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, November 1, 2024
8:30 a.m.

Zoom:
CPHS November 1, 2024, Full Committee Meeting

Meeting ID: 160 695 5489
Passcode: 758991

Location:
1215 O Street,
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Meeting ID: 160 695 5489

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
Allen Azizian, PhD
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Juan Ruiz, MD, DrPH, 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.
Larry Dickey, MD, MPH
John Schaeuble, PhD, MS
Maria Ventura, PhD
Jonni Johnson, PhD
Catherine Hess, PhD
Laura Lund, MA

Committee Members Present Remotely:

Allen Azizian, PhD
Alicia Bazzano, MD, PhD
Maria Dinis, PhD, MSW
Juan Ruiz, MD, DrPH, MP

CPHS Staff Present in Person:

Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Center for Data Insights and Innovation Staff Present in Person:

Agnieszka Rykaczewska, Deputy Director

California Health and Human Services Staff Present in Person:

Jared Goldman, General Council
Maggie Schuster, Attorney

California Health and Human Services Staff Present Remotely:

Francis Brown

California Department of Public Health Staff Present Remotely:

Michelle Miles, Vital Statistics Branch Chief
Josh Monteiro, Science Advisor, Research Scientist III

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

A. Welcome

a) Chair Updates

Dr. Delgado called the meeting to order and reminded members that are attending remotely to keep their cameras on during the meeting. Sussan Atifeh took roll call and established quorum. Dr. Delgado advised the committee this meeting is focusing only on administrative items at this meeting.

B. Update on Chair Transition

Dr. Delgado insisted she will remain chair until the end of the calendar year and wants to discuss the transition for a new chair. Page 13 of the policies and procedures were displayed on the screen showing the criteria and requirements for the CPHS Chair. The first criteria to be eligible to be the Chair the committee member must be a California Health and Human Services (CalHHS) active employee. The members that would fit this criterion would include Dr. Hess and Ms. Kurtural, Dr. Azizian, Dr. Ventura, and Dr. Johnson. In addition, the committee member must have been apart of CPHS for at least two years. Dr. Delgado notes that Dr. Johnson is close to the two-year mark but has not fully made the two years. Therefore Dr. Hess and Ms. Kurtural are the only members that are active CalHHS employees and have been on the board for over two years.

The formal process for this transition is to have the Chair nominated by CalHHS' Center for Data Insights and Innovation (CDII) Director. After the Directors approval it is voted upon by CPHS, and lastly approved and appointed by the CalHHS Secretary.

Dr. Delgado noted she has had some conversations with both Dr. Hess and Ms. Kurtural regarding the willingness to be the new CPHS Chair. Dr. Hess has expressed a willingness and interest in serving as CPHS Chair. Ms. Kurtural is fully committed to CPHS, and at this time has not expressed an interest in the position with her current roles and responsibilities.
Dr. Dickey advised of the 20 percent protected time which Dr. Hess advised her department would likely have to sign off on. If there are any questions, CPHS is willing to take those questions regarding the fulfillment of the new Chair position.

Dr. Delgado opened the floor up to the committee for any questions or concerns related to the transition of the Chair. No comments were made at that time.

Dr. Delgado noted the CPHS Vice Chair position does not have the same criteria or requirements as the CPHS Chair. Once a CPHS Chair is formally nominated, they can select and appoint a CPHS Vice Chair. Page 15 of the policies and procedures document was presented on the screen to display the requirements for the CPHS Vice Chair requirements, including steps for selection and appointment, tenure, duties, and responsibilities. The requirement is that the Vice-Chair must be a member for at least one year. The Vice Chair does not have to have active employment with CalHHS.

Dr. Delgado noted that members that did not have the two-year term with CPHS or did not meet the criteria due to not having active employment with a department within CalHHS would qualify to be nominated as the Vice-Chair.

Dr. Delgado expressed the next step for the transition of the Chair is to have John Ohanian, CDII Director, present his nomination, Dr. Hess, for the chair at the December meeting. The committee will vote on this item in the December 2024 full board meeting.

Dr. Delgado opened the discussion to the committee and the public for comment. There were no questions or comments internally. No public comments, virtually or in person.

C. Updates related to California Department of Public Health Vital Records Data

Agnieszka Rykaczewska, CPHS Administrator, noted the extra meetings are to work through different administrative processes and drafts. Dr. Rykaczewska expresses that she recognizes the committee's expertise and values the input that helps strengthen the drafts. The items on

today's agenda are designed to address the administrative items, strengthen administrative processes and approaches.

