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)

Subcommittee Members
Maria Dinis, PhD, MSW
Carrie Kurtural, JD
Laura Lund, MA
John Schaeuble, PhD, MS

Remote Attendees
Maria Dinis, PhD, MSW

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

Zoom:
CPHS November 8, 2024, Full Committee Meeting

Meeting ID: 161 838 8600
Passcode: 101616

Location:
1215 O Street,
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Meeting ID: 161 838 8600

CPHS Administrator
Agnieszka Rykaczewska

MINUTES

Committee Members Present in Person:

Laura Lund, MA
Carrie Kurtural, JD
John Schaeuble, PhD, MS

Committee Members Present Remotely:

Maria Dinis, PhD, MSW

CPHS Staff Present in Person:
Agnieszka Rykaczewska, PhD
Sussan Atifeh
Karima Muhammad
Nicholas Zadrozna

Also, Present (All via ZoomGov) Members from the Public
Evan White
Agnes Balla

A. Welcome

Ms. Lund called the subcommittee meeting to order and roll call was called to confirm quorum. Ms. Lund invited the public joining the meeting to introduce themselves via the zoom chat or by verbally introducing themselves. No one from the public introduced themselves at this time of the meeting.

B. Review Revised Materials and Drafts

Ms. Lund brought to the attention to the other committee members that CPHS has received numerous public comments regarding the regulation process. Ms. Lund noted after reading through all the public comments that there are some misunderstandings from the public in the documents being developed and the goal of the subcommittee. Ms. Lund suggests going through the document and discussion slower to explain the purpose of the document and what the subcommittee hopes to achieve with the document to clear up any confusing the public might have.

Two documents were submitted and shared in advance of the meeting that are posted on the CPHS website. The first, submitted by Dr. Schaeuble, is a revised framework for additional IPA review criteria. This revision, prepared in collaboration with Attorney Jared Goldman, incorporates changes based on the motion passed during the last meeting.

Ms. Lund emphasized that th**e** document does not represent any regulations language and is intended to be a supporting documentation that contains the committees' beliefs about potential risks in Information Practices Act (IPA) projects, the committees concern with those projects, and how the committee will move forward in reviewing those projects. Ms. Lund suggests referring to the document being discussed as the supporting document.

Ms. Lund invited Dr. Schaeuble to go over the supporting document and explain the changes that were made from the previous draft of the supporting document. Dr. Schaeuble informed the committee that the newest draft has no changes from the first page. On the second page, the final item in the middle section of the document was removed as requested from the last committee meeting. The third section was completely revised to reflect discussions with Attorney

Goldman. The intent of the final section is to clearly state what CPHS expects from researchers to the extent researchers can get a meaningful response when they apply for data if they also ask the question what the individuals were told when the data was originally collected. The committee understands that in many instances, researchers may not have the full answer, but if the information is available the committee would like to know.

Dr. Schaeuble informed the committee that the final item is stating that the risks have been identified in the middle portion of the supporting document as potential risks for a data research project. The researchers should identify which risks apply to their research, to which degree, and describe what the researchers are doing to minimize the impact of the risks.

Attorney Goldman advised overall the committees aim is to ensure the sufficiency of the privacy plan being submitted, for the plan to protect personal information from improper use and disclosure and ensure there's a sufficient plan to destroy information when the project is over. To ensure CPHS has sufficient written assurances personal information won't be reused or disclosed improperly. To understand the sufficiency of those plans and assurances, the subcommittee has identified risks to consider in determining the sufficiency of those plans and assurances.

Attorney Goldman mentioned the modifications in the last section of document was to make the language more efficient. The aim of the supporting document is to elicit information from researchers which would allow CPHS to identify and assess the risks that are described in the second section. The last sentence is a catch-all request for information about the risks. In addition to asking researchers to provide information about the identified risks, connected to a few of the risks in the supporting document is the request for researchers to provide information about their disclosure or consent process, if there was one.

