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Director & State Health Officer

Vital Statistics Advisory Committee (VSAC)
Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday June 10, 2015
9:00 A.M.



EDMUND G. BROWN JR.
Governor

ATTENDEES:

Convener:

Henry Montes, Chief, Data Management Unit

Committee Members:

Phone: Emily Putnam-Hornstein, Assistant Professor, University of Southern California, Shannon Muir, PhD, Science and Technology Fellow, Senate Health Committee, Jonathan Teague, Manager, Office of Statewide Health Planning and Development, Erlinda Valdez, Board Member, California Funeral Directors Association, David Grant, PhD, UCLA Center for Health Policy Research, Sun Lee, MPH, Los Angeles County Department of Public Health

California Department of Public Health (CDPH) Staff:

Present: Cindy Tanaka-Fong, Research Analyst II, Data Management Unit, Colin Chew, Research Analyst I, Health Information and Research Section, Laura Lund, MA, Science Advisor, Public Health Policy and Research Branch, Henry Montes, Chief, Data Management Unit

Public Attendees: No Public Attendees

CALL TO ORDER: The meeting was called to order at 9:00 A.M.

A/B. WELCOME/INTRODUCTIONS:

Staff present attending the meeting included: Cindy Tanaka-Fong, Research Analyst II, Data Management Unit, Colin Chew, Research Analyst I, Health Information and Research Section, Laura Lund, MA, Science Advisor, Public Health Policy and Research Branch, and Henry Montes, Chief, Data Management Unit.

Committee members on the phone included: David Grant, PhD, UCLA Center for Health Policy Research, Sun Lee, MPH, Los Angeles County Department of Public Health, Emily Putnam-Hornstein,

Assistant Professor, University of Southern California, Jonathan Teague, Manager, Office of Statewide Health Planning and Development, Shannon Muir, PhD, Science and Technology Fellow, California Senate Health Committee, and Erlinda Valdez, Board Member, California Funeral Directors Association.

Henry informed everyone that the meeting was being recorded to assist with note taking purposes. This meeting complies with the Bagley-Keene Open Act.

We have reserved a portion of the meeting for public comment. We would like to ask our public attendees to reserve comments until we arrive at that portion of the meeting.

C. APPROVAL OF MINUTES FROM THE PREVIOUS MEETING:

Erlinda Valdez motioned to approve the May 13, 2015 meeting minutes. Emily Putnam-Hornstein seconded the motion. Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye to approve the minutes. There were no oppositions. Motion carried. The minutes have been approved as distributed.

D. VSAC RECOMMENDATIONS FROM THE PREVIOUS MEETING:

The State Registrar's Responses to VSAC Recommendations are included in your agenda package as Attachment 1.

E. NEW BUSINESS:

Eleven projects were reviewed.

The first project reviewed by the Committee was:

Project Title: "California Cardiac Surgery and Intervention Project"

Principal Investigator(s): Joseph Carey, MD, University of California, Irvine

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Approved

Project No.: 12-06-0401

Expiration: October 3, 2015

File(s) Requested: 2011 Linked PDD/Death Data

Requested Identifiers: California Identifiers

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: A question was raised by Sun Lee wanting to know when the PI includes personal information, do they have to include everyone who has access to the data files? Everyone who is named who has access to the data should be included. Sun Lee pointed out that on page 10, there was only one person included under personal information but they named two people who have access to it. Tim Danielsen has access to the combination but is not working with the data. This generally has not been an issue at OSHPD as we have done a lot of work with them and used them as contractors.

This raises an interesting question that all the confidential data they send out to universities, we are aware that they are university IT staff who has access to their system. We don't have the details of that and we don't to see the names of all the IT support staff. For CDPH, we do not have a formal policy but we only ask researchers to identify the people who would be touching the data as part of the project. Jonathan said that the same approach is used with OSHPD.