To make administrative improvements, CPHS is working with the California Department of Public Health (CDPH). Specifically, CPHS is working with Michelle Miles, CDPH Vital Statistics Branch Chief, and Joshua Monteiro, a CDPH Science Advisor (Research Scientist III). Many of CPHS projects involve CDPH regarding vital records data. Recurring meetings have been set up to work through issues, troubleshoot, and facilitate collaboration to help move projects forward. Three items will be discussed today. The first item is a proposed workflow between CDPH and CPHS. The workflow was created due to frequent conversations from researchers inquiring about clarity for what application would come first in the process and the next steps. The second item is regards to the Letter of Support that CDPH has drafted and to gather feedback from the committee if anything is missing. The last item to be discussed is the vital records 5-year rule to gather more clarity on how CPHS should implement and follow that rule.

Dr. Rykaczewska started the discussion regarding the proposed workflow between CDPH and CPHS by giving a brief explanation. She noted the conversation started after CDPH brought up to Dr. Rykaczewska that there are vital statists statutes that raised concerns when it came to Letters of Support (LOS). The statues that CDPH raised to our attention were displayed on the screen and posted on the CPHS website. The specific statutes that were discussed were Health and Safety Code section 102231(a)(5), section 102430(c), and section 102465(a)(2). In the Health and safety code section 102430(c), Dr. Rykaczewska points out that it states, "…first be reviewed by the appropriate committee constitutes for the protection of human subjects…" CDPH brought up to the attention of CPHS, how can we provide the LOS when the statues state CPHS must review first. Dr. Rykaczewska explains to clarify and streamline the process between the two entities, a proposed workflow was created to gather the committee's thoughts to further refine the process for researchers.
Dr. Rykaczewska presents the proposed workflow on the screen and explain the process from start to finish. The proposed workflow is posted on the CPHS website and was sent out to the committee members in the committee package prior to the meeting.
Dr. Rykaczewska notes that the process would happen congruently between CDPH and CPHS to save researcher's time. The process from start to finish for a researcher that would like to request Vital Records Data:

1) Researchers start Vital Statistics Application. Researchers attach PDF copy of CPHS application to the Vital Statistics Application system as a placeholder to secure review.

And

2) Researchers start CPHS application. Researchers attach PDF copy of Vital Statistics application to CPHS application as placeholder to secure review.
3) CDPH completes preliminary review or application for completeness.

And

4) CPHS admin team completes pre-screen for completeness.
5) CPHS Reviewer(s) complete review and recommend a deferred approval pending CDPH Letter of Support (LOS).

Dr. Rykaczewska advised delays often occur when waiting for the LOS and recommends that CPHS reviewers review the protocol without the LOS and recommend a deferred approval, pending the LOS. Once the LOS is attached to the application the CPHS administrator would review and release the final approval letter to the researcher. Dr. Rykaczewska advised this recommendation would save reviewers time and help organize their dashboard. Dr. Dickey asked about implementing these changes was possible on the current system IRBManager. Dr. Rykaczewska let Dr. Dickey know the administrative team will explore different options, but at

the least the approval letters can be manually changed. The reviewers can select “clarifications needed” and leave a note when providing their review that the recommend a deferred approval, pending the Letter of Support. Ms. Lund expressed her support and recognized the change will save a lot of time for reviewers.

Going back to the work flow the next steps include:

6) CDPH provides Letter of Support (LOS) to researchers, based on preliminary review (New projects only).

AND

7) Researchers attach CDPH Letter of Support (LOS) to CPHS application.
8) CPHS Administrator approves application, providing CPHS Approval Letter to researchers.
9) Researchers attach CPHS Approval Letter to Vital Statistics Application.
10) CDPH completes comprehensive review including review by science advisor, Vital Statistics Advisory Committee (acronym VSAC, if necessary), and State Registrar (CDPH will conduct the comprehensive large review here).
11) CDPH releases Approval Letter to researchers.
12) CDPH extracts and prepares data.
13) Researchers receive secure access to data.

After the data is released, the researchers have to submit an annual CPHS Continuing Review Application with the approval letter submitted to CDPH. If any changes are made during the review process, both CPHS and the Vital Statistics applications will need to be updated. The amendment application would follow the same process except CPHS would not receive a new LOS from CDPH, which only occurs when CPHS receives a new project. In addition, CDPH staff have access to the CPHS IRBManager, and they do a comparison of the two applications to make sure they align once the approval letter is released.

Ms. Lund asked if CDPH conducts the comprehensive comparison between the researchers VSAC application and CPHS application, CPHS reviewers don’t have to?
Michelle Miles confirming that part of CDPH’s comprehensive review they double check to ensure the applications mirror each other once CPHS has approved the project. The researchers will then attach their CPHS application to the VSAC application, where CDPH will review both applications. Ms. Lund asked what CDPH will do if there are differences between the CPHS applications and the VSAC applications. Michelle Miles advised if there are differences, CDPH will reach out to the researcher for them to align the VSAC application with the final approved CPHS application.

