

Vital Statistics Advisory Committee (VSAC)
Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday, May 5, 2010
9:00 AM to 12:00 PM

Attendees

Convener: Linette Scott

Committee Members:

Present: Debbie Williams (W), Debbie Castanon (C),
Jonathan Teague

Phone: Peter Abbott, Sue Holtby, Erlinda Valdez, David Grant,

CDPH Staff:

Present: Debbie McDowell (M), Jane McKendry, Karen Roth,
Julie Turner, Karen Vinson, Cindy Tanaka-Fong

Phone: David Fisher

A. WELCOME

Linette welcomed all attendees. Debbie C was introduced and welcomed as the newest member of the committee.

B. Approval of minutes from the previous meeting

March 3, 2010 minutes approved as written.

C. Old business

6 projects were reviewed.

D. New business

21 projects require review.

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Project Title: Maternal and Infant Health Assessment (MIHA)

Principle Investigator(s): Paula Braveman, MD, MPH

Project Type: Continuing Research

CPHS Approval: Approved

Project No.: 98-02-04

Expiration: December 10, 2010

File(s) Requested: AD Hoc Birth Data File - January 2010 to July 2010

Requested Identifiers: Names, Certificate Numbers, Addresses

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: The Maternal and Child Health (MCH) Branch of Public Health contracts with Dr. Braveman to conduct the Maternal and Infant Health Assessment (MIHA), an ongoing, population-based survey of mothers delivering live infants in California. This is an ongoing research project for which Dr. Braveman is requesting BID Data for January through July 2009.

The primary objectives of MIHA are 1) to monitor progress toward decreasing modifiable risk factors for adverse maternal and infant health outcomes during the periods immediately prior to pregnancy, during pregnancy, and during early infancy; 2) to analyze relationships between (a) selected maternal characteristics, behaviors, and conditions that occur before, during and after pregnancy and (b) selected pregnancy outcomes; (3) to analyze relationships between (a) certain barriers and maternal characteristics and (b) utilization of health services; and (4) to serve as an information resource for the development, targeting, implementation, and monitoring of intervention programs funded by MCAH and other units of Public Health.

VSAC Discussion: Marital status and social security numbers will not be provided.

VSAC Recommendation: Approved with stipulations:

1. The requestor will be told that marital status will not be provided.
2. The requestor will be told that social security numbers can not be released on birth files.

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Project Title: Development of the Brain Basis of Cognitive and Social Behavior in Human Infants

Principle Investigator(s): Leslie J. Carver

Project Type: Continuing Research

CPHS Approval: Approved through February 4, 2011

Project No.: 02-02-12

Expiration: February 4, 2011

File(s) Requested: Birth data from Dr. Karen Dobkins (#98-10-15)

Requested Identifiers: Name, Address

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: Dr. Leslie Carver has been using birth records obtained by Dr. Karen Dobkins from San Diego County to recruit subjects. She provided an updated CPHS approval letter for continuing access to data from Dr. Dobkins. Dr. Dobkins' study (#98-10-15) is renewed annually by CPHS and VSAC.

The purpose of this study is to determine the brain events that underlie infants' social and cognitive behavior from the last half of the first year of life through the preschool years.

VSAC Discussion: This project is requesting the use of Karen Dobkins' data for a contact study.

VSAC Recommendation: Approved

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Project Title: Perinatal Profiles

Principle Investigator(s): Ralph Catalano, PhD

Project Type: Continuing Research

CPHS Approval: Approved through December 3, 2010

Project No.: 05-12-59

Expiration: December 12, 2010

File(s) Requested: 2007 Birth Cohort File

Requested Identifiers: No Personal Identifiers

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: This request is for the 2007 birth public use file for an ongoing research project. In July 2002-July 2005, the Perinatal Profiles was previously known as "Perinatal Quality Improvement Project", Project Number 03-04-61 under a contract with the California Department of Health Services (DHS) - MCAH. In July 2005, the project was renamed, Perinatal Profiles and a new contract was developed.

The point of Perinatal Profiles is to permit hospitals to review identified cases to improve their quality of care. The data will be used to create hospital specific quality improvement reports on birth outcomes (Perinatal Profiles Reports) in accordance with a grant from DHS - MCAH Branch, (contract#05-45195). Although the data requested is non-confidential, hospital-level data is released and may potentially be identifiable; therefore CPHS/VSAC approval is required.

VSAC Discussion: No comments.

