

Vital Statistics Advisory Committee (VSAC)  
Vital Records Protection Advisory Committee (VRPAC)  
Joint Meeting  
Meeting Minutes for Wednesday, May 11, 2011  
9:00 AM to 11:00 AM

**Attendees**

**Convener:** Laura Lund, Science Advisor for Health Information and Strategic Planning (HISP), Acting Chair

**Committee Members:**

**Present:** Jonathan Teague, Deborah Williams

**Phone:** Krista Hanni, David Grant, Erlinda Valdez

Sue Holtby was unable to attend but sent an e-mail regarding her comments on one protocol. Debra Castanon was also not present but would be abstaining.

**California Department of Public Health (CDPH) Staff:**

**Present:** Krista Christian, Julie Turner, Cindy Tanaka-Fong, Dave Fisher

**Additional Attendees:** Cheryl Walker, MD, Researcher

Meeting was called to order at 9:08 A.M. by Krista Christian

**A. WELCOME**

Krista Christian informed committee members that the meeting would be tape recorded to assist with minute taking.

**B. Approval of minutes from the previous meeting**

Erlinda Valdez made a motion to approve the minutes from March 2, 2011. Debra Williams seconded the motion. Committee members all voted aye to approve the minutes. Minutes approved as written.

**C. State Registrar's Response**

7 new projects and 2 continuing projects were approved for release of data. Persistent Organic Pollutants and Breast Cancer Risk: Chemicals Old and New (Peggy Reynolds) was tabled for this meeting as the committee had requested additional information. The researcher provided information on the policies and procedures of the Cancer Prevention Institute of California relating to security and confidentiality and clarified who has access to the data as listed on the application. Jonathan Teague made a motion to approve recommendation. Debra Williams seconded the motion. Committee members all voted aye.

**D. New business**

4 new projects and 7 continuing project were reviewed.

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The first project reviewed by the committee was:

**Project Title: "Pension Benefit Information"**

**Principle Investigator(s): Susan McDonald, President Pension Benefit Information**

**Project Type: Continuing Research**

**Committee for the Protection of Human Subjects (CPHS) Approval:**

Not required; as this is for fraud and law enforcement

**Project No.:** N/A

**Expiration:** N/A

**File(s) Requested:** 2008 Death Statistical Master File

**Requested Identifiers:** Name, Social Security Number, Address, Mother's Maiden Name

**Personal Contact:** No

**Identifiers Released:** Yes

**History:** Previous data requests

**Summary:** Pension Benefit Information, Inc. (PBI) provides a death audit service to identify deceased participants in pension files to eliminate overpayments and fraudulent activity. With the majority of retirees receiving payments via electronic funds transfer, there is a critical need to ensure that benefits are only being sent to those entitled to receive them. PBI services state, county, and local government, the Fortune 500, unions, administrators, and insurance companies responsible for distributing pension benefits. PBI compares the pension file provided to PBI with the deaths reported in our database.

**VSAC Discussion:** Jonathan Teague expressed concern on the sequence of acceptance and denials and why they were granted access. Julie Turner provided an explanation that the data may not have been available for those years-- PBI previously requested California state data but the request was revoked in 2004. PBI re-petitioned in 2007 and was provided access once again.

**VSAC Recommendation:** Krista Hanni motioned to approve recommendation. Jonathan Teague seconded the motion. Committee members all voted aye.

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The second project reviewed by the committee was:

**Project Title:** "San Francisco Mammography Registry: A Research Resource"

**Principle Investigator(s): Project Type:** Karla Kerlikowske, MD

**Project Type:** Continuing Project

**CPHS Approval:** Approved

**Project No.:** 10-08-51

**Expiration:** June 3, 2011

**File(s) Requested:** 2005-2009 Merged Death Data File

**Requested Identifiers:** Name, Certificate Number

**Personal Contact:** No

**Identifiers Released:** Yes

**History:** Previous Data Request

**Summary:** The previous project #04-DD-07 was for death data only. In 2010, they sought CPHS approval for linking cancer data to death data. In July 2010, CPHS granted approval through 2013 for death data under project #10-08-51.

The overall goal is to collect demographic, clinical, and risk factor information, as well as mammographic interpretations, cancer outcomes obtained through linkage with the California Cancer Registry, and vital status through linkage with the CDPH vital records. The registry data collection serves as a resource that provides investigators the opportunity to use robust data, and access to a well-characterized population, to conduct high quality, clinically significant research related to breast health and breast cancer.