Ms. Lund thanked Attorney Goldman. Ms. Lund advised when the committee talks about these risks, they are risks the committee is reasonably concerned about. It is the committee's goal to assess the risk of people's whose data are being used in the study. The risks identified by the CPHS subcommittee are not intended to convey to researchers that if these risks are identified in their study, it will mean that CPHS will not approve the study. That is not the case, these are simply risks CPHS needs to take into consideration and assure are mitigated prior to approving the study. Ms. Lund wants to make it clear to the public, since some of the comments from the public, there is concern that researchers will be denied access to the data if their study contains one or more of these risks, which is not the intent of enumerating these risks. CPHS' intent is to merely view the risks clearly and talk about risk mitigation.

Dr. Schaeuble agreed with Ms. Lund. Dr. Schaeuble noted it's important for the public to understand CPHS is not in the business of disapproving research. The committee works extremely hard with researchers to address concerns that arise during the review process. Dr. Schaeuble advised in his years working with the committee, there is only one instance where research was disapproved by the committee he can recall.

Ms. Lund brings up a concern with the language in the first item of the third section:

If the individuals whose information will be used were told, when the data were originally collected, that their information might be used for research, what language was used in that explanation, and the context or situation in which that explanation was provided.

Ms. Lund advised for the large administrative data sets that the state collects, such as the California Cancer Registry (CCR) and the various California Department of Public Health (CDPH) data sets it is unrealistic. Ms. Lund notes the wording sound like CPHS is asking for people to know for certain that individuals were provided with their privacy notice. Ms. Lund suggest that it is unrealistic expectation. Ms. Lund notes that it sounds like CPHS is asking researchers to know for certain that subjects were provided with their privacy notice. CPHS can't know that, and it is an undue burden. Ms. Lund suggested including language that refers to whether the agency obtaining the data has a process in place to ensure subjects receive the information. It is not the obtaining agency's fault and should not be the burden on the researcher if someone dropped the ball on giving a privacy notice. Ms. Lund suggests it is too high a bar for CPHS to require researchers to ensure every subject received the privacy notice.

Dr. Schaeuble advised he reads the language differently than how Ms. Lund is suggesting. If the obtaining agency didn't know whether subjects were informed in some way, Dr. Schaeuble suggest the obtaining agency would say so.

Ms. Lund referenced Dr. Schaeuble's example, advising that all obtaining agencies would say they don't know. In California, the birth data works under the law is the administrator/ hospital where the birth occurred and is responsible for filling out the birth certificate, submitting it to the county, providing it to the parent giving birth, including the privacy notice that goes along with it. The parent giving birth gets a thick packet from a birth clerk containing information about the new child's birth certificate. The hospital is supposed to have this process in place where they get all this information, then the administrator submits all this information to the county, the county submits it to the state, and the state turns it into the birth data that researchers are always requesting. The state releasing the birth data has no way of knowing that in each case, a birth clerk at the hospital provided the privacy notice to the parent giving birth, even though that process is in place and the hospital is required by law. There is no quality control check. If hospitals were put on the spot and asked if they knew for sure the birthing parents were aware their child's birth certificate data would be used, the hospital or administrator can say what's supposed to happen but would not know what happened in every case. Ms. Lund believes the same is true for all state data which is first locally collected, then given to the state.

Ms. Kurtural advised there are contractors responsible for this whether it's the 58 counties or the 21 regional centers. There are requirements and various healthcare services require contracts with the counties vs. the contracts with the regional centers with a business associate agreement which requires a Notice of Privacy Practices (NPP). The NPP has a requirement to have a minimum criterion of a contract requirement which the contractor is expected to follow.

Dr. Dinis asked the committee, when an agency advises their data is not going to be used for research purposes but give the data to researchers for research purposes. What does CPHS do in those circumstances?

Laura Lund responded the purpose of the regulations is to provide a basis for CPHS to evaluate data sharing. Most agencies have a privacy notice or multiple privacy notices, depending on how many databases are released and which statues are covered. She is not aware of an agency that tells subjects their data won't be used for research. Ms. Lund asked Dr. Dinis if she had a particular agency in mind.

Dr. Dinis advised the Student Aid Commission website has is a statement that their information is not going to be used for research purposes. Dr. Dinis suggest that it creates a problem because there are entities who collect private data and they're assuring the respondent that the data it's not going to be used outside of their organization. Which creates a conflict for CPHS.
Ms. Lund suggested slightly modifying the wording as such: "If the State agency releasing the data has a process in place to ensure that individuals whose information will be used…" The researchers can describe the process to the committee even though they can't ensure that in every case, the individual was, in fact, informed.