Ms. Lund asked the committee if the VSAC application is attached, is CPHS responsible for Dr. Dickey how does CDPH notify the researcher about CDPH-generated changes to the VSAC application and realign that application with the CPHS application? Joshua Monteiro advised the reason for this clarification is that before when CPHS would make changes to the application, CDPH would have to go through their review process again. Changes were being made from both CPHS and CDPH. Sometimes what researchers are communicating to CPHS is not consistent with what they’re requesting from CDPH. CDPH would instructs the researcher to go back and make the changes with CPHS and get confirmation that CPHS has approved the changes.

Dr. Rykaczewska advised if any changes needed to occur to the CPHS application when CDPH completes the comprehensive review, that the researchers would need to submit an

amendment to CPHS and would go back to the step that CPHS completes pre-screening for completeness. Ms. Lund asked to have that incorporated into the workflow.

Dr. Dinis asked if this a situation where it is a combination of Information Practices Act (IPA) and Institutional Review Board (IRB)? Ms. Lund answered Dr. Dinis that it could be either IPA or IRB regulations. It's a request for vital records data, and it does not matter to CDPH if it's an IPA or IRB project.

Dr. Schaeuble had two Language concerns. Referencing the box in the upper left-hand corner, the word 'system' does not belong in the sentence. It should just say, 'Attach PDF copy...' Dr. Rykaczewska advised that change could be made as it makes sense.
Dr. Schaeuble also expressed some concerns including logic of the process. The 3rd item in the process that states 'CDPH is reviewing the application for completeness' does not provide the information reviewers have really been looking for which is knowing from a preliminary reading, the agency expects the data could be released pending the final review process. Dr. Schaeuble notes that limiting it to 'completeness' is not what CPHS reviewers are really looking at here. It seems cumbersome to have the flowchart showing that CPHS will do its review without even receiving a letter from the agency. After the review is completed then the letter of Support will be attached. Any indication of where CDPH is in this process is unknown to CPHS at the time they're expected to do their review. This adds an extra step to release a deferred approval and add a letter later on and allow the process to go back to CDPH. Dr. Schaeuble asked why CPHS should have to wait that long to get a Letter of Support from CDPH. Ms. Lund advising this is a unique and cumbersome situation for vital records data which other state agencies do not have to deal with. VSAC is not a part of or employed by CDPH, thus CDPH cannot give us the Letter of Support based on VSAC until Vital Statistics Committee meets. The VSAC committee only meets every other month. Dr. Schaeuble asked if CDPH could give CPHS an interim letter that CDPH was pending approval from VSAC to release the data. Dr. Schaeuble brings to the attention that the flow chart only states CDPH is checking for completeness of the application and nothing else.

Dr. Dickey advised there is a missing box, which should mention the CDPH process before they can issue their preliminary letter of support. Dr. Dickey asked Who at CDPH issues a preliminary letter?

Ms. Lund asked Joshua Monteiro in the step of the process that mentions 'completeness', does 'completeness' include not only paperwork, but a review for statutory compliance so a LOS can be provided reflecting the things CPHS wants to hear as a committee?

Joshua answered, agreeing there is a missing step in the process regarding a CDPH manager review. Michelle Miles advised there is a CDPH manager review which happens before the LOS is released. Ms. Miles advised adding a step in the process that the manager review will review the project for statutory alignments.

Dr. Schaeuble advised this edit would help but still is curious on why CPHS has to wait on receiving the letter until after CPHS has completed their review. Why does the letter have to come after CPHS is done with their review? Dr. Dickey advised of the statues where it states CPHS will review first. VSAC needs action from CPHS before they can do anything.

Dr. Schaeuble asked if a preliminary letter would be to soon if it came before CPHS review? Dr. Rykaczewska answered that the concern raised by CDPH was that the statues explicitly state the first review is by CPHS, which is why sequencing is needed. Dr. Schaeuble responded

CPHS reviewers will have to assume that CDPH will be approving. Dr. Rykaczewska advised CDPH would notify the researcher, review CPHS findings, and compare the two applications. CDPH will look to CPHS to provide information supporting the application so they can review, ensure all changes are made, and have that inform CDPH's decision making.

Joshua Monteiro advised VSAC will only be reviewing requests for birth and fetal death data. Specifically for death data, CDPH needs CPHS to say the researcher has a valid scientific interest before CDPH approves the data to be released. For birth and fetal death data, CPHS needs to review first, then those findings need to be reviewed by VSAC. VSAC then makes a recommendation to the State Registrar that information shall be released.

