

VITAL STATISTICS ADVISORY COMMITTEE (VSAC)
VITAL RECORDS PROTECTIONS ADVISORY COMMITTEE (VRPAC)
JOINT MEETING
MEETING MINUTES FOR WEDNESDAY JANUARY 6, 2010
9:00 AM to 12:00 AM

Attendees

Convener: Linette Scott

Committee Members:

Present: Sue Holtby, Erlinda Valdez, Krista Hanni, Deborah Williams, Mia Orr

Phone: Kam Coveyou and David Grant

CDPH Staff:

Present: Linette Scott, Jane McKendry, David Fisher, Debbie McDowell, Julie Turner,
Karen Roth, Cindy Tanaka-Fong

Phone: None

A. WELCOME

Linette welcomed all attendees.

B. APPROVAL OF MINUTES FROM PREVIOUS MEETING

- November 4, 2009 minutes approved as written.

C. OLD BUSINESS – Updates

Project Title: Birth Outcomes and Infant Mortality among Blacks and Whites by Nativity

Principle Investigator(s): Dr. Irma, Elo, University of Pennsylvania

VSAC Decision: Approved

D. ORIENTATION: Linette explained that the interpretation of policy regarding birth data release has changed. Previously, birth NOPI files were released without VSAC approvals but this is no longer allowed. Health and Safety Code Section 102430 states that confidential birth data must be reviewed by VSAC and all of the "below the line" data is considered confidential. It was previously believed that if you removed all of the personal identifiers such as name, addresses, etc., that individuals could not be identified. However with today's electronics that is no longer the thought. So from now on all requests for birth data must be reviewed by VSAC.

David Grant asked if there is an expiration date/period on the use of the data. For public data, there is no expiration. For the public version, there is a signed agreement and a log kept but CDPH is now tightening the requirements.

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E. NEW BUSINESS

There were eleven data requests that were reviewed. Specific information on the requests and committee decisions follow:

Project Title: Development of Visual Perception in Human Infants

Principle Investigator(s): Dr. Karen R. Dobkins, Ph.D.

VSAC Approval: Requested

Project Type: Ongoing Research Project

CPHS Approval: Approved

Project No.: 98-10-15

Expiration: October 1, 2010

File(s) Requested: Continuing receipt of San Diego Vital Stats data

Requested Identifiers: birth and death data

Personal Contact: Yes

Identifiers Released: No

History: Continuing data request

Summary: The objective is to characterize the development of visual perception in human infants and to relate it to underlying neural mechanisms. Their laboratory focuses on the development of visual motion processing, spatiotemporal processing and color processing. Understanding how the infant's perceptual capabilities will help provide insight into development of underlying brain regions.

VSAC Discussion: David Grant asked whether there were multiple language, (e.g., Spanish) versions to their survey as it was not clear from their protocol. Linette commented that we review for security and appropriateness. We have to ask ourselves, will the data fulfill the researcher's needs? Although interesting questions might come up about the adequacy of the research protocol, this is not the committee's responsibility. Krista Hanni asked about security practices and if we had a check list for security purposes. Linette said that we do not have any guidelines and they need to be developed.

VSAC Decision: Approved

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Project Title: Quantification and Language Development

Principle Investigator(s): David Barner, Ph.D.

VSAC Approval: Requested

Project Type: Ongoing Research Project

CPHS Approval: Approved

Project No.: 008-10-04

Expiration: October 1, 2010

File(s) Requested: Special Request

Requested Identifiers: Using Dr. Karen R. Dobkins, Ph.D. existing contact list to contact parents regarding study

Personal Contact: Yes

Identifiers Released: No

History: Previous data requests

Summary: This project proposes to investigate the role of language in children's developing understanding of sets, logical relations between sets, quantification, and mathematical computation. The proposed experiments will examine both the representation of sets in language and how linguistic representation, magnitude representation, and statistical representations of sets). It will also investigate the relation grammatical number (plural nouns) and mathematical representations (numerals, addition, subtraction, etc.). Participants will include children aged 2 through 16 as well as adult control subjects.

VSAC Discussion: There was no discussion needed.

