff who will generate invoices, third-party billing company fees, etc. The estimated cost is $600,000.00, based on the number of applications. A little less than $500,000.00 would remain for CPHS.

Considerations included additional resources (staff, third-party billing company fees, etc.) needed to process fees.

Projected Revenue	$1,093,800.00
Projected Costs	$600,000.00
Remaining Funds	$493,800.00

The proposed regulations outline that only non-state entities will be charged fees for projects that meet CPHS review criteria. If pursued and approved, these regulations are expected to take effect on January 1, 2026.
Dr. Rykaczewska finalized this portion of the presentation with key points, reinforcing this would be for non-state entities which still meets the criteria for CPHS review.

The proposed regulations include the following provisions:

- Escalation: If an expedited review is escalated to a full board review, the applicant must pay the fee difference.
- Continuing Reviews: Projects that expire due to committee inaction are exempt from additional fees.
- Amendments: Substantial changes to a project will incur additional fees.
- Payment: Fees must be paid before the committee issues a decision.
- Fee Adjustments: The committee may adjust fees once every three years by a vote, with increases capped at 10% or $500, whichever is lower.

Revenue can only be used for the administration, management, and support of the committee, including operational costs, expert consultation, and IRB platform improvement.
Initial feedback includes a fee waiver for graduate students and grandfathering in approved research on the fee structure.

Will the fee waiver apply to public universities? The legal team will need to provide feedback. Dr. Delgado mentioned how CPHS works with the California Department of Corrections and Rehabilitation and is recommending an interagency agreement as CPHS continues to act as their IRB of record for Common Rule projects, but the public universities may not be in the same situation. The discussion about fee waivers continued:

Dr. Hess mentioned, when there is a research collaboration between two or more universities, CPHS can ask researchers to clarify which university is home to the PI and which university is administering the grant funds. Especially, copies of budgets are already attached to the applications. It would be more administrative work on CPHS's end.

Ms. Lund suggested refining the fee waiver policy for graduate students, noting that while the concept is sound in theory, its practical application may differ. She indicated that research conducted for dissertation thesis would justify a fee waiver. However, she expressed uncertainty about extending waivers to all graduate student research, especially since such projects can be more time-consuming to review than those submitted by more experienced researchers.

Dr. Schaeuble noted instances where graduate students submitted applications supported by faculty research and funding, suggesting such cases may not align with limited financial resources. Dr. Rykaczewska proposed implementing fee waivers based on committee approval, requiring graduate students to justify financial hardship.

Dr. Dickey inquired about its financial impact, and Dr. Rykaczewska explained that the initial years would see reduced revenue due to reliance on continuing reviews.

Dr. Schaeuble questioned the feasibility of indefinite grandfathering, noting that some projects could extend for decades, raising concerns about long-term applicability and recommended grandfathering of already approved projects for a limited period.

John Ohanian, CDII Director, questioned whether the fees would dissuade researchers and the level of impact, CPHS's ability to minimize incomplete research applications and/or understand why that happens, and if it would help for CPHS to streamline operational costs so the expenses are less than $600,000.00.

Dr. Rykaczewska acknowledged that the committee had not yet examined the duration for which Institutional Review Boards (IRBs) have been imposing fees. She proposed reaching out to other IRBs to gather insights on their experiences, particularly regarding any decline in application numbers following the introduction of fees. She emphasized that the goal is not to discourage researchers.

Dr. Hess inquired about the definition of a major change within an amendment, noting that amendments can vary widely. She advocated for a clear definition to help researchers understand the associated costs and to ensure transparency.

Dr. Delgado suggested that as the committee progresses through the regulatory process, certain aspects, such as grandfathering provisions, might be beyond the committee's control. She indicated that the Office of Administrative Law could impose specific requirements, limiting the committee's discretion in some areas.

Dr. Rykaczewska expressed her intention to incorporate the feedback received and to return in the coming months with updates. She emphasized that this was the first of several discussions on the topic and encouraged members to reflect and provide additional input via email.

Dr. Bazzano raised concerns about the proposed 60% revenue recovery fee, noting that, in her experience, such fees typically range between 6% and 25%. She questioned whether this percentage accounted for all activities involved in protocol evaluation or solely the revenue collection process. She also highlighted potential issues if revenue projections were overestimated, suggesting that a significant reduction in anticipated revenue could undermine the financial viability of the proposal. Additionally, she mentioned the potential conflict of interest when regulatory bodies are funded by those they oversee.

Addressing these concerns, Dr. Rykaczewska explained that the 60% figure was based on the number of studies processed in 2023 and that costs are directly related to the volume of fees handled. She clarified that the estimate focused on processing fees. She acknowledged the need for staff with financial expertise and potential collaboration with colleagues in California Department of Social Services (CDSS) for fund processing, and any kind of third-party platforms for payment processing, noting that while CPHS could streamline operations, it might limit payment options for researchers. She committed to providing more detailed information on the cost estimation in future presentations.

Dr. Dickey inquired about the integration of the fee structure within IRBManager. Dr. Rykaczewska responded that preliminary assessments regarding incorporating the fee system into IRBManager had been conducted. She emphasized the importance of establishing the fee structure before fully integrating it into IRBManager. She suggested that IRBManager could potentially provide upfront fee estimates based on the type of research, allowing researchers to be informed about potential costs early in the process.

No public comment at this time.

Dr. Delgado acknowledged the presence of public attendees and noted that there would be opportunities for public comment. She reminded participants that the state regulations process includes mandated public comment periods lasting 30 to 45 days and encouraged ongoing communication with administrative staff or committee leadership regarding the topic.

b) Scheduling September meeting

Regarding the scheduling of the September meeting, Dr. Rykaczewska asked about any need for moving the meeting from September 6th to September 13th, 2024, to avoid proximity to Labor Day. Two committee members preferred September 13th, while others had no preference between the two dates.