Ms. Kurtural advised that committee members should know the California Health and Human Services (CalHHS) departments process with the NPP. Ms. Kurtural suggests what Dr. Dinis described is when agencies connect state data with another entity's data, and the other entity has rules stating the data can't be used for research purposes. CPHS would not be informed on the other entities rules and recommends adding an application requirement if the researchers are informed on the outside agency.

Ms. Lund informed Ms. Kurtural CPHS does not have purview over the outside agency. The CPHS purview is over state data and ensuring the people's data collected by a state agency were told how their data was going to be used and if it was going to be used for research. If the data is given to another entity, that is outside of CPHS purview.

Dr. Schaeuble requested to backtrack the discussion advising there are two very different situations and only one situation was being discussed. There are instances when an agency receives data from several sources and compiles it together into information systems to share with researchers. The other situation is an agency is directly collecting information from individuals, which is different from compiling it from other entities.

Dr. Schaeuble suggests that as reviewers, CPHS has an obligation to understand what individuals were told. For the most part, CPHS does not know the total extent to which information was or was not conveyed, or the context in which it was conveyed. This should be the perspective that CPHS takes when assess the kinds of risks listed in the middle part of the supporting document. Which is very different from knowing that people were clearly told their information might be used for research, offered examples of the kinds of research it might be used for, and the kinds of protections that would be in place. These and similar statements are likely missing in the situations described, where agencies collected information from a variety of sources and are not aware of what was said, or very little information was shared.

Ms. Lund advised people do know because the privacy notice is standard, and data are collected on behalf of the state. The state is on the hook for data they collect from the counties, who get it from the hospital. The state is responsible for the privacy notice and the hospital is responsible

for making sure the privacy notice was administered. The California Cancer Registry (CCR) operates the same way. The privacy notice is about the state requirements and the state data. The state does not directly interact with the person whose data is being collected. Someone interacts on behalf of the state.

Dr. Schaeuble asked if CPHS can know the content of the privacy notice. Ms. Lund advised CPHS can find out the content of the privacy notice, whether it be in an CDPH immunization database, California Cancer Registry (CCR), and birth data.

Ms. Kurtural suggested changing the wording. Ms. Kurtural expresses her main concern as a project reviewer is when state data is mixed with outside entity data and CPHS does not know how the data is being used. Although CPHS can find out internally what each department is doing and make suggestions and recommendations.

Dr. Schaeuble asked if the language would be uniform across the privacy notices used by different agencies.

Ms. Lund advised the privacy notice language is not uniform within the same agency. The language in the privacy notice is specific to the statues that govern the data being collected. For example, the privacy notice for the CCR is different than the privacy notice for the birth data and the privacy notice for the immunization branch. The collection of data for those purposes falls under all different statues. The statues must be referenced in the privacy notice and what can be done with the data may be different across the statues. Ms. Lund summarized in the case for CDPH the NPP's are all different.

Ms. Kurtural advised its common in the NPP to have a research exception. Dr. Schaeuble asked how prominent this feature would be within the document. Ms. Lund Referenced the birth data example, advised the privacy notice for the birth data used to be at the bottom of the birth certificate the birthing parent had to sign. However, the privacy notice got too big to fit on the page and approximately 5 years, it was changed to a stand-alone privacy notice. The birthing parent signs the birth certificate and is handed the stand-alone privacy notice included in a stack of documents containing other information about the birth, including immunizations. For immunizations, the privacy notice is given at the time the information is collected and when the immunization occurs, and then is entered the database by the county. The prominence of the privacy notice varies considerably.

Dr. Schaeuble voiced his concern the language does not consider the agency of the individuals whose information is being used for the potential use of research information, if there was effective communication or not. Dr. Schaeuble talks about his personal experience at the hospital. In the NPP it typically has one sentence within many pages of a longer document in the midst of a stressful situation that says a patient's data will be used for research. Dr. Schaeuble believes this does not constitute what the committee would think of as informing people their information might be used in ways they do not anticipate. If CPHS does not ask the context and situation in which the communication takes place, CPHS cannot say they know anything about what patients have been told.