VSAC Decision: Approved

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Project Title: National Children's Study

Principle Investigator(s): Dr. Dean Baker, MPH

VSAC Approval: Requested

Project Type: New

CPHS Approval: Approved

Project No.: 09-04-54

Expiration: August 6, 2010

File(s) Requested: Birth Statistical Master File, 2004-2008, (Kern County, San Bernardino County, Orange County)

Requested Identifiers: Cert Numbers, SSNs, Addresses

Personal Contact: No

Identifiers Released: No

History: No

Summary: The goal of the project is to implement the National Children's Study (NCS) in four counties – Orange, San Diego, Kern, and San Bernardino. The study plans to enroll 100,000 pregnant women nationally, following them and their child from pregnancy until the child reaches 21 years of age. The study will take place in 105 locations that were selected to be representative of the USA population. The NCS will provide rich information to answer questions related to children's health and development and will form the basis of child health guidance, interventions, and policy for generations to come.

VSAC Discussion: There was no discussion needed.

VSAC Decision: Approved

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Project Title: Behavioral Health Surveillance of Combat Veteran's Mortality Data

Principle Investigator(s): Stephanie McWhorter

VSAC Approval: Requested

Project Type: New

CPHS Approval: Approval has not been obtained.

Project No.: pending CPHS approval

Expiration: pending CPHS approval

File(s) Requested: Death Statistical Master Files - 1980-88, 1989-98, 1999-2007,

Multiple Cause of Death Files – 1980-2006

Requested Identifiers: Certification Numbers and Names, Social Security Numbers and Mother's Maiden Name

Personal Contact: No

Identifiers Released: No

History: No

Summary: The Behavioral Health Surveillance of Combat Veterans (BHSCV) proposes to collect death certificate data directly from California and Florida for the years 1980-ongoing to merge with Career History archival Medical and Personnel System (CHAMPS) and deployment records. Using these records, BHSCV personnel will be able to report annual frequencies of veteran's deaths by manner and cause, and examine veterans' deaths with respect to different aspects of military service, such as combat deployments, negative personnel actions, medical incidents, and mental health diagnoses. Information from the data collection process and results from the statistical analyses will be incorporated into a report.

VSAC Discussion: It was mentioned that pending suicide on the death certificate might affect the outcome of the study. Linette explained that death records with pending coroner cases are filed to complete the death registration timely. Later, an amendment may be filed to include the final outcome. The committee is charged with reviewing whether the data is needed and is being protected, not necessarily to know the results of the research.

VSAC Decision: Approved

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Project Title: California Birth Defects Monitoring Program

Principle Investigator(s): Marcia Ehinger, MD, Chief

VSAC Approval: Requested

Project Type: Ongoing Research

CPHS Approval: Approved

Project No.: 82-08-01

Expiration: ongoing

File(s) Requested: 2008 Birth Master File – Names, Cert #s, SSNs, Address, 2006 Birth Cohort File – Names, Cert #s, Address, 2007 Death Statistical Master File – Names, Cert #s, MMN, 2007 Fetal Death Statistical Master File – With Names, Cert #s

Requested Identifiers: Names, Certification Numbers, Social Security Numbers, Addresses, Mother Maiden Names

Personal Contact: No

Identifiers Released: No

History: No

Summary: The California Birth Defects Monitoring Program (CBDMP) is an ongoing program with responsibility for determining the incidence of specified birth defects, selected developmental disabilities, childhood cancer, and reproductive outcomes anywhere in California. The program maintains an ongoing registry of children with one or more of the conditions in their purview. The CBDMP collects reports of birth defects from many sources. The only way to prevent duplications of reports on the same child is to link all records for the same child, which is best done by linking to the birth records. This establishes residency of the mother at the time of birth, and lets CBDMP determine whether the child is eligible for inclusion in the registry.

VSAC Discussion: It was brought up that they are receiving data, Jane asked if they will be rereleasing data. Linette discussed the description of the California Birth Defects Monitoring Program and how other programs were using the data. Staff includes a variety of contractors that are not state employees but are part of the program.

VSAC Decision: Approved

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Project Title: RAND State Statistics – Update subscriber database

Principle Investigator(s): Laura Cooper

VSAC Approval: Requested

Project Type: NOPI file

CPHS Approval: pending

Project No.: pending CPHS approval

Expiration: pending CPHS approval

File(s) Requested: 2008 Birth Statistical Master file – NOPI, 2007 Death Statistical Master file - NOPI

Requested Identifiers: Without personal identifiers

Personal Contact: No

Identifiers Released: No

History: No

Summary: Rand State Statistics will use selected fields from requested files without personal identifiers to update our data series used by researchers at institutional libraries and universities.