There was no public comment on this matter.

Motion:

It was moved by Ms. Kurtural and seconded by Dr. Ventura to reschedule the CPHS September 6th meeting to September 13th, 2024.
Approve: Ms. Kurtural, Dr. Ventura, Dr. Ruiz, Dr. Dickey, Dr. Bazzano, Dr. Dinis, Dr. Hess, Ms. Lund, Dr. Palacio, Dr. Schaeuble, Dr. Johnson
Oppose: None.
Abstain: None.
Absent: Dr. Azizian.

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

C. Follow Up on IPA and Common Rule Discussion

a) Review of submitted materials and discussion of suggestions for CPHS

Dr. Delgado summarized the ongoing discussions, noting that this was the third meeting addressing the Information Practices Act (IPA) and the Common Rule. She emphasized the importance of a deliberate approach, ensuring all voices were heard and that members had ample time to digest the information. In the first meeting, the committee reviewed a memo from legal counsel outlining CPHS's statutory and legal roles concerning the IPA and the Common Rule. The memo presented two potential paths:

1. Strict Adherence: Continue operations with a stringent interpretation of the IPA and Common Rule without deviation.
2. Consideration of Additional Variables: Explore other variables within the IPA's language, which would require clearly defining these variables and potentially pursuing regulations to ensure transparency and consistency in the review process.

In the subsequent July meeting, members were invited to contribute thoughts to help operationalize these considerations. The goal for the current meeting was to review submitted documents and decide on next steps, including whether to pursue regulations or adhere strictly to the statutory definitions within the IPA.

Attorney Maggie Schuster advised that any new regulations or criteria should align with the IPA's intent to safeguard data privacy and security

Ms. Kurtural expressed concerns about research projects combining state data with third-party data, suggesting such projects should undergo a more thorough, full board review rather than an expedited one. She proposed that projects using only state data could continue with expedited reviews, while those merging state data with external sources should require additional scrutiny. Ms. Kurtural also recommended that researchers provide approval letters from other involved entities' Institutional Review Boards (IRBs) when combining data from multiple sources. She acknowledged that obtaining individual consents for these more complex reviews might not be practical but emphasized the importance of establishing clear criteria and definitions for minimal risk under the IPA.

Ms. Lund emphasized the importance of precise terminology, suggesting the term "IPA only" instead of "data only" to avoid confusion. She explained that the Common Rule categorizes research into two types:

1. Direct or Indirect Contact with Human Subjects: Activities like interviewing individuals or extracting information from medical records, which require the subject's permission.
2. Data Only Projects: Involving secondary data sources containing personally identifiable information (PII). For example, a researcher using confidential birth certificate data with PII, and who is affiliated with a government agency or collaborating with an institution like UC Berkeley, would fall under the Common Rule. Such projects do not involve direct interaction with individuals and do not require the Health Insurance Portability and Accountability Act (HIPAA) waiver or informed consent but are still governed by the Common Rule.

In contrast, an "IPA only" project refers to situations where CPHS is not the Institutional Review Board (IRB) of record and is reviewing under the IPA. This occurs when a state agency releases data to a researcher for research purposes. Ms. Lund stressed that labeling projects simply as "data only" and categorizing them under "IPA only" overlooks those that should be evaluated under the Common Rule.

Dr. Dickey clarified that when data is released from a state agency or department without involving human subjects contact, it is not covered by the Common Rule. In such cases, the receiving institution's IRB is responsible for Common Rule review, while CPHS approves the data release under the IPA.
CPHS administrator, Dr. Rykaczewska, noted that CalHHS departments, such as the California Department of Social Services (CDSS), may have internal researchers conducting data-only research using CalHHS data. In these instances, the projects might be reviewed under the Common Rule. She emphasized the importance of distinguishing between data-only projects conducted internally by CalHHS and those by external researchers. For external projects with no CalHHS staff involvement or human subjects under CalHHS, the review falls solely under the IPA. Dr. Dickey added that when CalHHS departments receive data and conduct research on it, even if it's a data-only project, CPHS must review it under the Common Rule.

Dr. Schaeuble presented a document titled “Suggested Framework for Additional IPA Review Criteria (Fourth Draft),” aiming to consolidate ideas from recent discussions. The first section reiterated the minimum criteria specified in the IPA. The subsequent section listed attributes or situations that could heighten privacy risks, suggesting these should be considered during reviews. The first four items focused on variables and populations that might raise privacy concerns, such as sensitive physical health information (e.g., abortion and gender-affirming care) and data from vulnerable populations. The next two items addressed the potential expansion of data requests, including plans to gather additional data over time or from other sources, especially sensitive information. Dr. Schaeuble emphasized the importance of considering the possibility of re-identification, even when identifiers are removed or masked. He also highlighted concerns about making data available to other researchers or databases, which could lead to re-identification despite de-identification efforts. The final section discussed additional criteria to consider, such as whether consent obtained at the time of data collection sufficiently described the purposes of the proposed research.

Dr. Delgado raised concerns about the broad consent typically obtained in administrative data sets, noting that such consent might not sufficiently describe the purposes of proposed research, potentially eliminating many projects from review. Dr. Schaeuble acknowledged this concern, suggesting that the language could be adjusted to assess whether the original consent described situations similar to the proposed research. He emphasized that the absence of specific consent should not automatically lead to rejection but should be considered alongside other factors.

Ms. Lund suggested reconsidering the term “consent,” as individuals often do not have the option to consent to data collection but are informed about potential future uses. She proposed using language that reflects individuals being informed about future research uses of their data. Ms. Lund agreed that the criteria should serve as tools for ethical considerations rather than strict determinants for approval or rejection.