The overarching research questions that the San Francisco Mammography Registry (SFMR) serves to address relate to the practice and performance of screening mammography in the community and their impact on breast cancer outcomes. The SFMR study aims examine the sensitivity, specificity, and positive predictive value of mammography, as well as breast cancer rates and tumor characteristics, all in relation to numerous variables and risk factors, including different types of breast imaging procedures and methods, race/ethnicity, and age. In 2008, approval extended to include ovarian cancer.

Data collected by the SFMR will be used by researchers to author papers in medical journals that address various aspects of screening mammography performance, tumor biology of screen-detected cancers, and factors that influence risk of breast cancer.

**VSAC Discussion:** No comments

**VSAC Recommendation:** Krista Hanni motioned to approve recommendation. Jonathan Teague seconded the motion. Committee members all voted aye.

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The third project reviewed by the committee was:

**Project Title:** "Predictors of Recurrent Breast Tumors in Women with DCIS"

**Principle Investigator(s):** Karla Kerlikowske, MD University of California San Francisco

**Project Type:** Continuing Project

**CPHS Approval:** Approved

**Project No.:** Project #06-DD-01

**Expiration:** Approved through the life of the project

**File(s) Requested:** 2005–2009 merged death

**Requested Identifiers:** Name and Certificate Numbers

**Personal Contact:** No

**Identifiers Released:** Yes

**History:** Previous Data Request

**Summary:** The primary purpose of this study is to investigate the pathogenesis of breast ductal carcinoma in situ (DCIS) and to determine the rate of recurrent disease (DCIS or invasive breast cancer in the ipsilateral breast confirmed by pathology review) following lumpectomy alone in a population-based cohort. In addition, they will identify which epidemiologic, clinical and histopathologic characteristics and molecular markers independently predict recurrent disease. Results from the study will not affect participants directly and individual results will not be made available to participants. Benefits to medical science/society include knowledge of predictors of recurrence, which will be useful to future patients diagnosed with DCIS such that those who have a low risk of recurrence may avoid receiving unnecessary radiation therapy and those that have a high risk of recurrence may consider adjuvant radiation therapy or possibly mastectomy. A summary of the study results will be mailed to all live participants.

**VSAC Discussion:** No comments

**VSAC Recommendation:** Jonathan Teague motioned to approve recommendation. Krista Hanni seconded the motion. Committee members all voted aye.

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The fourth project reviewed by the committee was:

**Project Title:** "University of California San Francisco (UCSF) Breast Cancer Specialized Programs of Research Excellence (SPORE): Bay Area Translational Research Program – Outcomes Core"

**Principle Investigator(s):** Karla Kerlikowske, MD

**Project Type:** Continuing Project

**CPHS Approval:** Approved

**Project No.:** 05-DD-02

**Expiration:** for the life of the project

**File(s) Requested:** 2005-2009 Merged Death Data

**Requested Identifiers:** Name and Certificate Number

**Personal Contact:** No

**Identifiers Released:** Yes

**History:** Previous Data Request

**Summary:** The goal of the UCSF Breast Cancer SPORE program is to bring to clinical care settings novel ideas that have the potential to reduce breast cancer incidence and mortality--in particular, to increase their understanding of the events that lead to invasion and metastasis of breast cancer. In order to accomplish this goal, epidemiologists, pathologists and clinicians at UCSF, the California Pacific Medical Center (CPMC) and San Francisco General Hospital (SFGH) work collaboratively to plan, design and implement research programs that impact on cancer prevention, detection, diagnosis, treatment and control. The Breast Cancer SPORE is made up of a variety of research projects and cores (administrative, advocacy, animal, clinical, immunohistochemistry, tissue and outcomes) that provide services to the research projects. It is the responsibility of the Outcomes Core to obtain epidemiological and clinical information for the cohort of women diagnosed with breast cancer (in situ and invasive) at CPMC, UCSF and SFGH and to obtain consent for use of their breast tissue. The Core also provides input to the design of the relational database, and provides assistance in study design and statistical analysis. Benefits to medical science and society include establishing a database of women with breast cancer and following these women to see what new biomarkers being measured by the SPORE will predict survival and response to therapy. Such discoveries may be used in the future to develop clinical guidelines and make recommendations on

treatment of breast cancer based on demographic, pathology and biomarker profiles.

**VSAC Discussion:** No comments

**VSAC Recommendation:** Krista Hanni motioned to approve recommendation. Jonathan Teague seconded the motion. Committee members all voted aye.