Dr. Dickey asked if the death data never goes to VSAC?
Joshua Monteiro answered, advising in general, the death data does not go to VSAC which is mostly involved with birth and fetal death data. There is a Vital Records Protection Advisory Committee, and in that role, they recommend the opportunity to review linked death data sets.

Dr. Schaeuble referenced an earlier comment from Ms. Lund regarding past applications to VSAC and CPHS, were CPHS reviewers have seen differences in what years of data were being requested or what variables were being requested and discrepancies would be sorted out later in the process. Dr. Schaeuble suggests CPHS reviewers still needs to review the VSAC application as CPHS may want to request something different in the CPHS application if CPHS sees discrepancies.

Ms. Lund advised the proposed workflow along with Joshua Monteiro's description of CDPH's work process after CPHS approval, that is not necessary since CDPH will not release data if CPHS has not approved what is described. If the VSAC application looks different from what CPHS has approved, CDPH will take on the responsibility to work with the researcher and to make the changes to the VSAC application to mirror the CPHS application. Or will have the researchers submit an amendment to make changes to the CPHS application. It will be okay for CPHS to just review, to ensure the VSAC application is attached to the application, without having to review both applications together.

Joshua Monteiro advised if CPHS did not look at the initial CDPH application, there will likely be items that are missed and there will be more back and forth because CPHS will not be able to catch obvious items that will not be corrected until CDPH points them out. This would add time to the review process if inconsistencies were discovered. Dr. Schaeuble advised there are often inconsistencies in various places within the CPHS applications, then CPHS goes to the VSAC application to try and sort out inconsistencies in the CPHS application.

Dr. Rykaczewska advised the VSAC application is an additional source of information to help clarify responses researchers are providing. There is no issue for CPHS to look into the application for clarification on what the researchers are proposing. It is an option but not the responsibility of CPHS reviewer to conduct a comparison. CPHS should always use all the information at hand to help inform CPHS discussions with the researchers. There is nothing to preclude CPHS reviewers from looking at the VSAC application.

Ms. Lund asked if CPHS needs to provide more information that clearly states on the IRBManager or website that researchers need to submit an amendment if there are changes after the CPHS approval letter is released. Dr. Dickey advised it is likely CDPH will catch that discrepancy and have the researcher change the VSAC application. Laura advised of the consistencies in dates, and lack of descriptions in the 'procedures' section where the

procedures in the VSAC application are different from the CPHS protocol. She advised these two places are often inconsistent between the CPHS application and the VSAC application. Dr. Schaeuble also noted seeing inconsistencies in variables across the two applications as well in the past when reviewing.

The next item under this agenda are to receive the committee's feedback on drafted Letters of Support (LOS) from CDPH. Dr. Rykaczewska advised there are three letters drafted by CDPH for review that will be presented in the meeting and are available on the CPHS website. The three different Letters of Support include a 'General' letter, a letter specific to 'death data' only, and a 'continuing review' letter.

Dr. Schaeuble has suggestions on some minor changes in the language of the drafter letters. He advised there should be a 'period' after 'required' in the last sentence of the first paragraph of the letters. The sentence begins with the phrase, "If the proposed used of data has been modified…" makes it sound like the end of the sentence, "…release of the information will be in compliance with state laws." Is connected to the 'if' statement at the beginning, which is likely not what is intended. The word 'and' should be removed and the last part should be a separate sentence on all three letters. The committee and CDPH representatives, Michelle Miles and Joshua Monteiro agreed with the change.

The last item on this agenda item is regards to the vital records five-year rule. Dr. Rykaczewska provided some context that CDPH does not institute a separate annual review. Instead, when CPHS concludes their annual review, they send an approval letter to CDPH to inform them CPHS conducted the review, and the research is approved for another year. However, CDPH has a process called a continuing application, which is CPHS calls that application an amendment. Michelle Miles advised CDPH has started to have internal conversations regarding the language issue and is looking to change the CDPH 'continuing application' to be called 'amendment' to align with CPHS terminology.

Dr. Rykaczewska explained CPHS' take on the Five-Year Rule, advising researchers can request up to five years of data beyond what is currently available from CDPH. Before, researchers would need to submit a continuing application, to CDPH. For example, if a researcher requests 2023 data now, they can additionally request 2024, 2025, 2026, 2027, and 2028 data as those become available needing to go back to CDPH.

Michelle Miles explained the Five- Year rule pertains to the in the initial application where researchers can request an additional 5 future years of data and researchers don't have to come back to CDPH every year. Joshua Monteiro also advised the future data is not delivered unless they have a non-expired approval from CPHS.