Ms. Kurtural expressed concerns about the practicality of implementing these criteria, noting that researchers might not have access to information about consent processes conducted by various entities, such as counties or regional centers. She emphasized that departments might not have control over or access to such information, making it challenging to apply these criteria effectively. Ms. Kurtural appreciated the factors outlined by Dr. Schaeuble but highlighted potential difficulties in obtaining necessary information for review.

The Committee discussed the challenges of reviewing research applications involving data collected without explicit consent for research purposes.

Dr. Schaeuble acknowledged that researchers often lack information about what participants were told when their data were collected. He noted that some agencies provide general statements to individuals at the time of data collection, such as in student financial aid scenarios, indicating potential uses of their information beyond the immediate purpose. He suggested that researchers might obtain these statements from the data-providing agencies to understand the context of data collection.

Dr. Dickey highlighted that, according to the Common Rule, Institutional Review Boards (IRBs) should review the consent processes and policies of databases established for research purposes. He pointed out that CPHS had not consistently conducted such reviews, leading to uncertainties about the consent processes for existing databases. He emphasized the need for CPHS to define its role in approving and reviewing these databases.

Ms. Lund responded by clarifying that IRB oversight of database creation applies only when an agency establishes a database specifically for research. For data collected as part of an agency's routine operations and later used for research, prior IRB review of the database's creation and consent procedures is not required. She cited the example of financial aid data reviewed by the committee, which was collected during regular business activities, not for research purposes.

Dr. Dickey acknowledged this distinction but noted that many databases are created explicitly for research, such as cancer registries, which CPHS had not reviewed. He suggested that reviewing these research-specific databases could be part of the solution to the consent process issue.

Dr. Dinis proposed that recognizing any data collection involving personal identifiers as human subjects research, as per Office for Human Research Protections (OHRP) regulations, would address many of these challenges. She emphasized that such recognition would necessitate Common Rule review for data with personal identifiers, altering the current approach to data collection and consent.

Dr. Delgado mentioned that CalHHS Chief Counsel Jared Goldman had removed certain points from the document but later reinstated them. She invited Attorney Maggie Schuster to explain the rationale behind these decisions.

Attorney Schuster explained that the term "reasonable person" is a specific legal term, and its inclusion in the regulations might not align with the intended purpose. She noted that the bullet points in question required subjective interpretations of individuals' expectations and objections, which could be challenging to assess objectively. She suggested focusing on whether individuals were explicitly informed that their information would be used for research, as this is an objective criterion.

Dr. Schaeuble inquired whether making subjective assessments about individuals' expectations differed from other judgment calls in the review process, such as evaluating the sensitivity of information.

Attorney Schuster acknowledged that while subjective judgments are part of the review process, the bullet points in question required assumptions about individuals' thoughts, which could vary widely. She emphasized the importance of applying criteria consistently and objectively across different cases.

Dr. Schaeuble asked if the committee could discuss the inclusion of these criteria in future regulations.

Attorney Schuster confirmed that the discussion was just beginning and that there would be opportunities for further deliberation, including public comments, as part of the regulatory process.

Dr. Delgado reiterated that pursuing the regulations process would be lengthy, involving reviews by the Office of Administrative Law (OAL) and public comment periods. She asked Dr. Schaeuble if alternative language could be used to describe the concept of consent without using the term "consent."

Dr. Schaeuble suggested that only the first of the three items used the word "consent" and proposed rephrasing it to state that if individuals were informed at the time of data collection that their information might be used for research, that information should be considered.

The committee agreed to continue refining the language and criteria to ensure clarity and consistency in the review process.

Dr. Ventura suggested that instead of using the term “consent,” agencies should inform individuals that their information could be used for research purposes.

Ms. Lund noted that state agencies often collect data through satellite organizations like counties or nonprofits. She emphasized that while it might be challenging to ensure every individual receives specific information, agencies should have policies to inform individuals that their data might be used for research. She cited the California Department of Public Health (CDPH) as an example, where entities collecting information are required to provide privacy statements outlining potential data uses.

Dr. Schaeuble proposed that if individuals were informed at the time of data collection that their information might be used for research, and this description aligns with the proposed research purposes, it could address consent concerns.

Dr. Delgado agreed with this approach.

Dr. Hess raised concerns about the broadness of statements like “personal information may be used for research,” pointing out that individuals might not expect their data to be used in ways unrelated to their initial context. She provided an example where cancer patients’ data were linked to consumer credit data, leading to conclusions about financial risks that patients might not have anticipated.

Dr. Schaeuble acknowledged this concern, suggesting that the information provided should be specific enough to cover the intended research purposes.

Ms. Kurtural questioned whether the discussed criteria applied solely to third-party data sources or also to Health and Human Services data. She highlighted that counties and regional centers have their own privacy practices and that addressing this issue might require updates to annual contracts to include acknowledgments about data usage for research.

Dr. Delgado suggested that the board could recommend that all departments review their local contracts to ensure compliance with privacy protections related to research data requests.

Ms. Kurtural noted that many privacy notices are general and do not detail specific data uses, such as linking with third-party data. She suggested that collaboration across departments might be necessary to address compliance and that the proposed regulations might be more applicable to external data sources.

Dr. Dickey expressed concern about data being matched with other sources beyond the board’s control.

Ms. Kurtural acknowledged this concern, noting that researchers might not always know what individuals were told about data usage, especially when linking with external sources like Free Application for Federal Student Aid (FAFSA). She suggested that addressing this issue might be more challenging for state data.

Dr. Rykaczewska asked if the recommendation was to include more detailed language in contracts, specifying that data sets might be merged with others. Ms. Kurtural responded that while the board might not have the authority to mandate changes to privacy practices, collaboration with departments could lead to more detailed notices.

Dr. Schaeuble acknowledged the complexity of the issue and suggested that it might require further discussion during the regulation development process.

Ms. Kurtural indicated that she would support regulations applying to external data sources, with criteria included in applications as factors to consider, rather than absolute requirements.

Dr. Schaeuble asked what expectations the board should have for state agencies regarding informing individuals at the time of data collection.