Ms. Lund advised the bar may be too high for CPHS. As with the birth data, state law takes away the agency for many people whose information is collected for large databases. Birthing parents cannot refuse to provide birth data which is true for a lot of databases collected by state agencies. It's too high a bar for CPHS to ask researchers to ensure people are informed in a way that they truly understood. Informed consent is not possible in these situations. Asking state agencies to change their process way outside of CPHS scope. Ms. Lund suggests that as a reviewer she is looking that their a process is in place and that there was an opportunity for people to be informed their data could be used for research.

Dr. Dinis agreed with Ms. Lund that the bar is high for CPHS to require such information from agencies. Dr. Dinis is concerned that it is not clear in the privacy notices that data will be merged with other data sets, it just states it can be shared with researchers. Analyzing the data is much different from sharing the data. The privacy notices can be conflicting, noting identifiers will not be shared in one situation, but shared in another situation. Which is confusing to the person reading the privacy notice.

Ms. Kurtural advised privacy practices are usually posted on the entity's website which makes it accessible to someone or to outside agencies. The researchers can attach the privacy practices to the CPHS application, and CPHS can then consider the privacy practices on the analysis, rather than the reviewers locating them.

Ms. Lund summarized that the committee is discussing having an additional piece of information in the application to provide reviewers with assurance about mitigation of risks. If available, the researcher can provide privacy notices which were provided to people from whom data were collected for all the databases being considered in the application.

Ms. Lund asked Attorney Goldman on his thoughts about current discussion. Attorney Goldman expressed he does not have any strong views but does agrees with what Dr. Schaeuble initially proposed. Attorney Goldman expressed he agrees with striking the item and replacing with a requirement that the researcher provide, to the extent known, a copy of the notice of privacy practices that would ordinarily be provided to the subjects, along with the description of the process for providing it.

Ms. Kurtural agreed with Attorney Goldman's language on adding if available, the researcher provided any notices or practices originally provided to the individuals, that would be subject to know data and a description of the process.

Ms. Lund suggested language for replacing the last item in the supporting document to state: "If available, researchers will provide the privacy notices and the process for providing people with those notices associated with all databases that they're including in their application." Ms. Lund opened the discussion to the public for any comments.

Dr. Evan White from the California Policy Lab provided in the chat the link to the privacy notice on the Student Aid Commission website. "From CSAC's privacy policy (https://www.csac.ca.gov/post/privacy-policy): The Commission may disclose personal information to other government entities or other organizations for purposes related to the

Commission's management of state financial aid programs. These purposes may include research projects and outreach efforts that assist the Commission in meeting its objectives, consistent with the IPA, FERPA, and HEA, and the statutory provisions that govern each of the Commission's programs."

Dr. White also provided a public comment via zoom. Dr. White applauded the CPHS subcommittee on the careful consideration of these issues. Dr. White disagreed with the effort, advising the draft regulations are legally flawed and misguided from a policy perspective. Dr. White acknowledged Ms. Lund's distinction between the eventual regulations which will appear in the supporting material. The document in question falls outside of the Information Practices Act (IPA) which limits CPHS review to data security matters. Most of the IPA does not relate to CPHS, only sub-section T, which is where it is limited to a narrower scope. In addition, CPHS does not have the expertise, training, or legal authority to perform a legal review of whether the data being released complies with existing privacy policies or other laws and regulations. This is the responsibility of the agency releasing the data, who is already equipped with the expertise, training, and legal authority to make those determinations. The inquiry into what happened when the data was originally collected will lead to erroneous or outside-the-law determinations of what is legally permissible. Dr. White is far more worries about the policy implications. This effort appears to have arisen from a desire for CPHS to regain authority CPHS was exercising unlawfully in applying Institutional Review Board (IRB) authority to Information Practices Act (IPA)-only projects. When CPHS was informed they were exercising unlawful authority, CPHS wrote these regulations to regain that authority. The aims are laid out in the supporting materials reflect CPHS' desire to second guess considered judgements by federal and state legislatures and by the agency releasing the data, that is not the role of CPHS. Dr. White explained his level of subject matter expertise and advised CPHS to remove personal views since they cannot and should not be relevant to the review under the IPA. The IPA focuses on a plan to protect personal information, a plan to destroy it or return it, and written assurances against further disclosure. Dr. White mentioned that CPHS keeps uses IRB language such as minimal risk, consent, and vulnerable groups which are nowhere to be found in the IPA and are not a part of the limited review that the state assigned to this committee. Dr. White mentioned that he heard the new criteria will not be an automatic disqualifier and agrees. Although not automatic, it is still new criteria for disqualification. The IPA is currently about routine data security matters and CPHS is transforming it into something more complex by approximating an IRB review and in some cases exceeding the Common Rule. The committee may choose to call it risk mitigation, but when you ask a researcher to go back and get consent for pre-existing administrative data or go back or go back and find all the different things that were said to people when data was collected even when they were legally assured by the people responsible that it was permissible, it's implicitly grounds for disapproving the research. Dr. White advised this effort can and will prevent valuable research, which to date, is valuable social sciences.