VSAC Discussion: Debbie stated that the RAND website is subscription based. It is similar to CODMAN database of OSHPD data. They sell their data as it is subscription based. Data (race, death, birth) is available on a monthly basis. David Grant stated that it is difficult to determine what they want to do with the data. He also stated that the application looked different and therefore, it was not clear as to how to review or evaluate the request. Debbie suggested we subscribe to the service to see what is actually available to subscribers to the website. Krista asked if companies can purchase the data base. Linette stated in Section 102231, you can request data but cannot post the data on the internet. If aggregate data is released vs. line item data, ok, but it is not legal for them to release line item data that will identify subjects.

VSAC Decision: It was agreed that once we are assured about the use of the data, we would release the data. There will be an addendum to the minutes that will state the final action taken, approved or denied.

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Project Title: Requested CPHS Protocol - Request

Principle Investigator(s): Clea Sarnquist

VSAC Approval: Requested

Project Type: NOPI files

CPHS Approval:

Project No.:

Expiration:

File(s) Requested: 2008 Birth Public Use File

Requested Identifiers: N/A

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: Data will be used to help evaluate the California Rapid HIV testing at Labor and Delivery Project- Centers for Disease Control and Prevention-funding study aimed at reducing mother to child transmission of HIV. Especially interested in prenatal care rates at each of the participating hospitals, as well as the demographics of women lacking prenatal care. This information will be extracted using SAS, and will be compared to hospitals self-report of prenatal care rates, rapid HIV testing rates (as all women without prenatal care should receive a rapid HIV test), and demographics.

VSAC Discussion: Complete protocol was submitted via email January 6. They are requesting the NOPI file (without personal identifiers). The request was approved by the Stanford University IRB. This is not based on human subjects. Research is focused on facility not care of patient.

VSAC Decision: Approved

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Project Title: Birth Rates and Total Fertility Rates in California

Principle Investigator(s): Joe Hayes

VSAC Approval: Requested

Project Type: NOPI file

CPHS Approval: pending

Project No.: pending

Expiration: pending

File(s) Requested: 2007, 2008 Birth Public Use Files

Requested Identifiers: Birth Public Use Files (sub-set of birth statistical master file)

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The 2007 and 2008 Birth Public Use NOPI Files are requested for a research project that will describe birth rates and total fertility rates in California by mother's age, race/ethnicity, and county.

VSAC Discussion: Why would they need to purchase the file if they could use the query system on the internet to obtain the information? More information is needed. We did request information but have not received a response. They need CPHS approval.

VSAC Decision: Pending further information. There will be an addendum to the minutes that will state the final action taken, approved or denied.

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Project Title: Chronic Economic Stress and Birth Outcome

Principle Investigator(s): Angela Pike

VSAC Approval: Requested

Project Type: Research

CPHS Approval: no

Project No.: no

Expiration: no

File(s) Requested: Birth Statistical Master Files (without personal identifiers)

Requested Identifiers: Addresses

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: Prenatal psychological stress is associated with the adverse birth outcomes of shortened gestation and low birth weight. The purpose of the proposed study is to examine the relation between chronic stress exposure (home foreclosures) and birth outcomes (length of gestation and birth weight). Home addresses will be used to assign a home foreclosure index score to each woman and then link this score with each woman's birth outcome. We anticipate that higher rates of home foreclosures will be associated with shortened gestations and also lower birth weight. In order to preserve confidentiality, each woman will be assigned a participant identification number.

VSAC Discussion: OHIR has requested additional information from Ms. Pike. Her protocols imply that addresses are used and the data she would receive from us does not include addresses. Therefore we need to know if she uses addresses and how she gets addresses if they are used. A protocol was emailed January 6 but requires review. She does not have CPHS approval and is requesting an exemption from CPHS

VSAC Decision: Pending further information regarding how they are getting mothers address and receipt of approvals from CPHS. There will be an addendum to the minutes that will state the final action taken, approved or denied.

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Project Title: California Child Welfare Performance Indicators Project/California Children's Services Archive

Principle Investigator(s): Barbara Needell, Ph.D.