Ms. Lund advised Dr. Dickey and herself are responsible for the Five-Year Rule. Ms. Lund provided additional background about a past application that was requesting vital records data with a 20-year end date. Ms. Lund and Dr. Dickey felt uncomfortable approving a study for 20-years because, at that time, CPHS had several adverse events in a row involving vital records data for long-term studies where the PI changes but then is not made aware of the rules surrounding the vital records data and the updates to the data sharing agreement. This led CPHS to propose the Five-Year Rule, a reasonable timeframe for a researcher to have to go back to CDPH and have their project reapproved before CPHS approved a continuing annual review. Since laws change, PI's change, and might not be aware of the rules surrounding the data. Ms. Lund emphasized the implementation of the Five-Year Rule is troublesome for staff specifically, and asked CDPH if there is a better way or if there are modifications in approving

these long-term projects. Dr. Dickey advised CPHS was having trouble getting CDPH to review and approve the long-term projects and were advising researchers to reapply to CDPH once the data request surpassed five years while CDPH's rules may have been different.

Dr. Rykaczewska recommended two ways to implement the rules.

1) CPHS check VSAC approval letters during the continuing reviews. When researchers want to add additional years of data, they must submit an amendment to CPHS. CPHS would then check to see if the researcher already received approval from CDPH to have an additional year, or to see if they passed the five-year mark. Timeframes would be checked during the amendment process when the researcher is asking for additional data.
2) Add an expiration date to the CDPH approval letters so CPHS is aware of the end date or alert CPHS of the moment to support our teams in terms of the date CPHS should look at.

Ms. Lund asked how CPHS will handle a situation where there are continuing reviews changing the end date of the project but no request for additional years of data? Dr. Rykaczewska suggested CDPH needs to make sure the end date of the project is aligned. The end date in the CDPH system needs to match what is in the CPHS systems, as through the continuing reviews, an additional year can be added to their end date if the researcher requests it. CPHS will ensure the end date aligns with the project expiration date in the CDPH system.

Dr. Dickey summarized researchers can go into the VSAC/CDPH system through the portal and extend their project end date. Ms. Lund advised this will create an issue. Michelle Miles advised CDPH is talking about putting in a 5-year expiration date into the system. If CPHS gets an amendment, CDPH requires CPHS to push the researcher back to CDPH so CDPH can have the correct information for that project.

Michelle advised CDPH understands a continuing review to be a time for a researcher to request an additional year of data. Ms. Lund advised that a continuing review from CPHS does not require the researcher to request something additional, it's just a check-in with CPHS. Researchers apply to CPHS to continue their project for the next year. The continuing review does not approve access to data, just approval to keep the research project alive. Michelle Miles advised once CPHS extends the project for another year, CDPH's system captures the new expiration date. Michelle Miles advised CDPH runs reports monthly to ensure CDPH applicants have a valid expiration date with CPHS.

Dr. Dickey asked how does CDPH would gather that information? Michelle Miles advised CDPH runs monthly reports, and if project expiration dates are coming due CDPH will send emails to researchers to alert researchers to input a valid project expiration date. Researchers then would need to attach the approval letter into their application. Joshua Monteiro advised CDPH is always checking for changes if an amendment to CPHS is submitted. If researchers request an additional year from CDPH, they need to submit a continuing application, This is built into the current process. CDPH likes the proposal that CPHS will review during the 'continuing review' that happens every year, which is the best way to capture the request for additional years of data if CDPH approves the application for five years, CPHS would have that time. Joshua Monteiro during internal CDPH discussions, this was the best way to implement and check in on projects on a regular basis.

Dr. Rykaczewska summarized that when CPHS conducts the continuing reviews and the researcher is asking to extend the end date of the project by a year, that CPHS checks the end date is consistent with what the researcher put in with CDPH.

Dr. Dickey asked how CPHS would check that as reviewers. Dr. Dickey advised CPHS does not have access to the CPDH system to check the project end dates. Dr. Rykaczewska advised this is where the new expiration date on the approval letter comes into play. The expiration date would align with what the researchers are saying the end date of the project will be. Ms. Lund advised CPHS will not know what a CPHS reviewer approval will mean for the expiration date on the project. Dr. Rykaczewska advised the expiration date is based off the five years. Dr. Dickey asked if the expiration date is in the letter, and CPHS gets it a year six, and CPHS approves another year, how does CPHS know they will inform CDPH? Dr. Rykaczewska asked if CDPH will release a new approval letter with a new expiration date once the expiration date is reached?

Dr. Schaeuble asked if CPHS could have within the IRB Manager, an area that shows both the expiration date that CPHS is working with and from the CDPH approval letter? This would ensure the CPHS reviewers would see the dates at the same time. Ms. Lund suggested adding a question for the researchers to fill out on the application, “What’s the expiration date on your CDPH approval letter?”