Agnes Balla the Director of Research Policy and Analysis & Coordination within the University of California (UC) Office of the President provided a public comment for the committee. Ms. Balla advised she works on a range of topics, including working with UC IRB directors and have been discussing the CPHS efforts with them. Ms. Balla mentions she has submitted a public comment in writing ahead of this meeting and after listening to the discussion today the comments provided are even more true. There is concern CPHS is muddling its role. Ms. Balla

explains how she understands the roll of CPHS that they are the IRB for California Health and Human Services Agency (CalHHS) for the studies funded and supported by CalHHS. Separately, CPHS conducts reviews laid out under the Information Practices Act. However, a lot of the discussion today seems falls more into the role of an IRB as opposed to a technical and security review laid out by the IPA. That is troubling for many reasons, not only does it complicate an already complicated picture for our researchers, but it does not get us anywhere. Ms. Balla fully supports and echo what Dr. White mentioned, when using terms like minimal risk that are defined under the Common Rule for something that is unrelated to conducting a review under the Common Rule really complicates the picture, and suggests that is not the direction CPHS should be going in. The other point Ms. Balla mentioned is that there is a legitimate concern around privacy protections, but mainly around how state agencies are collecting state information. Ms. Ball referenced the case that was discussed about the birth certificate example, how do we guarantee state contractors are providing notice of privacy practices. Ms. Ball is very concerned that researchers are going to be penalized for state agency action. If state agencies have that concern, it should be legislated, but not by this committee. Ms. Balla strongly suggests this effort be revisited and not carried forward.

Dr. Evan White asked the committee in the chat "What is the status of the proposal to impose fees that was mentioned at the August meeting?"

Dr. Rykaczewska advised there will be an update on the fee's conversation at the December meeting. Dr. Rykaczewska mentioned that the December agenda is not finalized, but the proposal is being revised based off the feedback received during the August meeting.
No more public comments were provided for this agenda item.

Ms. Kurtural suggests adding to the language, if available and if the data is linked with other sources. Ms. Kurtural mentioned that CPHS contracts with all departments within CalHHS and should not place the burden on the researchers. Dr. Schaeuble asked and Ms. Kurtural as reviewers how do we have that information. Ms. Kurtural suggested reaching out to the departments that we have contacts with to gather that information and some departments have it posted on their website

Ms. Lund advised this would be difficult since some departments have so many data set's and no one is centrally in charge of all the datasets, advising the burden needs to go with the dataset itself. Ms. Lund agrees with Ms. Kurtural suggestion since this is when the level of risk goes up. Dr. Schaeuble advised if there is no proposal to link data, CPHS will not otherwise know what privacy information was provided to individuals.

Ms. Lund asked if there was concern over CPHS having the privacy notices for the requests for single databases. Dr. Schaeuble advised it would be a case-by-case basis and would depend on the sensitivity of the information and the way it is being used. Which in some instances Dr. Schaeuble suggests he would want to know that information.

It was discussed that many of the examples discussed point to a category of information where many pieces of information are not concerning in CPHS reviews, but in some instances the

requested variables would lead to greater concern from CPHS. In that case, reviewers need to know the process in which people are advised of the potential for research.