Ms. Kurtural explained that each department has a privacy officer and that discussions often occur within groups facilitated by the California Department of Technology (CDT). She suggested that addressing the issue might start with reviewing and aligning departments' notices of privacy practices and could involve compliance checks.

Dr. Dickey asked if the board could recommend that departments be more specific about the types of research for which data might be used.

Ms. Kurtural agreed that the board could make such a recommendation and noted that it might be beneficial to review current notices of privacy practices across departments.

Dr. Dickey suggested modifying notices to specify that data might be used for research related to health and welfare purposes, thereby excluding unrelated areas like financial services.

Ms. Kurtural agreed that this was a point for consideration and suggested that the board could start by reviewing each department's notice of privacy practices. She also raised concerns about how to obtain assurances from departments not contracted with the board, such as the California Department of Corrections and Rehabilitation (CDCR).

Dr. Schaeuble noted the challenges in determining agency policies and expressed uncertainty about the information provided to individuals during data collection. He questioned whether individuals are informed that their data might be used beyond its initial purpose, such as processing tax returns or maintaining driver's records. He observed that this issue is consistent across both state and other agencies.

Ms. Kurtural shared her personal experience, stating that when she applied for services for her son, there was no discussion about data usage; she simply completed the necessary paperwork. She mentioned that online applications, like those for social services and Medi-Cal, are user-friendly and connect various services. However, she emphasized the importance of ensuring that privacy practices are clearly presented, whether through digital platforms or paper applications.

Dr. Delgado suggested developing regulations based on agreed-upon sections from Dr. Schaeuble's form. She proposed that CDII convene privacy officers from each department to address issues encountered during research reviews. The goal would be to align consumer privacy notices with the discussed standards, pursuing this alongside the regulatory process.

Dr. Johnson recommended inquiring about existing privacy statements used by departments, including their content and the periods during which they were issued. She highlighted the need to consider these factors, especially in potential longitudinal studies where privacy notices may have changed over time.

Dr. Delgado agreed, suggesting an assessment of the current state of privacy notices, including their development timelines, delivery methods (paper versus electronic), and specific content, to understand their implications for research.

Dr. Dickey asked whether this assessment would encompass all state departments.

Dr. Delgado clarified that it would include every department under the California Health and Human Services Agency (CalHHS).

Dr. Dickey noted that under the Information Practices Act (IPA), all state departments are involved.

Dr. Delgado acknowledged that while they serve as the Institutional Review Board (IRB) for CalHHS, their direct control is limited to their own departments, which is still a positive step.

Ms. Kurtural suggested that starting within their own departments, they could incorporate acknowledgments or require departments to attach their privacy statements to contracts. This approach would provide assurance to the board and establish a solid foundation within CalHHS.

Dr. Dickey pointed out that some problematic projects involved data from outside agencies, such as those using FAFSA and California Community Colleges data.

Ms. Lund explained that the criteria list is intended to evaluate whether individuals received adequate information. If there are concerns about the project's nature, data usage, potential re-identification, or lack of proper disclosure by the agency, these factors could justify denying research approval. She emphasized that under the IPA, their responsibility is to approve the release of state data for research. While they can consider whether state data will be linked with other data, they cannot control non-state data, as those fall under the jurisdiction of other IRBs. Their focus should be on state data within their purview.

Dr. Dickey questioned whether other IRBs should be responsible for reviewing consent for their respective data sets and whether there is trust in their processes.

Ms. Lund responded that while other IRBs are responsible under the Common Rule for ensuring informed consent, CPHS concern should be limited to state data under the IPA. They cannot oversee how non-state data were collected or what information was provided to individuals; that responsibility lies with the respective IRBs.

Dr. Dickey suggested that this perspective might conflict with Dr. Schaeuble's viewpoint.

Ms. Lund clarified that the concern arises when state data are linked with other data sources, creating larger datasets with more fields than originally intended. Individuals may not have been informed that their state data could be linked in this manner. Their focus should be on whether individuals were adequately informed about the potential use of their state data, not on how other data sources handled their information.

Dr. Dickey proposed modifying forms to indicate that research may include linking with other databases.

Ms. Lund provided an example involving birth certificate data, where the privacy statement specifies that data will be used in accordance with state law for health-related research. She noted that some data sources have specific regulations limiting their use, while others do not. Her concern is that individuals may not be aware that their data could be linked with other datasets, increasing privacy risks.

Dr. Schaeuble agreed, emphasizing that linking data can significantly increase privacy risks for individuals.

Dr. Dickey asked whether privacy statements should include information about potential data linkage. He noted that while other IRBs may review their respective databases, their focus should be on the risks associated with creating larger, linked datasets.

Dr. Dinis cited an example involving a Berkeley project where financial data were considered exempt, but when combined with student loan data, it raised concerns. She pointed out that individuals applying for financial aid may not be aware that their information could be matched with other datasets, such as credit reports, which is not disclosed in privacy statements.

Ms. Kurtural asked whether addressing these issues through contracts, privacy statements, and requiring IRB approval letters from external sources would be a workable solution.

Dr. Schaeuble expressed skepticism, noting that in practice, researchers' institutions often consider secondary data as exempt and do not review them. This lack of review means that the considerations being discussed may not receive attention unless incorporated into their own processes.

Dr. Delgado suggested that while it is important to consider these issues now, over time, as privacy statements improve, the need for such considerations may diminish.

Ms. Kurtural proposed developing a template for privacy statements, noting that privacy exceptions are generally consistent across organizations.

Dr. Dickey affirmed that as the IRB, they have the authority to make recommendations.

Ms. Kurtural agreed, stating that they could recommend specific language for privacy statements, gather input, and report back to the board.