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The fifth project reviewed by the committee was:

**Project Title:** "Childhood Autism Risks from Genetics and the Environment (CHARGE) Study"

**Principle Investigator(s):** Irva Hertz-Picciotto, PhD

**Project Type:** Continuing Project

**CPHS Approval:** Approved

**Project No.:** 01-12-13

**Expiration:** February 3, 2012

**File(s) Requested:** 2009 Birth Statistical Master File, 2009 infant death file

**Requested Identifiers:** Name and Addresses

**Personal Contact:** Yes

**Identifiers Released:** No

**History:** Previous Data Request

**Summary:** The purpose of the study is to assess associations with exogenous exposures, susceptibility factors, and the interplay between these two in the etiology of autism and its phenotypic variation. Chemicals with known or suspected neurodevelopmental toxicity, such as polychlorinated biphenyls (PCBs) certain pesticides, and metals, will be investigated. They will also pursue several hypotheses that have recently gained attention as possible causes of autism, including the combined measles, mumps, and rubella vaccine and ethyl mercury present in vaccines given during infancy and early childhood. Additionally, biochemical susceptibility will be examined through characterization of metabolic, immunologic, and neuronal gene expression profiles and genetic polymorphisms.

Because there is so little understanding of the underlying and contributing causes of autism, direct research on human subjects with this disorder is needed. The cases may benefit from the detailed evaluation that is

performed, in that the diagnosis may be clarified, and the possibility of directing intervention to maximize positive results will be increased. The greatest potential benefit would come to future individuals if the relationship between genetic susceptibility and environmental triggers in the etiology of autistic spectrum disorders can be elucidated, providing the possibility for prevention in the future.

Subjects for this study must be 2-5 years old, born in California, and live in the catchment area for the study. There are 3 subject groups: children having autism (AU), children having developmental delay but no autism (DD), and children randomly selected from the general population (GP).

**VSAC Discussion:** David Grant commented that the method of accessing phone numbers from identifiers listed in the birth statistical master file was unclear. Any commercial vendor that is used to conduct a reverse-lookup on the address should be listed in the protocol; however, both David Grant and Jonathan Teague agreed that the protocol did not have to be reviewed again by the Committee for the Protection of Human Subjects (CPHS). His recommendation was for the researcher to specify a method of access. Krista Hanni agreed with David's comments.

**VSAC Recommendation:** Jonathan Teague motioned to approve recommendation with stipulation to the state registrar for release of data. The requestor must provide information on the method of accessing phone numbers. David Grant seconded the motion. Committee members all voted aye.

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The sixth project reviewed by the committee was:

**Project Title:** "Trends in Regional Specialty Care Hospitalization for Children in California"

**Principle Investigator(s):** Paul Wise, MD, MPH (Requestor: Vandana Sundaram)

**Project Type:** Continuing Project

**CPHS Approval:** Approved

**Project No.:** 05-12-57

**Expiration:** October 07, 2011

**File(s) Requested:** 2009 Death Statistical Master File

**Requested Identifiers:** No Personal Identifiers

**Personal Contact:** No

**Identifiers Released:** No

**History:** Previous Data Request

**Summary:** The purpose of the proposed research study is to assess changes in the regional distribution of pediatric specialty care hospitalizations in California. The primary goal of this project is directed at providing a strong empirical base for constructive programmatic and policy development that will assure continued improvement in specialty care for children in the state.

The project will focus on three arenas of high morbidity and mortality among children: (1) trends in the hospitalization of high risk neonates, (2) pediatric trauma hospitalization, and (3) trends in hospitalization among children with special health care needs. In each arena, they will focus on two aims. First, they will define patterns of specialty health care utilization and outcomes based on hospital specialty care designations. Second, they will examine whether there are social differences in these utilization and outcome patterns, based on insurance and sociodemographic characteristics. For both these analyses, they will examine residence proximity to specialty hospitals, indicators or severity, length of stay, procedures, total financial charges, and mortality, among other relevant variables.

The project will also investigate the burden of adult discharges on children's hospitals and follow the trends and demographics of chronic illnesses of childhood as they present in adulthood.

**VSAC Discussion:** No comment

**VSAC Recommendation:** Debra Williams made a motion to approve recommendation. Jonathan Teague seconded the motion. Committee members all voted aye.