It was explained to the Committee that these are requests that are to linked OSHPD Vital Statistics data files. There is no stand-alone vital statistics file that is being requested. Instead it is a linked product that OSHPD prepares, so the request comes to OSHPD. Over time, it was felt that VSAC also needed to approve these requests because it does embody vital statistics data in the request. We have not asked and VSAC has not requested these researchers fill out an independent application because the understanding was that OSHPD would handle the distribution of the linked file. Each department would handle separately distribution of their own standalone data files.

The Science Advisor (SA) said the Committee did not review these types of applications until 2 or 3 years ago when we realized that we were out of compliance with the law by not having VSAC review of vital records prior to distribution to researchers. We started having this Committee look at the requests for OSHPD linked data to make sure VSAC had a chance to review and comment and make a

recommendation to the State Registrar on whether or not the vital records data should be released.

The reason there is not a Vital Statistics application is that they are not applying to CDPH for the release of the data. They already applied to OSHPD, so VSAC is reviewing these to make sure that the vital statistics component is appropriate.

The rule of this Committee is to strictly advise the State Registrar on release of vital records data. OSHPD cannot make the decision to release vital statistics data without the State Registrar's approval. The State Registrar can delegate the release to OSHPD, the State Registrar can say yes, that is okay with me go ahead and release that data but OSHPD cannot do it without the State Registrar's approval. That is why the Committee sees those applications and it goes through CPHS and OSHPD review. From the Committee's perspective, the Science Advisor recommended that they review those whether or not the vital statistics records are appropriate. If you have any questions or concerns, this would be the place to bring them up so the State Registrar is aware of anything that he should be aware of.

Jonathan suggested that it may be useful for a departmental level discussion on how to keep the process as efficient as possible. All the approval steps are pretty much required, but if there is a way to expedite the approval process, researchers would be happy. Since Ellen was not here, we might defer this discussion to a meeting when she is here. One of the things that Ellen has suggested about the OSHPD applications, because they have already been through a review by the time they get to VSAC and problem free, she suggested that we might introduce the consent calendar where all those would be grouped as block and anyone on the Committee could review the applications and say no I want to discuss this an individual application. If no one has any concerns about any of the applications on the block, they are all approved at the same time, we move on to those which would need more discussion. If the Committee would like to discuss this at the next meeting we can.

VSAC Motion: Jonathan Teague motioned to recommend approval of the data release. Sun Lee seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending

approval of the data request. There were no oppositions. Motion carried.

The second project reviewed by the Committee was:

Project Title: "Evaluation of Longterm Pediatric and Neonatal Surgery Resource Utilization and Outcomes in California"

Principal Investigator(s): Howard Hao-Chung Jen, MD, Tufts University, School of Medicine

Project Type: New Project

CPHS Approval: Approved

Project No.: 14-09-1714

Expiration: April 1, 2016

File(s) Requested: 2005-2012 Linked PDD/Birth Cohort File, 2005-2013 Non-Public PDD, 2005-2013 Non-Public EDD, 2005-2013 Non-Public ASCD

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: No

History: New Data Request

VSAC Discussion: Sun Lee had a question regarding the distribution of data. Jonathan said that OSHPD had two options on how the requestor is set up to handle data receipt. Traditionally, it is sent via encrypted CD-ROM and the documentation and the passcode is transferred under separate cover. More recently, we have been using the Accellion secure file transfer protocol. They will check with the requestors to make sure they have a receiving station on the other end that can accept the data and allow them to manage it securely. It is up to the user.

Sun Lee had a question regarding their physical safeguards as they said they would be mailing 500 or more records of PID. Jonathan told her that if the data is in motion, they want to know what they are doing to secure it.

VSAC Motion: Jonathan Teague motioned to recommend approval of the data release. Dave Grant seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye to in favor of recommending approval of the data request.. There were no oppositions. Motion carried.

The third project reviewed by the Committee was:

Project Title: "Development of State-wide Perinatal Quality Improvement Metrics with OSHPD PDD/Birth Certificate Linked Data"

Principal Investigator(s): Jeffrey Gould, MD, Stanford University

Project Type: Continuing Project

CPHS Approval: Approved

Project No: 12-06-0393

Expiration: August 7, 2015

File(s) Requested: 2012 Linked PDD/ED/Death Data

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: Sun Lee had a question concerning small cell suppression rule for anything under 15, they are not supposed to present it. In that case, what other kind of guidelines have you given them?