During the meeting, Ms. Lund acknowledged that resolving all details was not feasible at that time. She emphasized the importance of capturing the valuable points raised and questioned whether the committee had achieved the agenda's goal: continuing the discussion on the IPA and reviewing documents submitted by Ms. Kurtural and Dr. Schaeuble. Ms. Lund noted a general interest in regulations without objections and suggested forming a subcommittee under the Bagley-Keene Open Meeting Act to ensure public participation. She proposed moving forward with drafting regulations and establishing a subcommittee to develop language for the board's consideration.

Dr. Dickey noted two points, pursuing a regulations package and standardizing privacy statements related to research within the agency, indicating a dual approach. Dr. Delgado noted agreement among members.

John Ohanian, Director of CDII, informed the group about ongoing work with the Data Exchange Framework which focuses on real-time information sharing among health and social service providers. He highlighted key areas like identity management and consent, mentioning national discussions and local pilots on consent. Director Ohanian offered to present early findings in future meetings, emphasizing the need to address these issues statewide in the coming years.

Dr. Schaeuble noted the absence of objections to the discussed document and inquired if it could serve as a framework for the committee to collaborate with legal counsel in developing regulations. Dr. Dickey suggested establishing a subcommittee, which would operate under the Bagley-Keene Act, to work out details. Dr. Schaeuble questioned if the committee was ready to use the current document as a starting point for the subcommittee's collaboration with legal counsel.

Dr. Delgado shared her perspective, acknowledging the lengthy discussion but recognizing significant progress. She recalled a previous conversation with CalHHS Chief Counsel Jared Goldman and Attorney Schuster, where the group was advised to decide between pursuing regulations to formalize IPA review criteria or maintaining the current approach. Dr. Delgado perceived a consensus favoring regulations to protect sensitive data, using the discussed document as a starting point. She proposed forming a subcommittee to refine the document line by line, eventually presenting it to the full committee for approval before involving legal teams in the regulation development process, which could take about a year.

Dr. Dickey inquired about the possibility of a motion to proceed. Dr. Delgado anticipated two motions: one to pursue regulations and form a subcommittee, and another to discuss privacy notices with departments.

Dr. Maria Dinis asked if both motions would proceed simultaneously. Dr. Delgado affirmed, noting the importance and long-term nature of both initiatives

First Motion:

It was moved by Ms. Lund and seconded by Dr. Hess that the committee move forward to create regulations regarding requirements for IPA-only project reviews and that a subcommittee be established to draft language to bring to CDII legal and to this board for regulations.

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

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

Dr. Delgado opened the floor for public comment.

A member from the public, Satish Kumar, spoke about future research possibilities, such as CDII linking various datasets from human services and health, and the role of Artificial Intelligence (AI) in creating unforeseen research opportunities over the next 3 to 5 years. Mr. Kumar questioned how such future research would be communicated to individuals whose data is used, suggesting public websites listing ongoing and planned research using datasets up to 10 years old. He also expressed concerns about data linkage potentially re-identifying individuals, even without personally identifiable information (PII), citing cases where small population sizes made individuals identifiable. Mr. Kumar mentioned the committee's role in setting standards that could influence not only California but also broader regions.

Dr. Delgado acknowledged the comment and noted no additional virtual hands raised.

Second Motion:

It was moved by Ms. Kurtural and seconded by Dr. Dickey that CDII obtains from each CalHHS Department their current notice of privacy practices and bring back to the board for review and consideration.
Approve: Ms. Kurtural, Dr. Dickey, Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Dr. Hess, Ms. Lund, Dr. Palacio, Dr. Schaeuble, Dr. Ventura, and Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Azizian.

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

Dr. Delgado opened the floor for public comment on this issue; no comments were made.

Dr. Delgado thanked the committee for their commitment, acknowledging the extensive work, especially by Dr. Schaeuble and Ms. Kurtural, in preparing documents. She also thanked researchers on the call for their patience, recognizing the importance of the discussed issues.

Ms. Lund suggested naming subcommittee members. Dr. Delgado invited nominations, noting that if more than two people were interested, the subcommittee would be subject to Bagley-Keene Act requirements and should be established through a public meeting.

Ms. Lund proposed having 3 or 4 members to thoroughly discuss the language, expressing hope that Dr. Schaeuble would volunteer due to his significant contributions. She acknowledged that while the Bagley-Keene Act could be inconvenient, it was important.

Dr. Dinis and Ms. Lund agreed to join the subcommittee. Dr. Delgado concurred that the subcommittee should hold open meetings under the Bagley-Keene Open Meeting Act, given the topic's importance and public interest. She asked Dr. Schaeuble if he was willing to participate, considering his involvement in multiple subcommittees. Dr. Schaeuble accepted. Ms. Kurtural also agreed to join.

Dr. Delgado confirmed that the subcommittee would consist of Dr. Schaeuble, Ms. Lund, Dr. Dinis, and Ms. Kurtural. She mentioned that CDII legal counsel could attend meetings without being official members, anticipating involvement from both Attorney Goldman and Schuster. Dr. Schaeuble emphasized the necessity of legal counsel's involvement. Attorney Schuster agreed, stating they would provide counsel without being official members.

D. Review and Approval of Meeting Minutes

Dr. Delgado requested a motion for the approval of the CPHS June 7, 2024, meeting minutes.

Motion:

It was moved by Dr. Johnson and seconded by Ms. Kurtural to approve the June 7th, 2024, meeting minutes.

Approve: Dr. Johnson, Ms. Kurtural, Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Dr. Palacio, Dr. Schaeuble, and Dr. Ventura.
Oppose: None.
Abstain: Dr. Hess, and Ms. Lund.
Absent: Dr. Azizian.
(Dr. Dickey was unable to vote due to technical difficulties and a lost connection.)

Total= 10, In Favor- 8, Opposed- 0, Abstained- 2

E. Projects with Reported Adverse Events and/or Deviations

None.