Dr. Hess suggested a spot on the IRB Manager where researchers are required upload their approval letter. Then CPHS would have the correct date and wouldn’t have to ask the researchers. Dr. Schaeuble advised it would be better if the CDPH expiration date could be captured as a data item that is stored in the IRBManager application rather than asking the researcher for a response or trying to locate an approval letter.

Dr. Dickey inquired on who enforces this? CPHS sends out reminder letters to researchers to alert them their project is about to expire, but the owners of the data are responsible to send letters to researchers to alert them to extend their project expirations dates. If the data owners do not get a response from the researchers, they should stop the researchers use of the data.

Michelle Miles advised if CDPH does not receive a response from the researcher, CDPH will cease delivery of additional data and advise researchers to destroy the data they have on hand. Researchers should no longer use the data until they acquire a valid approval letter from CPHS with valid expiration dates.

Ms. Lund voiced concern that when Principal Investigator’s (PI) change, and new PIs don’t know the rules and CDPH is not always informed. Ms. Lund asked how CPHS can ensure that when the continuing review comes through, that it is okay to approve the research for another year, or that the researcher has hit the five-year mark and CPHS needs to tell the researcher to go back to CDPH.

Dr. Rykaczewska advised the CPHS administrative team will continue to work with CDPH to resolve the issues of the Five-Year Rule and work towards how to make these implementations. Ms. Lund agreed with two suggestions that the researcher applying for the continuing review either enter the expiration date from the letter or attach the letter so CPHS reviewers can confirm it and regardless of what is happening on the CDPH side, it provides CPHS reviewers with assurance that CPHS is acting responsibly in approving another year. Dr. Rykaczewska advised she will confirm with the IRB Manager vendors to see if that section could be added to the application.

Dr. opened the floor to the public for any public comments. Evan White asked about progress and updates for the Common Application. Dr. Rykaczewska advised the Common Application is still in the works and have been working with five departments to identify the questions asked of researchers combining them into a common set of questions, department specific questions, common Data Use agreements, and the CPHS section of the application. Since there are a lot of interdependencies for the CPHS surrounding the Common Rule and IPA for this project, it was best to slow down to make sure it reflects the current processes.

D. Discussion of draft Decision Tree

Dr. Rykaczewska presented the draft decision tree for IPA and Common Rule reviews to gather feedback from the committee. The draft decision tree has been posted on the CPHS website for reference. Dr. Rykaczewska notes that the CPHS admin team has been facing challenges on identifying the review types, and CPHS is receiving questions from researchers about guidance on when the IPA applies and when does the Common Rule apply. The intention of the draft decision tree is to create a simple tool for CPHS, committee members, and researchers to understand which laws apply to them. Dr. Rykaczewska notes that she recognizes that CPHS continues to have discussions around IPA and Common Rule and the CPHS sub-committee still meets to discuss draft regulations. The intention is to make this decision tree independent of what the subcommittee is still working on. The flowchart provides differentiation on when the IPA applies or when the Common Rule applies. Dr. Rykaczewska worked closely with Maggie Schuster to develop this reference tool.

Since the IPA and the Common Law are two separate laws that operate independently of each other. In this flowchart, the two laws are separated out into two separate questions. Sometimes research studies can fall under both IPA and the Common Law.

Dr. Rykaczewska presents and goes through the decision tree for the committee. Starting first with the section for the Common Rule. The series of questions that has to be answered starts with is this a research study, per regulatory definition? Reference material is provided on the document that defines research under 45 CFR 46.102(l). If the answer to that question is yes, the next questions is, does the research involve human subjects, per regulatory definition? The reference material for this question is the guidance from 45 CFR 46.102(e)(1).

Ms. Lund thanked Dr. Rykaczewska in capturing both the interacting with human subjects and the use of data sources, both under Title 45. Data only studies that are subject to the Common Rule. Dr. Dickey advised the operative word in this section is ‘obtains’. If data is being ‘obtained’, then one is engaged in human subject’s research. Dr. Dickey advised CPHS receives a lot of IPA-only requests which are not considered human subject’s research.

The next question is CalHHS is involved in the research, per regulatory definition? The reference for this question comes from Office for Human Research Protections (OHRP) guidance in 2008 that clarifies the criteria for if an institution is considered engaged in the research. Ms. Lund requested clarification on the ‘engaged’ definition. Atty. Goldman advised ‘funding’ does not mean ‘engaging’. Ms. Lund sought confirmation that if a CalHHS department is funding a research study, CPHS does not have Common Rule purview as a board over that study? Atty. Goldman advised that was correct, as it wouldn’t prevent a department from requesting an IRB review. Departments control their own information and can request an IRB-level review.