Ms. Lund asked Dr. Schaeuble based on his concern should the committee go back to the original wording, or does he suggest only when the data is linked with other data sets.
Ms. Kurtural suggests making a motion in the case that the researchers are linking data or to make a motion at the next meeting and get proposals from the full committee on this topic before making a motion.

Ms. Lund agrees with Ms. Kurtural taking this back to the full committee for discussion and decision. Dr. Schaeuble suggested having two separately worded alternatives be developed by the subcommittee and presented to the full committee instead of vaguely discussing the topic. Ms. Lund advised the CPHS subcommittee ask for CPHS full board input on the restriction of request for NPP documents to studies where multiple data will be linked, the second option, if CPHS wants an NPP and a description of procedures provided with every study that's submitted for IPA review. The third option does CPHS want an NPP, and a description of the procedures provided only for studies meeting one of the risk criteria in the CPHS supporting document.

No more public comments were presented to the committee.

Motion: Ms. Kurtural moved, and Ms. Lund seconded that the subcommittee take the supporting document draft text back to the CPHS full board for review and recommendations, further the subcommittee will take the following questions to the full board:

1. Do we want to restrict requests for NPP documents and description of procedure to only studies that propose to link data from multiple data sources? or
2. Do we want to include requests for NPP documents and description of procedure to all studies reviewed under the IPA? or
3. Do we want to have the NPP and description of procedures only for studies meeting one of the risk criteria enumerated in the document?

Approve: Ms. Kurtural, Ms. Lund, Dr. Dinis, Dr. Schaeuble
Oppose: None.
Abstain: None.
Absent: None.

Total= 4 In Favor- 4, Opposed- 0, Abstained- 0

a) Review Proposed revisions to criteria and outline of regulations

The Proposed Regulation Text document was shared on the screen for the committee members and displayed in the meeting via zoom. Ms. Kurtural suggested to clarify that these regulations are for IPA-only review process. Ms. Kurtural reviewed the CPHS policy and procedures and Health & Safety Codes which outlines CPHS's statutory authority. Since CPHS has not

developed regulations before, Ms. Kurtural drafted a comprehensive outline, including what should be included in the regulations.

b) Review and discuss questions regarding proposed definitions

Ms. Kurtural advised the purpose of regulations is to make the law specific and provide clarification. Ms. Kurtural suggest that CPHS clarifies more than just the criteria and include definitions. She noted this will be helpful for the public to know the process of CPHS as a committee.

Ms. Kurtural requests feedback from the subcommittee in defining an 'IPA-only project', 'hybrid project', and 'Common Rule-only project'.

Ms. Lund agreed with Ms. Kurtural for including a definition section and suggested what was presented at the CPHS full board meeting on November 1 regarding the Common Rule vs. IPA could be included in this Proposed Regulation Text document.

Ms. Kurtural suggests starting with collecting suggestions from the subcommittee, committee and the public for definitions on what should be defined as an IPA only project, a Common Rule project, and a Hybrid project. After the definitions, the subcommittee would then start working on the criteria and requirements.

Ms. Lund advised the definition are already defined but need to be put into text. The Common Rule is defined in the Federal Wide Assurance (FWA) and Attorney Goldman can provide his input. Attorney Goldman suggest not to repeat the requirements in the Federal Wide Assurance (FWA) or in the Common Rule. Attorney Goldman suggested limiting the regulations to additions to the Common Rule or clarification needed for the IPA. Attorney Goldman also recommends the scope be narrowed down and approach the regulations in small chunks rather than trying to put an entire regulation package together.

c) Discuss regulation topic to review for next meeting

Attorney Goldman suggested that CPHS subcommittee does not draft regulations but turnover policy statements to have the legal team draft the regulatory language and come back to the CPHS subcommittee for full approval.

No public comments were virtually or in person.

C. Discuss Potential Revisions

Ms. Lund suggested that Agenda item C was incorporated in Agenda item B, and asked the subcommittee if there was anything additional, they should address.

No public comment virtually or in person

D. Next Meeting

The CPHS subcommittee is scheduled to meet next on January 10th, 2025.

No public comment virtually or in person.

The next CPHS **full board committee** meeting is scheduled to be held on Friday, April 25th, 2025.

E. Adjournment

This meeting was adjourned at 10:36 A.M on November 8th, 2024.