F. New Projects – Full Committee Review Required

1. Project # 2024-128 (Kurtural)

Title: Expectant and Parenting Youth in Foster Care: A Qualitative Inquiry
PI: Justin Harty, PhD, MSW, BA
Co-PI: Kristen Ethier, PhD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:
This project is part of a larger study and explores the nuanced experiences and needs of expectant and parenting youth (EPFY) within California's foster care system. Eligibility criteria for participants include being aged 18-21, currently in California's foster care system, either expectant or actively parenting, proficient in English, and having internet access for participation in virtual discussions. The study employs a qualitative research methodology known as interpretive description. Participants will be asked to participate in individual interviews or focus group interviews. Recruitment will not take place directly through the California Department of Social Services (CDSS), and there is no request for data from CDSS. The Principal Investigator (PI) of the project wants to avoid recruiting directly through workers. The PI has been part of the California Youth Transitions to Adulthood (Cal YOUTH) study team, and through them, he has asked CDSS to distribute the recruitment materials to adult-aged youth via individuals who have already established relationships with the participants, making it easier for the subjects.

The PI and Co-Investigator (Co-I) will contact CDSS, the County Welfare Directors Association of California (CWDA), and California foster youth organizations to inform them of the study and provide electronic study forms for distribution. These forms will be shared through a password-protected link. Recruitment will be facilitated by caseworkers and staff, who will receive instructions and relevant documents. Interested participants will contact the PI to receive consent forms via Qualtrics, provide contact information, and complete a screening form. Qualified participants will be scheduled for interviews, and upon completion, will receive an electronic gift card. All collected data will be securely stored.

The questions in the attached scripts to the application are open-ended, allowing participants and focus groups to be prompted to explain their personal experiences as expectant youth. The recruitment flyer was updated to include the risk of disclosing personal information shared by others. Form 2.1 lists the items and elements for which subjects will be asked to consent. They can choose to participate in none, one, some, or all components. Electronically signed consent is required for participation. Participants can choose to consent to an interview or a focus group interview. For focus groups, they can consent or not consent to having the session recorded, and they will be asked for their preference regarding participation in specific focus groups.

To comply with the Common Rule, additional information must be included in informed consent Form 2.1 to describe the project and its reasonable and foreseeable risks. The PI clarified that the consent form is a combination of Form 2 and Form 2.1, with Form 2.1 essentially serving as a signature page. It was suggested that the PI combine these two forms into one. An electronic signature will be requested via computer, using a mouse or trackpad, or on a phone where participants can sign with their finger. The sentence in the consent form indicating that all private information that would allow someone to easily identify the subjects as study participants will be removed is misleading because subjects' characteristic information might still be disclosed. This sentence should be revised. It was clarified by Committee members that identifiable information and private information are not the same. The information provided by the subjects during interviews will be private information. The sentence should be adjusted to convey that all information that could identify the participants will be removed.

It has been noted in the application that when reporting findings, data will be presented in aggregate form whenever possible. Ms. Kurtural recommended that the PI conduct statistical de-identification or masking for certain cell sizes, following the guidelines described in the California Health and Human Services Data De-Identification Guidelines (DDG), and clarify in the application which method will be used in aggregate reporting. Dr. Hess suggested looking into best practices for protecting confidentiality in sensitive situations like this. The PI clarified that obtaining signatures for the consent forms in focus group and individual interviews will be done electronically. Participants should be informed in the consent form about the possibility of being recontacted and asked whether they are willing to be recontacted. The PI clarified that there is no intention to contact participants after the interviews and will review the consent form language to ensure clarity. Dr. Delgado appreciated the PI for sharing his lived experience and the value it brings to this project.

Motion:

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

1. **Noting in your protocol the de-identification methodology for when you publish aggregate data.**
2. **Combining consent form and the signature page.**
3. **Revising the risk section of the consent form to adequately describe the risks of disclosure of personally identifiable information.**

Approve: Ms. Kurtural, Dr. Ventura, Dr. Ruiz, Dr. Bazzano, Dr. Dinis, Dr. Hess, Ms. Lund, Dr. Palacio, Dr. Schaeuble, Dr. Johnson.
Oppose: None.
Abstain: None.
Absent: Dr. Azizian.
(Dr. Dickey attended the meeting remotely when discussing this project. Due to connection problem his vote could not be heard or recorded.)

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

2. Project # 2024-128 (Kurtural)

Title: Is There A Link Between Prostate Cancer and HPV?
PI: Wendy Cozen, DO, MPH
Co-PI: Arash Rezazadeh Kalebasty, MD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:
Dr. Hess introduces the committee members to a new project from UC Irvine titled "Is There a Link Between Prostate Cancer and HPV?" Dr. Hess then introduces Dr. Wendy Cozen, who provides a brief overview of the project.
Dr. Wendy Cozen explains that her husband established a twin registry at USC twenty years ago, which combines DMV and birth records of twins. In the early 2000s, a questionnaire was distributed to this group, receiving responses from over fifty thousand participants about various health conditions, including prostate cancer. Dr. Cozen has identified approximately 300 twins from this registry who indicated in the original questionnaire that they had prostate cancer. She now seeks to link this twin database at USC with the California Cancer Registry (CCR) data. This linkage would provide updated information on whether any of the twins have passed away. Importantly, if one twin has died, they will not contact the surviving twin.

The purpose of the study is to determine whether HPV might be a risk factor for prostate cancer. Dr. Cozen explains that before moving on to the tissue studies section of the protocol, she wants to explore this potential link using twins, as they share the same environmental factors, making them ideal subjects for comparison. Dr. Cozen mentions that this is primarily a serology study, where researchers will visit both twins' homes to collect blood samples and measure HPV antibodies to assess exposure. If the twin with prostate cancer shows significantly higher HPV antibody levels, it could suggest a potential link, warranting further studies. Blood samples from both twins are essential to establish whether a link exists. The assays will be conducted by the German Cancer Research Center, where Dr. Tim Waterboer, an HPV specialist, can measure 50 different HPV antibodies using just 50 microliters of serum. The German Cancer Research Center will only receive de-identified serum samples and will provide the antibody information back to Dr. Cozen and her team, who will then link it to the original data.