VSAC Approval: Requested

Project Type: New

CPHS Approval: Yes

Project No.: 04-12-09

Expiration: October 29, 2010

File(s) Requested: Birth Statistical Master File (1999-2007)

Requested Identifiers: Name, Certification Numbers, Social Security Numbers, Addresses

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The project examines trends, dynamics, and outcomes of children served by California's child welfare system. This research is critical for program and policy understanding and improvement so vulnerable children and families can be served in the best possible manner (Bath et al., 1994; Courtney & Collins, 1994; Drake & Johnson-Reid, 1999; Goerge, 1990; Wulczyn et al., 1999).

VSAC Discussion: This is a continuing project on the trends of the California Welfare System.

VSAC Decision: Approved

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Project Title: Medication Uses and Outcomes in Pregnancy/Fetal Risks of Immunosuppressive Drugs Used in Autoimmune Disease

Principle Investigator(s): Dr. Craig Cheetham, PharmD, MS/Wansu Chen

VSAC Approval: Requested

Project Type: Continuing

CPHS Approval: Yes

Project No.: 09-10-59

Expiration: October 1, 2010

File(s) Requested: Fetal Death Statistical Master Files – 2007

Requested Identifiers: Name and Certificate Numbers

Personal Contact: No

Identifiers Released: History: No

Summary: The California Fetal Death Master Statistical file data will be used for two studies: the FDA funding Medication Use and Outcomes in Pregnancy (FDA Med Preg) study and the AHRQ funded Fetal Risks of Immunosuppressive Drugs Used in Autoimmune Disease (Fetal Risk). Both studies are multi-site, retrospective cohort studies that focus on potential relationships between maternal medications used during pregnancy and fetal outcomes. The use of drugs during pregnancy is a major concern given the potential for congenital anomalies secondary to fetal exposure. The FDA Med Preg study will develop the infrastructure necessary to link maternal medication use and fetal outcomes data from multiple healthcare organizations in order to facilitate future collaborative research on this topic. The Fetal Risk study is designed to assess the risk of congenital malformations and adverse fetal outcomes following maternal exposure to immunosuppressive drugs.

VSAC Discussion: There were concerns with why Kaiser needed the data for all events, not just those that occurred to their members. Could Kaiser use the information and then deny people coverage? Linette explained that the committee should look at the project before them and make their decision based on this project's presentation. Explanation: Two studies are planned, and one requires comparisons among Kaiser and other plans, so all events are needed.

VSAC Decision: Approved as a continuing project.

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Additional Discussion Topics:

- Continuing Projects: When a project is a continuing project (PI is seeking additional data and there is NO change to the protocols) does the committee want to review continuing projects or let Vital Statistics Section process the request based upon prior approvals. The committee will allow continuing projects to be handled by the Vital Statistics Section within the Office of Health Information and Research. Continuing projects which receive data will be displayed on the AGENDA ATTACHMENT 3 – RECAP OF DATA REQUESTS APPROVED IN THE VITAL STATISTICS SECTION.

- Expiration date: A discussion was held on the expiration date of the project. The project is approved for a set time and at the end of this period the PI is to return or destroy the data they received from the Office of Health Information and Research.

- Jay Patel: Market Share Request: Request for market share data from three counties was presented as informational. This type of request does not require VSAC review/approval.

- David Grant suggested that additional protocols not listed on the agenda were sent and that there had not been adequate time to review them properly. He expressed appreciation of the long-time relationship between researchers and OHIR staff and how that may have allowed OHIR staff to evaluate requests based on the researcher's past standing.

- Protocols: Debbie asked the Committee if they would like the protocols sent with the agenda or on a flow basis. The Committee agreed that they want protocols sent with the agendas. . David mentioned that it is difficult when protocols are received just before the meeting. Linette stated that we know that is difficult but with the change to our review practices we were trying to accommodate as many researchers as possible. In the future we should not have this situation occur but since VSAC meets every other month we make every effort to include as many protocols as are ready. There would be no add-on protocols. Continuing protocols will be brought once.

- Information discussed at VSAC: Erlinda Valdez stated she would be going to a meeting and wanted to know what she can report. Linette responded that information discussed at VSAC is public information.

- Draft of the Minutes: Debbie asked the committee if they would like the minutes sent prior to the agenda or with the agenda. . They agreed that the minutes could be sent with the agenda.

- Attendance: Erlinda asked, how she would know when she is supposed to attend in person or whether she could attend by phone. A few of the members would have taken advantage of the teleconference option. Debbie responded that the norm should be that they can attend by phone but when they are needed to attend in person they will be so instructed.