Jonathan said generally they have been pointing to publication constraints that CPHS suggested. Most researchers do not have problem adhering to that in terms of publication. This is something that California Health and Human Services has been looking at as a whole. There is discussion going on as there is a wide range of cell size limits that are in play: Bureau of Census will use 5, OSHPD has used 5 and 10, CPHS recommends 15, and CDC uses 50. A lot has to deal with the context.

VSAC Motion: Sun Lee motioned to recommend approval of the data. Jonathan Teague seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The fourth project reviewed by the Committee was:

Project Title: "Impact of the Affordable Care Act (ACA) on Hospital Care Utilization and Cost"

Principal Investigator(s): Atul Gupta, PhD Candidate, Stanford University

Project Type: New Project

CPHS Approval: Approved

Project No.: 14-09-1720

Expiration: April 1, 2016

File(s) Requested: 2011 Linked PDD/Death Data

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: Yes

History: New Data Request

VSAC Discussion: No Discussion

VSAC Motion: Jonathan Teague motioned to recommend approval of the data. David Grant seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The fifth project reviewed by the Committee was:

Project Title: "Safety in Childbirth Estimating Benefit of Risk Appropriate Obstetrical Care"

Principal Investigator(s): Kimberly Gregory, PhD, University of California, Los Angeles, School of Medicine

Project Type: Continuing Project

CPHS Approval: Approved

Project No.: 13-12-1453

Expiration: April 1, 2016

File(s) Requested: 2011 Linked PDD/Birth Cohort File

Requested Identifiers: California identifiers only

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: This request is similar to Jeffrey Gould's request. These are supplemental requests, where the project or the personnel have not changed but they are simply asking for a new year's of data. OSHPD is trying to set up a description process where there is not a lot of administrative processing necessary that they can rely on the previous submittal. That is why the forms look a little different than their typical data request form. This is called rapid cycle request.

VSAC Motion: Shannon Muir motioned to recommend approval of the data. Sun Lee seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The sixth project reviewed by the Committee was:

Project Title: "Probalistic Inference and Categorization Development in Infants"

Principal Investigator(s): Fei Xu, PhD, University of California, Berkeley

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Approved

Project No.: 12-04-01

Expiration: October 2, 2015

File(s) Requested: 2014 Preliminary Birth Records (select variables) and 2014 Infant Death Records (select variables)

Requested Identifiers: Birth Records (Name and Address), Infant Death Records (Name, Address, and Mother's Maiden Name)

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: Sun Lee wanted to know if the 2014 data requested would be coming from AVSS. The Science Advisor stated that we tighten up some of the language and semantics around that. We can release data directly from AVSS in rapid cycle fashion. We do it now for several applications, for example, Elliot Main's study. We are trying to get away from a fixed BSMF vs. a custom data created file, whether that is annually or in rapid cycle monthly fashion. We are currently working on the language and in the coming months, we will be providing more information on how we are changing the process and how we will be changing the application forms. It would come from AVSS here at the State to the researcher if it is not an annual file.

Sun wanted to know if the death data would come from EDRS. The SA responded that it does not come from EDRS. What we are doing at the State is building an integrated platform for all our electronic registration system and data dissemination systems, called VRBIS, Vital Records Business Intelligence System and nothing should come from EDRS anymore.

We completely implemented the functionality for death data in VRBIS. All death data should come from VRBIS. It is refreshed every 30 minutes so you can have real time data if you want it. Researchers who ask for something that is not a standard annual file, will get their data from VRBIS, not from EDRS. We plan to have the same functionality implemented for birth and fetal death within the next 18 - 24 months. We will no longer pulling from AVSS, we will be pulling everything from VRBIS.

David Grant felt that there was very little information provided as to whether the postcards they were using to recruit patients were in

English and Spanish. Jonathan commented that this was an amendment and wondered if there was more information provided on the original request.