Dr. Hess advised that departments that fund studies are engaged. Most state funded projects will have a level of involvement by state staff. Dr. Dickey advised if state staff oversee the contract, is that considered engagement? Atty. Goldman advised just because Agency has a contract with someone does not engage Agency in research, and the cases being brought up are all fact specific and does not want to make any broad generalities.

Dr. Delgado advised it is the distinction, as a grants manager performs very different activities than a staff member who is helping to develop questions or review iterations of and editing said findings. Dr. Hess advised there could be places where departments try to exploit their level of involvement in the research. Should the distinction be made in writing on what constitutes engagement on behalf of a CalHHS department? Ms. Lund suggests when CPHS asks requestors to list the research staff involved, if there is anyone with a department email, CPHS can consider that department is engaged in the research as opposed to having a contracts manager be involved. Atty. Goldman advised including a link to the OHRP guidance which defines 'engagement' so people refer to the rule in place.

Dr. Azizian asked about during a program evaluation, what happens if later after the findings, the researchers want to present the information in a conference or publish? Will the researchers need to come back to CPHS for us to approve and review? Dr. Dickey advised publication is not part of the standard for generalizable knowledge, and because they publish it does not make it research. Ms. Lund advised researchers can publish a program evaluation as long as it is an evaluation. As for generalizable knowledge, researchers can publish if it is specific to the one program. Dr. Dinis advised there are journals that won't accept publication without IRB review. Dr. Dickey explained the traditional workflow on this process for CPHS and advised there are applicable forms for researchers to complete to declare if the project is 'not research' or 'exempt'. The decisions are then made by the CPHS Chair before those projects even get to the CPHS Committee. Researchers must specifically apply for it. Dr. Dickey explains 'Generalizability' is a vague concept and the OHRP guidance says that just because something is published does not make it 'generalizable'. The researchers would have to make a judgement call. Ms. Lund advised the form language discussion can be resolved in another meeting. Dr. Rykaczewska suggested an addendum could be useful (instead of trying to fit all the examples into the box on the flowchart), as well as specified guidance on generalizable knowledge and reviewing with the committee.

The next question in the sequence is, does the research qualify for a regulatory exemption? The reference section contains the eight different exemptions from 45 CFR 46.104. Ms. Lund noted that items 7 and 8 do not apply to CPHS, since the committee decided not to engage and noted that broad consent is optional for the committee to adopt or not. Dr. Dickey noted a lot of IRBs consider the research projects exempt where CPHS does not consider then to be in the exemption category due to different reasons such as vulnerable populations. The process for exempt application is to be screened by the CPHS Chair and Vice Chair. If they do not qualify for exempt, then the project is reviewed under the Common Rule. If it does qualify to be exempt it is not reviewed under the Common Rule.

Ms. Lund was thankful and advised this version is much clearer than the last flowchart. She noted it generally captures the process. Dr. Delgado advised CPHS wants to be consistent as a committee in discussion and processing of information.

Dr. Rykaczewska noted that is the end of the Common Rule side of the flowchart, and there is the Information Practices Act (IPA) side of the flowchart. The first question on this section is, does CalHHS have purview under the IPA?

The next question is, is the researcher requesting the disclosure of personally identifying information for the purposes of conducting scientific research? Ms. Lund suggested changing the language to say 'PII from a state agency…', Dr. Rykaczewska agreed with the language edit MS. Lund suggested. If the answer is No for this question, then, CalHHS CPHS does not have purview under the California IPA. If the answer is Yes, then CalHHS CPHS has purview under the California IPA.

Dr. Dickey advised there are other ways researchers can use data and they would go to a different section of the IPA. Attorney Schuster advised there is not specific definition of 'scientific research' in the IPA that CPHS can refer to. Dr. Bazzano suggested looking at other IRB's definitions to stay consistent and not start from scratch. Attorney Goldman suggested CPHS has conversations to work to reach a mutual understanding on but cannot issue a policy on. Ms. Lund asked, and Attorney Goldman if this is something that can be included in the regulations. Attorney Goldman let Ms. Lund that is something he will have to look for into.

Dr. Rykaczewska noted at the bottom of the flowchart it has a key to suggest if researchers answered Yes or No to the two different flow charts CPHS would have purview or not. Researchers must answer both questions to know if the project needs to be reviewed under Common Rule, IPA, or both.

Ms. Lund expressed her gratitude for the flowchart and noted that the summary at the bottom to explain if the project should be reviewed under Common Rule, IPA, or both was a great way of pulling out all this information.

Dr. Rykaczewska opened the discussion for public comments on the agenda items. There were no public comments made.