VSAC Recommendation: Approved

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Project Title: Replication of Draper Study of Leukemia, Brain Tumors and Distance to Power Lines in California

Principle Investigator(s): Myles Cockburn for/with Leeka Kheifets

Project Type: Continuing Research Project

CPHS Approval: Approved through February 4, 2010

Project No.: 08-12-56

Expiration: February 4, 2011

File(s) Requested: 11,464 paper birth certificates

Requested Identifiers: Birth Certificate

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: This project seeks to explore the association between exposure to extremely low frequency electric and magnetic fields and child leukemia that has led to the classification of magnetic fields as possible human carcinogen. Additionally, the project seeks to evaluate socio-demographic and other factors such as ethnicity, parental education, socio-economic status, birth weight, parity and others that can be associated with increased risk of childhood leukemia.

The certificates are required to complete the study because older data files that were previously provided to the requestor did not include residence addresses on the data file. Only the state file numbers and addresses are being requested.

VSAC Comments: Debbie C questioned if there is a data use agreement between USC and their UCLA consultants involved with this project, if there is a standard consultant agreement process in place for requestors, and if the consultants get identifiable data. Linette explained that at this time no standard verbiage for consultant agreements is provided to requestors. Linette stated that whether or not a consultant receives identifiable data is dependent on how and what the need is for the data as described in a given protocol. The committee agreed that a copy of the security agreement should be requested and reviewed by OHIR. Debbie C wanted to know what was in the agreement between Myles and the power company (contractors). Jonathan commented about having them return the data or giving us a destruction date. Debbie C questioned how OHIR receives proof that the data has been destroyed if not returned and if there is an audit process.

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VSAC Recommendation: Approved with stipulations:

1. The requestor must provide OHIR with a copy of the security agreement between USC and UCLA (consultant) for review. If the agreement is appropriate, OHIR can release the data and a copy of the data agreement will be placed as an attachment to the minutes from the meeting. If the agreement is not approved, no data can be released.
 2. Ask for destruction plan—whether certificates will be destroyed or returned.
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Project Title: Language Development in the Human Brain: Neural Correlates of Infant Word Learning

Principle Investigator(s): Jeff Elman, PhD

Project Type: Continuing Research

CPHS Approval: Approved through June 4, 2010

Project No.: 07-06-01

Expiration: June 4, 2010

File(s) Requested: Birth data from Dr. Karen Dobkins (#98-10-15)

Requested Identifiers: Name, Addresses

Personal Contact: Yes

Identifiers Released: No

History: Prior Data Request

Summary: Dr. Jeff Elman has been using birth records obtained by Dr. Karen Dobkins from San Diego County to recruit subjects. He provided an updated CPHS approval letter for continuing access to data from Dr. Dobkins. Dr. Dobkins' study (#98-10-15) is renewed annually by CPHS and VSAC.

This project involves three studies aimed to help reveal when and where brain areas are active during behavior associated with word acquisition in young infants between the ages of 12-24 months (Studies 1 and 2). Study 1 will reveal the regions that are most associated with processing familiar words. Study 2 has a similar goal, but will investigate eye gazing, an important component of joint attention (JA), a social behavior for word learning. Taking into consideration the findings from the first two studies, the goal of Study 3 will be to directly investigate the effects of JA/non-JA on word learning.

The study will record the child's brain waves with magnetoencephalography (M-E-G) and electroencephalography (E-E-G) and will also take pictures of the child's brain during the MRI brain scan. The child's brain waves will be measured as they listen to different words or try to follow the gaze on an experimenter.

VSAC Discussion: As a demographer, David Grant commented that Latino statistics for 12-24 month infants would be underrepresented if 1990 census data is used. The committee wants to know why the protocol states that 1990 census data is being used. Linette said they should be using 2000-2010

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for more accurate/current data. Debbie C wanted to know if the laptops were encrypted.

VSAC Recommendation: Approved with stipulations:

1. The requestor must provide an explanation as to why they are using the 1990 census when use of 2000 census data would be more representative of the racial breakdown they are researching.
 2. That all data placed on a laptop be encrypted.
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Project Title: Learning to Listen Ahead in English and Spanish

Principle Investigator(s): Anne Fernald, PhD

Project Type: Continuing Research

CPHS Approval: Approved through February 4, 2011

Project No.: 04-02-03

Expiration: February 4, 2011

File(s) Requested: Ad Hoc Birth Data File

Requested Identifiers: Name, Certificate Numbers, Address

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: The primary goal of the research project is to investigate how infants and young children develop efficiency in understanding and using language. Over the 6-year period remaining in the 10-year project, they estimate that they will need to successfully recruit 5000 children. She is requesting access to the birth records of Santa Clara and San Mateo Counties that includes baby's birth date, weight in grams, baby's first, middle, and last name; mother's and father's first, middle, and last names; mother's and father's place of birth; address; city; zip code; date of last menses; complications; abnormalities; and hospital code.