David was asked if he wanted to ask the researcher this. His response was that he did not want to hold up the approval but if there is a way we can note it to the researcher that if they are not recruiting in Spanish, the Committee could advise them to consider doing so. David said that we could make this a suggestion to the requestor.

Emily commented that this project was listed as an Information Practices Act project. It was her understanding that they have a separate more complete protocol concerning the actual research and they were providing us with enough details, so we understood how the vital records were being used. The SA commented that this was correct and that the Committee's purview was the vital records data. David withdrew his suggestion.

VSAC Motion: Jonathan Teague motioned to recommend approval of the data. Shannon Muir seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The seventh project reviewed by the Committee was:

Project Title: "Health and Economic Toll of Tobacco on California's LGB population"

Principal Investigator(s): Wendy Max, PhD, UC San Francisco, Institute for Health and Aging

Project Type: New Project

CPHS Approval: Approved

Project No.: 15-02-1894

Expiration: April 1, 2016

File(s) Requested: 2013 Death Statistical Master File (select variables)

Requested Identifiers: No Personal Identifiers

Personal Contact: No

Identifiers Released: No

History: New Data Request

VSAC Discussion: No Discussion

VSAC Motion: David Grant motioned to recommend approval of the data. Jonathan Teague seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The eighth project reviewed by the Committee was:

Project Title: "Long-term Impacts of California Student Aid Commission's Cal Grant Entitlement Program"

Principal Investigator(s): Oded Gurantz, PhD Candidate, Stanford University

Project Type: New Project

CPHS Approval: Approved

Project No.: 15-02-1895

Expiration: April 1, 2016

File(s) Requested: 1982 Birth Statistical Master File (select variables)

Requested Identifiers: Name

Personal Contact: No

Identifiers Released: No

History: New Data Request

VSAC Discussion: The Science Advisor had a question for the Committee that this isn't really research, and isn't related to public health or medical outcomes, is it an appropriate use of the birth files since they are asking for names? This is the kind of thing that the Committee is intended to advise the State Registrar on.

Emily agreed it is not related to public health or medical outcomes and not sure if it something that fits the criteria for how we review the different applications vs. is it an appropriate use of the data. Emily felt that it was an innovative use of data, rather than doing an exact match between the information in the birth records and education data, they were doing a statistical match to assign weighted probability to the names to help them empute ethnicity in their files. Emily felt it did contribute to what seems to be a valid and clearly laid out research endeavor. The only question was if it is public health, health, and medical outcomes and don't know if that is one of the criteria that CDPH and the State have in accessing these records.

The SA stated that the statute does not require that the research be related to public health, health, or any kind of medical outcome. The language of the statute says that the research has to have legitimate scientific merit. That is what this Committee is for, and you may interpret as you wish.

The Committee wanted to make sure that the SA did not have any concerns or that it was one that they needed to take a closer look at. The SA said given the minimal risk, she had no concerns but she wanted to make sure that because this was so different that the Committee was aware that it isn't related to anything in the public health or medical field, and whether or not that may be a concern.

VSAC Motion: Emily Putnam-Hornstein motioned to recommend approval of the data. David Grant seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The ninth project reviewed by the Committee was:

Project Title: "Longitudinal Study of Hospital Outcomes for California Children"

Principal Investigator(s): Geraldine Oliva, MD, Linda Remy, PhD, Co-PI, UC San Francisco

Project Type: Continuing Project with Changes to the Protocol

CPHS Approval: Approved

Project No.: 13-02-1077

Expiration: April 1, 2016

File(s) Requested: 2013 Birth Statistical Master File (select variables), 2013 Death Statistical Master File (select variables)

Requested Identifiers: BSMF (Name, Certificate Number, and Address), DSMF (Name, Certificate Number, Address, MMN, and SSN)

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

VSAC Discussion: The SA had concerns and wanted to know if the Committee was okay with the open ended nature of this request. The requestor is asking for all data fields, for all years and to keep as long as they like, and to do very generally described future research.