Dr. Hess asks whether they are requesting birth and death data from VSAC. Dr. Cozen is uncertain whether they will receive this data from VSAC or CCR. Dr. Hess clarifies that Dr. Cozen will need to apply through VSAC for the death certificate information, as it is separate from CCR data. Additionally, Dr. Hess notes that the IRBManager application will require both the CCR Letter of Support (LOS) and the VSAC application, as they are distinct entities. She also mentions that VSAC will not release data until CPHS approves it.
Dr. Hess asks about the recruitment letter sent to the twins, particularly a statement indicating that participants might be receiving the letter because their twin had cancer. She raises concerns about this potentially breaching the privacy of the twin with cancer, assuming the unaffected twin is unaware of the diagnosis. Dr. Cozen explains that the baseline survey asked twins whether they or their twin had cancer. If the respondent indicated that their twin had cancer and provided the date of diagnosis, the researchers would know that the twin is aware. If they are unsure or did not confirm this, the researchers will contact the twin with cancer to ask if they are willing to reach out to their twin. The researchers will only send a letter if they are confident that the twin is aware of the diagnosis. Dr. Cozen asks Dr. Hess if this approach is sufficient, and Dr. Hess agrees.
Dr. Hess also seeks clarification on why the RedCap survey includes identifiable information such as date of birth, sex, twin type, and other demographic details. She asks for justification for collecting this information, given that they already have it. Dr. Cozen explains that it is to verify that there are no errors in their data and to double-check the accuracy of their records. Dr. Hess requests additional justification for collecting this information, as well as details on how it will be stored and protected. Dr. Cozen assures that once the correct individuals are identified, this information will be deleted from the survey. Dr. Hess confirms that the survey will be purged of all identifiable information except for a unique identifier code, which will be kept separate from the participants' identities. Dr. Cozen agrees to implement these changes to the survey.

Dr. Cozen informs Dr. Hess that they will obtain verbal consent over the phone for the questionnaire and in-person written consent for the HPV assay, which will be conducted by a phlebotomist from a third-party company. Dr. Hess asks whether the phlebotomists can address questions or concerns on-site, or if participants will be referred back to the project staff. Dr. Cozen notes that the phlebotomists will be trained to answer questions, but the project staff will also be available by phone if needed. Dr. Hess requests that this process be included in the protocol, including the role of the phlebotomist in obtaining consent and addressing participant questions. Dr. Hess also asks whether Dr. Cozen is requesting a waiver of written consent for the questionnaire. Dr. Cozen explains that they typically don’t include consent on the first page of the survey since it is implicit and conducted remotely. If participants do not wish to participate, they can simply decline to complete the questionnaire. Dr. Hess suggests starting with written consent, noting that while it may pose a recruitment challenge, a waiver of written consent can be requested later if necessary.

Dr. Mallory Bernstein asks Dr. Hess whether including the consent form on the first page of the online survey would suffice, ensuring participants review and sign the consent form before taking the survey. Dr. Hess agrees that this would work. Dr. Cozen mentions that implementing these changes may take some time, as she needs to obtain approval from her IRB before updating the questionnaire in IRBManager.

Dr. Hess opens the floor for additional questions from the committee. Dr. Ventura raises concerns about participant privacy and suggests allowing individuals to choose the location for blood collection, rather than defaulting to their home or workplace. Dr. Ventura also asks why USC is listed under the password controls section of the application. Dr. Cozen explains that the twin registry is currently housed at USC, but they are in the process of copying the database and moving it to UCI for linkage. Dr. Hess clarifies that a data security letter from USC is not necessary since the linkage will occur at UCI, but requests that a data use agreement be included in the IRBManager application for the record. Dr. Cozen mentions that obtaining the new materials might take some time.

Dr. Schaeuble notes that the survey involves sensitive information about males with prostate cancer and asks whether a male contact person could be made available in addition to the project manager. Dr. Cozen agrees to have a male recruiter available to address any questions. She also adds that the consent form will include a statement allowing participants to skip any questions they find uncomfortable.

Motion:

It was moved by Dr. Hess and seconded by Dr. Ventura to grant the project a deferred approval for one-year, minimal risk pending the following specified revisions, which require expedited review and approval by a CPHS subcommittee of Dr. Hess.

1. **In the IRB protocol, address in writing the seven questions that Dr. Hess sent over email, including the VSAC application.**
2. **That the protocol will be amended to note that you will be contacting the twin with cancer first if the other twin didn't know and that the location of the blood draw is left up to the participant, provide copy of data use agreement between UCI and USC for the twin registry data, and that there will be a male contact person.**
3. **Add the informed consent to survey.**

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

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

G, Full Board Continuing Review

None.

H. Amendments – Full Committee Review Required

1. Project # 2022-004 (Lund)

Title: The Impact of Racism-Related Socio-Environmental Factors on African American Non-Small Cell Lung Cancer (NSCLC) Mutational Signatures
PI: Loretta Erhunmwunsee, MD
Board Decision: Approved Pending Conditions - Designee Review

Discussion:
This amendment is scheduled to be discussed in this full board meeting due to significant changes requested by the researchers to the consenting process, which differ from the originally approved plan. The study, initially a pilot for NIH funding, has now expanded under an R37 grant. The project examines the impact of racism-related socio-environmental factors on African American non-small cell lung cancer (NSCLC) mutational signatures. The researchers seek approval to change the study aims, increase the sample size to 100, extend cohort dates to align with the R37, and add a new recruitment site, Public Health Institute (PHI). PHI will serve as a data repository and specimen delivery service. The consent process is proposed to be simplified into a one-part consent form, allowing participants the option to complete it independently. The study's California recruitment has been expanded from 40 to 100 Black/African American participants, with PHI added to meet this goal. The one-part consent form covers both the questionnaire and medical release, and participants will receive a $75 Visa gift card upon completing the consent and required documents with $25 for completing the questionnaire and $50 for completing the medical release form). This change addresses participant feedback that preferred not to receive follow-up calls for additional consent. However, there are concerns about the new consent process. Participants receives a lot of documents including the consent form, which is lengthy (10-11 pages), an introductory letter from the Principal Investigator (PI), a second introductory letter that is attached to the questionnaire, and HIPAA authorization, all written at a 12th-grade reading level which may be challenging and overwhelming for participants to fully understand. Given the sensitive nature of the study, it is important to ensure that individuals fully read and understand the documents.