E. Discussion of Committee Member Continuing Education

a) Discuss Continuing Education requirements

Dr. Delgado thanked the admin team for the work on researching the trainings for the committee and asked Dr. Rykaczewska to provide the update on the continuing education. Dr. Delgado noted to the committee she mentioned in a previous committee meeting requiring training. She did not understand the length of the training. Dr. Dickey, CPHS Vice-Chair, advised that most research institutions do require researchers to complete training, and IRB's tend to enforce it.

Dr. Rykaczewska presented page 12 of the policies and procedures. The policy and procedures are located on the CPHS website for reference. Dr. Rykaczewska suggested two different approaches to the continuing education. The first approach is to do the training through Health and Human Service (HHS) that is a 5 and a half hour training and includes 5 different lessons.

1) Lesson 1: When HHS Regulations Apply
2) Lesson 2: What is Human Subjects Research
3) Lesson 3: What are IRBs
4) Lesson 4: IRB Review of the Research

5) Lesson 5: Institutional Oversight of Human Research

The other option Dr. Rykaczewska presented was CITI trainings. The trainings available through CITI include 6 different trainings ranging from various content.

1) IRB Member (Length of section: 15- 20 hours)
2) IRB Protocol Review (Length of section: 2 hours)
3) QA/QI: Human Subjects Research (Length of section: 2 hours)
4) Information Privacy & Security (Length of section: 1-2 hours)
5) Becoming an Effective Leader (Length of section 2-3 hours)
6) IRB Administrative Comprehensive (Length of section 5-6 hours)

Dr. Rykaczewska suggest the required courses for the committee members would include IRB Member and Information Privacy & Security. The total hours for the training would be around 16- 22 hours. The remaining trainings would be optional for the committee members to pursue additional topics.

The CPHS administrative staff required courses would include IRB Administrative Comprehensive and the IRB Protocol review. The total hours for those trainings would be around 7-8 hours.

Dr. Rykaczewska opened the discussion to the committee members. Dr. Hess advised as a researcher the CITI training is superior to the HHS trainings. Noting that the CITI training is more comprehensive and useful.

Dr. Schaeuble asked if these trainings are required or strongly recommended. Dr. Schaeuble noted that he does not have an extra 22 hours available in his schedule.

Dr. Rykaczewska expressed recognizing that the committee members are on a volunteer basis. Dr. Hess mentioned as a researcher she was required to have completed CITI trainings before she was able to submit a protocol. Dr. Dinis advised she was required by Sacramento State, but the training was less burdensome and was only 2-hours long.

Dr. Azizian asked if there is a timeline on which this training is supposed to be completed.
Ms. Lund suggested adopting the CITI training based on the recommendations in the discussion. The work CPHS does is very important, and it makes a difference to be educated on the work that we do. Ms. Lund asks if a possible time frame would be within the next year?

The CITI training provides a certification upon completion, and the certification expires after three years. Dr. Hess explains that CITI offers refresher courses that are very useful.

Dr. Delgado aired concerns about the mandated completion date and CPHS staff rushing to complete the training at the last minute. Dr. Dickey asked about CalHHS reimbursing the time for completing the training, specifically if it is required. Dr.

Rykaczewska let Dr. Dickey she will look further into it. Dr. Delgado advised the state-wide budget cuts should be considered in this ask. Dr. Schaeuble asked what the enforcement would be. Dr. Rykaczewska advised looking further into some of the questions before feeling comfortable taking an action on this agenda item.

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Dr. Rykaczewska opened the discussion to the public for comments. No comments were presented.

F. Public Comments

Dr. Delgado acknowledges that CPHS has received public comments in email and the emails have been posted the CPHS website and distributed to the committee members. Dr. Delgado encouraged the public to continue to and the board wants to continue to engage with the public on these topics. Ms. Lund expresses her concern for the level and scope of misinformation that is being circulated in the research community for the subcommittees efforts to develop regulations for the IPA. Ms. Lund wants to be clear that the committee is not entertaining going back and retroactively obtaining informed consent for peoples whose information was presented in a state administrative database. The subcommittee is not interested in changing anything regarding to the Common Rule review of projects, and the intention of the regulation is strictly to help make clarifications on how IPA only projects are reviewed. Ms. Lund notes that the subcommittee has not yet developed regulations but are finalizing a document that provides the underpinnings for how CPHS approach reviews of IPA only projects, and what criteria to consider in the reviews. Ms. Lund encourages the public to attend the meetings to hear the discussions that the subcommittee are having.

G. Next Meeting

The next CPHS full board meeting is scheduled to be held on Friday, December 6, 2024.
The next CPHS sub-committee meeting is scheduled to be held on Friday, November 8, 2024.

H. Adjournment

This meeting was adjourned at 11:33 AM on November 1, 2024.