The experimental methods rely on videotaped behavioral observations of verbal and nonverbal communication between parents and children. The research combines field and laboratory methods to investigate the development of communication and language capabilities by English- and Spanish- learning children over the first four years of life. Dr. Fernald sends one letter to parents which explains the study and invites them to participate. The information provided from the birth records is only used to contact the families once and is destroyed after the invitation is mailed.

VSAC Discussion: No discussion

VSAC Recommendation: Approved

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Project Title: Epidemiology of Functional Status in Older Hispanics Sacramento Area Latino Study on Aging (SALSA)

Principle Investigator(s): Mary N. Haan, MPH, DrPH

Project Type: Continuing Research

CPHS Approval: Approved

Project No.: 04-DD-04

Expiration: Approval in effect for the life of the project

File(s) Requested: 2006, 2007, and 2008 Death Statistical Master File

Requested Identifiers: Name, Certificate Number, Social Security Number

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: Sacramento Area Latino Study on Aging (SALSA) is a cohort study of 1,789 older Latinos of primarily Mexican descent who are community-dwelling, non-institutionalized and were aged 60 years and older at enrollment. The initial baseline data collection for SALSA began in 1998 and field work was completed in 2008. The study is continuing to do mortality surveillance through 2015. After field work was completed, Dr. Haan (PI) relocated from University of Michigan to UCSF. This study examines whether risk factors such as diabetes, hypertension, smoking and obesity increase the risk of dementia, memory loss, peripheral or central neuropathies, physical functional impairment, and decline in cognitive and physical functioning.

The study includes only Latinos since extensive data on dementia and functional status in non-Latinos have already been collected. This study has increased the understanding of the causes of chronic diseases in older Latinos.

VSAC Discussion: No Discussion

VSAC Recommendation: Approved

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

Principle Investigator(s): Irva Hertz-Piccioto

Project Type: Continuing Research

CPHS Approval: Approved through February 11, 2011

Project No.: 01-12-13

Expiration: February 4, 2011

File(s) Requested: 2008 Birth Statistical Master File, Infant Deaths

Requested Identifiers: Name, Certificate Number, Social Security Numbers

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: This continuing project will compare children with autism to both normally developing controls and developmentally disabled or delayed children. Continued CPHS approval has been granted through February 4, 2011.

The aims are 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 PCB's, 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, rubella vaccine and ethylmercury 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.

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.

VSAC Discussion: The committee members discussed the confidentiality of date of birth and the process of data destruction.

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VSAC Recommendation: Approved with stipulation: The requestor will be told that social security numbers can not be released on birth files.

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Project Title: Predicting Adverse Pregnancy Outcomes Using an Existing Prenatal Screening Program

Principle Investigator(s): Laura Jeliffe

Project Type: Continuing Research

CPHS Approval: Approved through April 30, 2010

Project No.: 07-06-56

Expiration: April 30, 2010

File(s) Requested: 2007-2008 Birth Statistical Master File, 2007 Birth Cohort File, 2007-2008 Death Statistical Master File, 2007 Fetal Death Statistical Master File

Requested Identifiers: Name, Certificate Number, Social Security Number

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The files will be used to evaluate the relationship between analytes considered in prenatal screening and birth outcomes including low-birth weight, preterm birth, small-for-gestational-age birth and fetal or other demise within one year of birth. CPHS has approved this project through April 30, 2010.

Adverse obstetric outcome data will be collected via the linkage of second trimester screening results to California fetal death, death, and birth records for 2005-2008 using identifiers present in screening, fetal death, death, and birth records.

Use of social security numbers is essential for completing linkages, particularly for women who may have moved between screening and the report of a fetal death or live birth.

VSAC Discussion: We will need an updated CPHS approval letter before data will be released.

VSAC Recommendation: Approved with stipulation: The requestor will be told that social security numbers can not be released on birth files.