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The seventh project reviewed by the committee was:

**Project Title:** "Costs of Prematurity in California and the United States"

**Principle Investigator(s):** Cheryl Walker, MD, UC Davis Department of Obstetrics & Gynecology, Guibo Xing, PhD, UC Davis Center for Healthcare Policy & Research

**Project Type:** New Project

**CPHS Approval:** Approved

**Project No.:** 08-10-57

**Expiration:** December 2, 2011

**File(s) Requested:** PDD/Linked birth data 1991-2008

**Requested Identifiers:** California Identifiers

**Personal Contact:** No

**Identifiers Released:** No

**History:** New Research Project

**Summary:** This is a study of hospital costs associated with birth before 36 completed weeks of gestation in California during the time period 1991-2008. They will stratify by gestational age and birth weight as in the prior study by Dr. Gilbert using 1996 data, and use costs associated with those births occurring at term as the referent population. They will use an algorithm to impute gestational age from birth weight and gender for those for the roughly 20% of births for whom the variable is missing.

They have identified six sub-projects to this broad study. They will (1) stratify by birth year to account for technological and standard-of-care improvements over the 18-year study period; (2) Stratify by etiology of prematurity, as possible with an administrative database such as this, separating by diagnosis codes into groups including maternal infection, hypertensive disorders, placental abnormalities, and congenital anomalies; (3) Assess trends in costs attributable to maternal and neonatal/infant infectious morbidity; (4) Examine the data for racial/ethnic, regional and seasonal disparities in costs; (5) Develop an algorithm to identify potentially avoidable premature births that occur between 34 and 36 completed weeks gestational age, and assess costs related to them; (6) Model these data with national maternal demographic characteristics to estimate national costs of prematurity.

**VSAC Discussion:** No comment

**VSAC Recommendation:** Jonathan Teague made a motion to approve recommendation. Krista Hanni seconded the motion. Committee members all voted aye.

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The eighth project reviewed by the committee was:

**Project Title:** "Death Records Search"

**Principle Investigator(s):** Billy Chen, Principle, Land Co. Development Resources, Inc.

**Project Type:** Commercial

**CPHS Approval:** Required- Protocol will be forwarded to CPHS after approval by VSAC.

**Project No.:** Pending CPHS review

**Expiration:** Pending CPHS review

**File(s) Requested:** Death Statistical Master File

**Requested Identifiers:** Name, Certificate Number, Address

**Personal Contact:** No

**Identifiers Released:** Yes

**History:** New Research Project

**Summary:** The data will be used to construct a map showing locations of deaths by address. The name and certificate number fields will be used to request informational death certificates from the appropriate agencies.

The location of the decedent will be shown in a graphical format thru Google Earth or MapQuest. Users will be able to map out the location of historical deaths in the local area of a specific address.

Location of the decedent plotted on the map will be the only information shown on the public site. If the user would like additional information, the name, year of death, cause of death, and location of death is available as a paid service.

**VSAC Discussion:** Dave Fisher wanted to know what "true research" is. The protocol did not appear to reflect an appropriate definition of research. He wanted to know if there were any historical approved cases. Kristi Hanni felt that the security measures needed improvement and inquired if this meets the standards of allowing rerelease of data. Jonathan Teague asked if staff has consulted with counsel. The principle investigator is requesting the state file number. Laura Lund said that review of the governing statutes is needed to make a determination regarding approval.

**VSAC Recommendation:** Since there were many unanswered questions, Jonathan Teague made a motion to table the discussion and recommendation until the next VSAC meeting. Krista Hanni seconded the motion. Staff will furnish information regarding the governing statutes to committee members.

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The ninth project reviewed by the committee was:

**Project Title:** "Follow-up of Infants Born to Pregnant Women with Confirmed or Probable 2009 H1N1 Influenza with Symptom Onset from April 1 through December 31, 2009"

**Principle Investigator(s):** Meileen Acosta, MPH, CDPH, Division of Communicable Disease Control, Communicable Disease Emergency Response Branch

**Project Type:** New Project

**CPHS Approval:** Approved

**Project No.:** 10-10-54

**Expiration:** December 2, 2011

**File(s) Requested:** Birth Cohort 1984-1990, 1993-1997, and 1999

**Requested Identifiers:** No Personal Identifiers

**Personal Contact:** No

**Identifiers Released:** No

**History:** New Research Project

**Summary:** They plan to link information on pregnant women with confirmed or probable 2009 H1N1 influenza reported to CDPH with symptom onset from April 1, through December 31, 2009 to data from birth and fetal death certificate data (obtained from the California Vital Statistics) in order to determine fetal and infant outcomes (e.g., higher rates of preterm birth, low birth weight, fetal deaths).

The hypothesis is that infants born to women with 2009 H1N1 influenza infection during pregnancy are at increased risk for adverse infant and fetal outcomes (e.g., higher rates of preterm birth, low birth weight, and fetal deaths).

This study is a data linkage project of previously collected data on pregnant women with influenza to infant data from birth and fetal death certificates.