The Committee asked if we should be asking them to more clearly outline some of the surveillance and research related questions that they have. The Committee has in the past, provided an approval to linked data but specified that specific research projects that would use those data would need to come back before the Committee.

On Page 7 of their protocol, they stated that they do not have research questions per say.

The first concern that the SA had was that this is a continuing application and they have been accustomed to getting this data in the past. Part of that is because in the past, they used to do this sort of work as a contractor for the State. We were giving them our data to do our work for us and giving it back, but they are no longer in the relationship with us. They are really asking for us to turn over everything and all the files to them to use as they seem fit without describing the use. We don't have any other researchers that we do that with.

The second concern is that this Committee historically requires researchers to say what their research is and approve the data specifically for that research. When you want to do something else, you come back, you describe that new research and the data can be approved for that new research. The idea that they have the data in

hand and decide to do whatever they want with it, runs very counter to that philosophy.

Jonathan stated that they have similar issues with OSHPD data as well. Generally, what they have done is they would need to see it tied to some specific research project which has worked fairly well. He suggested that we may want to defer this to a subsequent call when they can speak to that.

The issue here is a lot of the research projects with the kind of data they are accumulating are not possible unless someone has done a lot of ground work in advance. An example is the linked file with death and birth data. This has been a huge help for the researchers as they don't have to establish these linkages. Jonathan sees a similar work here with what UCSF is trying to do. They are trying to enable research, and arrange a project that wouldn't be feasible for any individual researcher without this undertaking having been done. There are still issues controlling the use of the files.

The SA told the Committee that one of the ways they have handled this in the past, is that they have asked the requestor to be specific about the database building request. Describe to us this combined database you are going to build and how you incorporate the vital records data and to come back any time there is a research use of the database. There also has to be an understanding they can build it but they cannot re-release. They will have to be a co-PI with anybody who wants to use the data they create.

The Committee asked if they were re-releasing data, would they submit a new application or a supplement application to the original application? The SA said they would need to submit a research application for the use of the data. If it is a modification of an existing research project, they can modify and amend an existing request. If their first request is to build a database, and the Committee says yes, and their second request is to do research Project "A", and the Committee can say yes to that and have research Project "B", which is different from "A", they would have to submit a separate application for that. Given how the statutes are written, they can't have an open ended research application. Each of those applications would have to be reviewed by this Committee and by CPHS before they move forward.

The interest of CPHS is from a human subject's perspective and not necessarily whether or not the release of the data complies with the law governing vital records. That is this Committee's purview.

This raises some interesting policy questions on how to relate to these kind of endeavors given the amount of investment it takes to build some of these data sets that can support a wide range of research. You don't want to see these things built and then evaporate; there should be some way of leveraging the work that's done. But the problem becomes acute when you start looking at some of the projects we have seen where people have been looking at genetic disease transmittal down to generations, where you actually need a 30 year run of data, to look at these multiple cohorts in the projects. The Committee is not sure what the long term solution is. The State has an interest in supporting these kinds of research endeavors at the same time we have the specific responsibility to make sure the data is not abused and people don't acquire a sense of private entitlement in how it gets deployed.

Sun wanted to know if State or OSHPD, has projects in the past where there have been 2 or 3 decades running kind of projects where you have been providing data. Jonathan responded that they have been collecting Patient Discharge Data since 1982. Most of the requests don't look back beyond 1990 because that was when they started collecting SSN, and hence providing the record linkage number. They are seeing it more and more and appreciate the level of statistical overhead that it takes to build and gets these files. There needs to be some way to put a balance for a need for State stewardship of the data with these initiatives in the university research communities.

Jonathan was not sure what to recommend. They could recommend approval but there is no specific research enterprise that they would be approving. We would either need to condition it pretty heavily with a motion or maybe invite them to carry this over and talk to the Committee more about it.

The SA stated that her main concern is that we remain in compliance with statute. Statute would not allow them to re-release the data under any circumstances other than being a Principal Investigator or Co-PI on the project. That is one thing they would have to make clear in their application before the State Registrar could sign off on it. The other thing is they can build their integrated very large scale database. This Committee has approved it before, but they do have to have a very specific research project associated with that before they can use it.