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Project Title: Three projects: (1) San Francisco Mammography Registry: A Research Resource; (2) Predictors of Recurrent Breast Tumors in Women with DCIS; (3) UCSF Breast Cancer (SPORE): Bay Area Translational Research Program-Outcomes Core

Principle Investigator(s): Karla Kerlikowske, MD

Project Type: Continuing Research

CPHS Approval: Approval effective for the life of the project

Project No.: 05-DD-02, 06-DD-01, 04-DD-07

Expiration: N/A

File(s) Requested: Merged Death Data File

Requested Identifiers: Name, Certificate Number

Personal Contact: No

Identifiers Released: Yes

History: Previous Data Request

Summary: Dr. Kerlikowski has been approved for 3 projects that will be using the same data. She previously received approval for the confidential merged death data for the years 1985-2006 and the Merged Death Files for the year 2007. She is now requesting 2005-2008 Merged Death Files. She has projected that she will be using confidential death data thru 2010 for all three projects and has been approved by CPHS through the data year 2010. If she will then use data after that date she would have to revise the protocol to project the years she would be using at that point.

Project # 04-DD-07: The San Francisco Mammography Registry (SFMR) maintains a computerized database of women undergoing mammography in San Francisco and Marin Counties. The SFMR includes demographic, clinical and risk factor information, mammographic interpretations, and cancer outcomes obtained through a standardized questionnaire, clinic mammography data systems, and linkage with the Surveillance, Epidemiology, and End Results (SEER) program and the California Cancer Registry. The SFMR serves as a resource for conducting high quality, clinically significant research related to breast cancer.

Project # 05-DD-02: The National Cancer Institutes established the Specialized Programs of Research Excellence (SPORE) to promote interdisciplinary research and speed the move of research findings from the laboratory to the clinic. The UCSF Breast Cancer SPORE is made up of a

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variety of research projects and cores that provide services to the research projects. This project aims to obtain (1) epidemiological and clinical information for the cohort of women diagnosed with breast cancer at the California Pacific Medical Center, San Francisco General Hospital, and UCSF, and (2) consent for use of their breast tissue in research.

Project Number 06-DD-01: This project will use the confidential death data to study the pathogenesis of breast ductal carcinoma in situ (DCIS), to determine the rate of recurrent disease among women who underwent lumpectomy alone for treatment of DCIS, to identify epidemiologic and clinical factors associated with recurrent disease following lumpectomy, and to identify histopathologic characteristics and molecular markers associated with recurrent disease following lumpectomy.

VSAC Discussion: We need to query them on their data destruction. Debbie C was unclear on the destruction of data.

VSAC Recommendation: Approved with stipulation: The requestor needs to provide us with information on when and how the data will be destroyed.

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Project Title: Gestational Age Measurement in California Birth Records

Principle Investigator(s): Martin Kharrazi

Project Type: Continuing

CPHS Approval: Approved through August 6, 2010

Project No.: Pending

Expiration: Pending

File(s) Requested: 1997-2008 Death Statistical Master File, 1997-2008
Fetal Death Statistical Master File

Requested Identifiers:

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: This study will link California birth and death records to data collected by the Department of Public Health, Genetic Disease Screening Program's (GDSP) Prenatal Screening (PNS) and Newborn Screening (NBS) Programs to compare multiple methods of dating pregnancies and the potential impact on preterm delivery rates.

This study aims to:

- Compare gestational age from the obstetric estimate on birth records since 2007 to ultrasound and last menstrual period (LMP) estimates from the PNS Program and explore factors related to discrepancies;
- Compare preterm delivery rates by gestational age dating method across demographic subgroups defined by race/ethnicity, birthplace, insurance type, education, maternal age and parity, available from birth records;
- Compare birth weight distributions by gestational age among deliveries before 37 weeks as defined by LMP, obstetric estimate, and ultrasound, to examine whether a bimodal birth weight distribution is observed among early gestations;
- Determine whether preterm delivery rates have declined in California overall and among specific racial/ethnic groups between 1996 and 2008 based on LMP from birth records and other dating methods like ultrasound from Prenatal Screening records;
- Compare trends in the shift of the birth weight distribution over time using LMP, ultrasound and other dating methods;

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- Examine the impact of changing fetal death rates on observed preterm delivery rates, overall and by race/ethnicity.

The results will inform the use of LMP and obstetric estimate data from birth records and will be prepared for publication in a major medical or epidemiologic journal.