**VSAC Discussion:** No comments

**VSAC Recommendation:** Krista Hanni made a motion to approve recommendation. Debra Williams seconded the motion. Committee members all voted aye.

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The tenth project reviewed by the committee was:

**Project Title:** "The Effect of Speed Limits on Infant Health, Accidents, and Travel Time"

**Principle Investigator(s):** Arthur van Benthem, Stanford University

**Project Type:** New Research Project

**CPHS Approval:** Approved

**Project No.:** 11-04-21

**Expiration:** April 6, 2012

**File(s) Requested:** Birth Cohort

**Requested Identifiers:** No Personal Identifiers

**Personal Contact:** No

**Identifiers Released:** No

**History:** New Research Project

**Summary:** The main research question of the project is: How do the benefits (reduced travel time) compare to the costs (worse infant health and more accidents) of higher speed limits? The California birth cohort data will be used to estimate a key component of this research: the effects of higher speed limits on infant health. Specifically, they plan to answer the following questions:

What is the effect of a speed limit change on California freeways on fetal deaths and infant health at birth (e.g., low birth weight)?

What is the effect of a one-unit increase in the concentration of Carbon Monoxide (CO), Nitrogen Oxide (No<sub>x</sub>) and Particulate Matter (PM10) on the health outcomes stated above?

The research design compares infants whose mothers lived close to a freeway where the speed limit was raised (e.g., within two miles) with mothers who lived further away.

**VSAC Discussion:** Sue Holtby was unable to attend the meeting but sent an email. She wanted more information on how they will attribute poor outcomes to freeway proximity. She would also like to know if the non-motor vehicle deaths will be analyzed by cause of death, with the hypothesis that there will be higher rates of cardiopulmonary causes of deaths among infants living near freeways.

Krista Hanni wanted to know if there were certain standards for the use of laptops. David Grant felt there was confusion regarding the computer that would house the data. Committee members agreed that clarification was needed regarding: 1) where the data would reside; 2) if there is firewall and intrusion detection for network connections; and 3) how the computer is configured and connected.

The purpose of the protocol may be questionable and the research design may need clarity. The title mentions accidents, but the protocol implies an environmental impact study with Zip Codes as a factor.

**VSAC Recommendation:** Krista Hanni made a motion to conditionally approve recommendation to the State Registrar to release data based on additional information to be furnished by the principle investigator: (1) the use of an appropriate firewall, (2) intrusion detection software for the computer on which the data resides; and (3) clarification regarding whether the computer housing the data is a laptop or personal computer. Jonathan Teague seconded the motion. Committee members all voted aye.

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The eleventh project reviewed by the committee was:

**Project Title:** "Tracking the Well-Being of Children in California"

**Principle Investigator(s):** Mark Mather, PhD, Associate Vice President,  
Domestic Programs Population Reference Bureau

**Project Type:** New Research

**CPHS Approval:** Approved

**Project No.:** 11-02-20

**Expiration:** February 3, 2012

**File(s) Requested:** 2008 and 2009 Birth Statistical Master File, 2008 and  
2009 Death Public Use

**Requested Identifiers:** No Personal Identifiers

**Personal Contact:** No

**Identifiers Released:** No

**History:** New Research Project

**Summary:** The purpose of the project is to use California's 2008-2009 birth statistical master files (without personal identifiers) to report state- and county-level statistics on low-birth weight babies, infants whose mothers received prenatal care, teen births, and preterm births in California. Data will be cross tabulated by age of mother and by race/ethnicity. Previously, the birth public use files were used; however, since this file is no longer available the principle investigator is requesting access to the 2008-2009 BSMF.

California's 2008-2009 death public use files (without personal identifiers) will be used to report state- and county-level statistics on deaths of children and youth in California. Data will be cross tabulated by leading cause of death, gender, age group, and race/ethnicity.

**VSAC Discussion:**

Discussion included a comment about displaying aggregate data on the Kidsdata.org website. Jonathan asked if there is a policy on redistributing data. There is no California Department of Public Health policy on re-tabulating files.

**VSAC Recommendation:** Jonathan Teague motioned to approve recommendation to the State Registrar to release data. Krista Hanni seconded the motion. Committee members all voted aye.

The committee was asked to look over Attachment 3, Data Requests which were approved internally and released since the last meeting.

Krista Christian asked if there were any attendees from the general public with questions or comments. None were on the phone. Jonathan Teague motioned to adjourn the meeting at 10:12 A.M. Krista Hanni seconded the motion. Committee members all voted aye. Krista Hanni said that there were no public attendees in Monterey.