David suggested that we can have them submit a proposal that would be clear in its purpose to build the database and not release any of that information without a subsequent VSAC application. That is a reasonable approach and it sounds like there is some precedent for this Committee to take that approach.

The State Registrar cannot release the data for research projects until the VSAC provides a recommendation.

After the discussion, the SA said she heard from the Committee that what they would like to have from the researcher provide a revised application specifically describing how the database would be put together and that the requestor would specify that there would not be any use of the database for research purposes unless there was a VSAC application for that research request. This covers re-release because they can't use the database unless VSAC sees what it is going to be used for. Jonathan pointed out that if they wanted a specific data request, they can do it here as part of their application.

The Committee had asked if we could ask the researcher to provide a full listing of who was working with these records as they only listed two individuals. One of the things the State Registrar is charged with is making sure the only named people have access to the data. If that list of names become very long, and they aren't all institutionally involved at the same place, that creates some concerns about data security.

VSAC Motion: David Grant motioned to recommend approval to revise and resubmit the application to reflect a database endeavor only. Subsequent applications for research uses of the data be submitted to VSAC for review as they arise. Jonathan Teague seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending the motion as stated. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar request the requestor to revise and resubmit the application to reflect a database endeavor only. Subsequent applications for research uses of the data would need to be submitted to VSAC for review as they arise. The requestor will be invited to join the call at the next meeting.

The tenth project reviewed by the Committee was:

Project Title: "Evaluating the Effectiveness of a 13-Valent Pneumococcal Conjugate Vaccine among Children"

Principal Investigator(s): Laurene Mascola, MD, Christine Wigen, MD, Los Angeles County Department of Public Health

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-11-0944

Expiration: April 1, 2016

File(s) Requested: 2005-2013 Birth Records

Requested Identifiers: 2005-2013 Birth Records from Los Angeles County

Personal Contact: No

Identifiers Released: No

History: New Data Request

VSAC Discussion: There were concerns from the SA as the requestor cannot transfer these files to CDC. CDC will need to request the files directly, and can then designate LA County as their collaborator to perform the file preparation work. The requestor was contacted, and added CDC as Co-PI.

The County can give the data out internally but externally, they would have to get this from CDPH.

VSAC Motion: Jonathan Teague motioned to recommend approval of the data. Sun Lee seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

The eleventh project reviewed by the Committee was:

Project Title: "Brain Mechanisms of Visual Development"

Principal Investigator(s): Scott Johnson, PhD, UCLA Department of Psychology

Project Type: New Project

CPHS Approval: Approved

Project No.: 12-09-0707

Expiration: February 5, 2016

File(s) Requested: 2015 Real-time Birth Records and 2015 Real-Time Death Data

Requested Identifiers: Selected variables

Personal Contact: Yes

Identifiers Released: No

History: New Data Request

VSAC Discussion: The concern of the SA was that California law does not permit electronic data files to be released directly from the local health department to an external entity. The requestor will need to modify their application to request all data files for the study from the State Registrar.

VSAC Motion: Sun Lee motioned to recommend approval of the data. Emily Putnam-Horstein seconded the motion.

VSAC Vote: Jonathan Teague voted aye, Emily Putnam-Hornstein voted aye, Erlinda Valdez voted aye, David Grant voted aye, Shannon Muir voted aye, and Sun Lee voted aye in favor of recommending approval of the data request. There were no oppositions. Motion carried. The Committee has voted to recommend that the State Registrar approve the use of the data as described in the protocol.

F. ITEMS FOR DISCUSSION: Henry asked the Committee to refer to Attachment 3, Recap of Data Requests Approved in the Vital Statistics Unit.

G and H. Public Comments and AGENDA ITEMS: Sun Lee was informed that the 2014 VRBIS data would be released something in July or August.

There were no public comments.

I. MEETING ADJOURNMENT: Sun Lee motioned to adjourn the meeting. The meeting was adjourned at 10:25 A.M.