VSAC Discussion: No comments.

VSAC Recommendation: Approved

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Project Title: Development of a research-ready pregnancy and newborn biobank in California

Principle Investigator(s): Martin Kharrazi

Project Type: New Research

CPHS Approval: Approved through August 6, 2010

Project No.: 09-08-60

Expiration: August 6, 2010

File(s) Requested: 1980-2008 Birth Statistical Master File, 1980-1997 Birth Cohort File, 1999-2007 Birth Cohort File, 1980-1988 Death Statistical Master File, 1980-1998 Death Statistical Master File, 1999-2008 Death Statistical Master File, 1980-1988 Fetal Death Statistical Master File, 1989-1998 Fetal Death Statistical Master File

Requested Identifiers: Name, Certificate Numbers, Social Security Number

Personal Contact: No

Identifiers Released: No

History: No

Summary: The goal of this infrastructure development project is to create an efficient, high throughput, low cost newborn screening and prenatal/maternal screening specimen biobank and linked data base that could be used by large numbers of researchers around the world for a wide range of studies through the following aims:

- (1) establishment of highly efficient protocols and procurement and integration of automated systems for pulling and processing specimens;
- (2) development of an integrated specimen tracking system into the Department's existing web-based Screening Information System (SIS);
- (3) development of a computerized system to track application requests for specimens and data;
- (4) development of a linked screening program-vital records database that is organized into a life course, client based system.

These aims will be accomplished through expansion of the Department's award-winning Screening Integration System to include web-based tracking of specimens and research requests, and use of an innovative machine-learning record matching application for high-performance linkages. After the two-year grant period is completed, the California Research Ready

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Biospecimen Bank (CRRBB) will be able to provide researchers with valuable biological specimens in a timely, cost-effective manner, thereby enabling a dramatic expansion of epidemiological research nationwide.

Screening data will be linked to live births, fetal deaths, and deaths, using combinations of personal identifiers. The resulting CRRBB database will reside within SIS at GDSP. Data will be incorporated into CRRBB on an ongoing annual basis as they become available.

This project utilizes existing specimens and data. No contact will be made with any human subjects. No specimens or data will be provided to any investigators as part of this protocol.

The project in itself is not a research study. The resulting biobank and associated database will enable hundreds of future studies which could result in discovery of novel screening markers, causal exposures, and interventions to detect and prevent diseases and disorders of pregnancy, childhood, and potentially adult diseases.

VSAC Discussion: Questions and concerns were the ownership of data once in the database, what review process for researchers, and the use of social security number – linkage of birth and death data.

The Office of Health Information and Research (OHIR) specifically Jane, Dr. Scott Fujimoto, and Debbie M have been meeting with Dr. Kharrazi and his team. At this time OHIR is not clear on the exact linkage process being used. The CRRBB is proposed to electronically process and track data use. Dr. Kharrazi is aware that approvals are required for each request. Each project will be reviewed by VSAC with the possibility of developing a review process with VSAC that allows data to flow quickly.

The proposal is making blood samples, available to researchers. Permission to use part of the data set must be approved by VSAC. Jonathan had several questions he brought up. He wanted to know what was maintained in the databank, what is being released, and was consent was given to use the information? Linette said that people sign consent that information may be used for research. Jonathan commented that we are not looking at people who will use the tissue specifically.

Linette said that we are not looking at human subjects but the data administrative aspect and the security of individuals and data management. The medical portion would not be released unless they go through VSAC. In the future, VSAC can state that measures will be taken for breach of privacy. Peter felt comfortable to approve the linkage of data but with stipulation. OHIR will be discussing the release of data, no SSN, and their security measures with Dr. Kharrazi. GDSP does many projects, in past the re-release is the top concern. It is clear that the approval is for data linkage only. The

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committee will have to focus on the protocol. Jonathan felt that research should not stop the approval.

Jonathan wanted to know the workload this project would create for VSAC?

Debbie M said that they estimate 24-30 requests per year. They have offered staffing and assistance if it is needed. They plan to allow OHIR and VSAC to electronically access the biobank data to review, comment, and approve or deny a biobank-request. Further discussions with in VSAC will need to be held once a clear picture of how approvals will be handled with in the CRRBB. Each biobank-requestor will have access to the CRRBB to respond to the comments. Debbie C wanted to know if the laptops were encrypted.

Linette said that this was the first time OHIR and VSAC has had a project of this kind. All comments received have been very good comments and will help us as we continue to work on this project with Dr. Dr. Kharrazi and his team.