It was clarified in the meeting that the option to use DocuSign is available when participants request to complete the consent electronically. Participants would receive a QR code or link to access and sign the consent form and HIPAA authorization via DocuSign. They can also choose to complete the questionnaire either online or over the phone by contacting the researchers, as outlined in the introductory packet. Researchers clarified that if participants choose to complete the survey over the phone, researchers will first check if the informed consent is on file. If the informed consent is missing, researchers will inform the participant that it must be completed before proceeding with the survey. Participants can either complete the consent form with the researchers during the call or independently before scheduling a follow-up call to complete the survey. It was also requested that this process be clearly outlined in the application. Researchers mentioned that the address information is retained after the study for conducting geospatial assessments, which may reveal associations with different tumor markers and may be used for future secondary findings. The data is securely stored and de-identified when shared, ensuring that addresses are not disclosed to other folks even with their bio statisticians. Regarding the amendment, it was noted that website outreach was initially included but has since been removed. The current amendment focuses on changes to the consent process and an increase in sample size.

In terms of the involvement of the Public Health Institute (PHI), Ms. Lund mentioned that PHI can act as a contractor for the California Cancer Registry (CCR) and is not necessarily a research partner. PHI's role is primarily to operate the cancer registry, including managing the tumor repository. If PHI is to be considered a research partner, researchers need to specify PHI staff involved and provide a Data Security Letter from PHI. However, since PHI's role aligns with CCR's operations, listing them as a research partner may complicate the amendment unnecessarily. The researchers acknowledged this clarification and noted that tumor samples are sourced from separate repositories, including PHI's own, which was why PHI was initially listed as a research partner. It was suggested that researchers reconsider PHI's designation in the amendment to streamline the process.

Dr. Ventura expressed agreement with the concern regarding the self-administered consent form, noting that it was confusing to read. She requested that all materials, including the cover letter, be simplified to an 8th-grade reading level. Ms. Lund also requested that the independent consent form meet the same reading level.
Dr. Schaeuble raised concerns about the lack of clarity in the consent form regarding the sharing of genetic data with an NIH database, which was mentioned only under the HIPAA waiver. He noted that the protocol did not discuss the risks of sharing such data and suggested that there should be a separate permission section within the consent form for this type of data sharing. He emphasized that participants should have the option to agree or refuse, or at least confirm their consent to data sharing separately. He also pointed out that the consent form was unclear about which specific data, including survey data, geolocation, medical records, and genetic information, might be shared, and suggested that this needs to be addressed. Researchers responded that they could consult with their IRB to offer patients the option to opt in or out of biobanking their specimens. They clarified that no identifiable data is planned to be shared in the future and that access to identifiable data in the current study is very limited. They agreed to clarify in the consent form how data sharing might occur in the future, ensuring that it is de-identified and cannot be traced back to the patient. Dr. Schaeuble stressed the importance of being clear about what information might be shared and ensuring that participants understand whether their data is protected. Researchers agreed to make these points clearer in the consent form.

Motion:

It was moved by Ms. Lund and seconded by Dr. Ruiz to grant the discussed amendment a deferred approval under the common rule, classifying it as minimal risk, pending the following specified minor revisions, which require expedited review and approval by a CPHS subcommittee of Ms. Lund.

1. **The reading level for all of the materials that the participants will receive, including the introductory letter, the cover letter, and the consent, form and HIPAA authorization will be modified to achieve an 8th grade reading level or as closely as possible.**
2. **The consent form will separately list biobanking the tissue as an option, and researchers will confirm with the other IRB that there can be an opt-in or opt out option for that.**
3. **The consent form will more clearly describe what information about the participant will be shared,**
4. **The role of PHI in this study will be clarified or they will be removed completely.**
5. **The risks associated with the sharing of genetic information will be included in the protocol.**

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

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

I. Second Review Calendar

None.

J. New Projects – Expedited Review Requested

Some projects listed may require full committee review and others are recommended for approval by expedited review. Project approvals may be ratified by the committee. See meeting materials for list of projects. Total Project Count (14)

K. Projects Requiring Continuing Review

Some projects listed may require full committee review and others are recommended for approval by expedited review. Project approvals may be ratified by the committee. See meeting materials for list of projects. Total Project Count (71)

K1. Projects Requiring Continuing Review – Administrative Action Taken

Some projects listed may require full committee review and others are recommended for approval by expedited review. Project approvals may be ratified by the committee. See meeting materials for list of projects. Total Project Count (25)

L. Amendments – Projects with Revisions Approves through Expedited Review

Some projects listed may require full committee review and others are recommended for approval by expedited review. Project approvals may be ratified by the committee. See meeting materials for list of projects. Total Project Count (25)

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

None.

N. Exemption/Not Research Approvals

Total Project Count (7)

O. Final Reports

Total Project Count (8)

P. Public Comments

None.

Q. Next Meeting

The next CPHS meeting is scheduled to be held on Friday, September 13, 2024.

R. Adjournment

This meeting was Adjourned at 1:09 PM on August 2, 2024.