VSAC Recommendation: Approved with stipulations and only for development of the linkage of the data.

1. There will be no release of linked data until this request is resubmitted to VSAC for review and approvals.
 2. The requestor will be told that social security numbers cannot be released on birth files and do not exist on fetal death files.
 3. This project will need to be reviewed annually by VSAC.
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Project Title: Mental Rotation in Human Infants

Principle Investigator(s): Dr. David S. Moore

Project Type: New Research

CPHS Approval: Approved

Project No.: 07-12-02

Expiration: December 3, 2010

File(s) Requested: San Bernardino Ad Hoc data

Requested Identifiers: Names, Addresses

Personal Contact: Yes

Identifiers Released: No

History: No

Summary: The goal of the current study is to evaluate whether or not human infants are able to mentally rotate 2-dimensional representations of 3-dimensional objects. They will be able to determine the age at which infants are first able to recognize familiar pictured objects after they have been rotated in 3-dimensional space. Furthermore, it will permit them to accomplish our goal of determining if male and female infants differ in terms of when during development this ability appears.

This research is significant because it has the potential to show that human infants are able to form mental representations that are visual in nature and that can be used in the service of recognizing objects that have not previously been seen from a particular perspective. Of equal importance is the potential that this study could reveal any sex differences in mental rotation ability that exist before extensive social experiences contribute differentially to boys' and girls' cognitive competencies. Regardless of whether or not a sex difference is found, this research will establish the conditions that exist early in life, from which the sex differences seen in this domain among older children and adults ultimately develop.

VSAC Discussion: Linette said it was not uncommon to use the birth file for sampling. Jonathan mentioned that he could not see how the study could be done without the birth data. This is a broad based sample. Debbie C wanted to know if the laptops were encrypted as they mention security measures of data on a laptop.

VSAC Recommendation: Approved with stipulation: The requestor will be instructed that all data placed on a laptop must be encrypted.

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Project Title: Two protocols: (1) Normal and Abnormal Spatial Vision in Infants and Form and Motion Integration; (2) Pediatric Low Vision

Principle Investigator(s): Anthony M. Norcia, PhD

Project Type: Continuing Research

CPHS Approval: Approved

Project No.: 98-12-01, 01-12-10

Expiration: December 3, 2010

File(s) Requested: Ad Hoc birth data from San Francisco, San Mateo, and Santa Clara

Requested Identifiers: Names, Certificate Numbers, Addresses

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: This request involves data for two projects: "Normal and Abnormal Spatial Vision in Infants and Form and Motion Integration" 98-12-01 - This research project involves the studies of normal and abnormal processes of visual development in human infants and children. The studies are designed to describe the development of visual mechanisms involved in the recognition of objects and patterns in both normal and abnormally developing visual systems. Data will also be recorded from visually normal and visually abnormal adults, infants and children with strabismus (crossed eyes) and/or amblyopia (loss of visual acuity due to abnormal visual experience during development. "Pediatric Low Vision" 01-02-10 - This research project involves studies of visual development in human infants and children designed to 1) describe the development of visual mechanisms involved in the recognition of objects and patterns in both normal and abnormally developing visual systems, and 2) develop clinically useful tests of visual function that can be applied in non-verbal pediatric patients. Data will be recorded from visually normally developing infants, children, and also from adults and in patients with pediatric eye disease, including strabismus, amblyopia, retinopathy of prematurity, cortical visual impairment and other ocular/visual pathway abnormalities such as aphakia and nystagmus.

VSAC Discussion: No comments

VSAC Recommendation: Approved

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Vital Records Protection Advisory Committee (VRPAC)
Joint Meeting
Meeting Minutes for Wednesday, May 5, 2010
9:00 AM to 12:00 PM

Project Title: The Development of Object Representation in Infancy

Principle Investigator(s): Lisa M. Oakes, PhD

Project Type: Continuing Research

CPHS Approval: Approved

Project No.: 07-04-06

Expiration: April 1, 2011

File(s) Requested: Ad Hoc Birth data

Requested Identifiers: Name, Mother's Address

Personal Contact: Yes

Identifiers Released: No

History: Previous Data Request

Summary: The research project will examine how infants perceive, remember, and categorize objects. Using behavioral measures (e.g., how long infants look at pictures, how long they handle objects), this project proposes to answer key questions about infants' perception of, memory for, and categorization of objects. Dr. Oakes and her team will investigate how changes in motor development (e.g., the ability to sit unassisted, the ability to effectively reach for and obtain objects) enhance infants' perception of object properties. Also, the project proposes to establish how changes in cognitive abilities, such as memory and attention, contribute to how infants perceive, learn about, and remember novel objects. Each of the individual studies within this project will lead to papers published in scientific journals, presentations given at national and international conferences, and will provide pilot data for applications for grant funding.

VSAC Discussion: No comments

VSAC Recommendation: Approved

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Project Title: Postpartum Depression in Asian Americans: Diagnosis Rates and Risk Factors

Principle Investigator(s): Latha Palaniappan, MD, MS

Project Type: New Research

CPHS Approval: Pending

Project No.: Pending

Expiration: Pending

File(s) Requested: 2000-2008 Birth Statistical Master File

Requested Identifiers: Name, Certificate Number, Social Security Number

Personal Contact: No

Identifiers Released: No

History: No

Summary: The proposed study will examine diagnosis rates of postpartum depression (PPD) in Asian American (AA) subgroups using existing electronic health records (EHR) combined with patient self-reported racial/ethnic information and California birth record data. EHR data will be drawn from the Palo Alto Medical Foundation (PAMF). The proposed study will use EHR to determine the association between biological (gestational diabetes mellitus, pregnancy induced hypertension) and selected social risk factors (infant gender) and the diagnosis of PPD.

The overall goal of this study is to address a substantial gap in existing knowledge regarding racial/ethnic differences in the diagnosis rate of PPD among Asian subgroups compared to non-Hispanic Whites (NHWs). The aim is to examine racial/ethnic differences in specific biological and social risk factors for PPD. Our intent is to obtain baseline data for much needed future intervention studies, and to subsequently increase awareness of PPD among health care providers who care for childbearing AA women.

VSAC Discussion: Sue thought it was an interesting hypothesis and use of data.

VSAC Recommendation: Approved with stipulation: The requester will be told that social security numbers can not be released on the birth file.

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Project Title: A Comparison of Surveillance Strategies for Non-Traffic Motor Vehicle-Related Injury to Young Children

Principle Investigator(s): Thomas Rice, PhD, MPH

Project Type: New Research

CPHS Approval: Pending

Project No.: Pending

Expiration: Pending

File(s) Requested: 1999-2007 Death Statistical Master File, 1989-1998
Death Statistical Master File

Requested Identifiers: Name, Certificate Number

Personal Contact: No

Identifiers Released: No

History: No

Summary: Non-traffic motor vehicle-related injury is an important cause of death for young children. This project aims to improve surveillance of these events involving children in California. Non-traffic events typically occur in private driveways, parking lots, and other residential parking areas that are not considered a part of the public traffic environment. The incident and victim characteristics often differ from those observed in traffic collisions; victims are usually younger, often toddlers, and the driver is often a family member. The goals of this project are to describe the incidence and characteristics of the various types of fatal non-traffic injury and to gain an understanding of the quality and completeness of data obtained through several injury surveillance strategies.

VSAC Discussion: No comments

VSAC Recommendation: Approved pending CPHS approval

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Project Title: Predicting Autism Secondary to Mitochondrial Disease

Principle Investigator(s): Marie Roberson, PhD

Project Type: New Research

CPHS Approval: Approved

Project No.: 10-02-55

Expiration: February 4, 2011

File(s) Requested: 2008 Birth Statistical Master File

Requested Identifiers: Name, Certificate Number, Social Security Number

Personal Contact: No

Identifiers Released: No

History:

Summary: The primary intent of this project is to determine if infants that will subsequently manifest symptoms of regressive autism can be identified at birth.

The study will use only existing data sources; no new data will be collected and there will not be any contact with subjects or their medical care providers. After linkages are complete, a deidentified data set will be distributed to all co-investigators for analytical purposes.

Children with autism and idiopathic mental retardation receiving services from DDS have been identified by CDPH staff with the California Center for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) autism program (in DEODC/EHIB).

The purpose of this request is to obtain permission to use birth certificates already obtained for 2005-2007 and to obtain the file for 2008 (and 2009 when available) for use in this project.

The linked DDS/Birth files will be linked to the CDPH NSP data. Social security numbers will be used to facilitate matching between the NSPfile and the DDS/Birth file maintained by CADDRE.

The human subjects to be included in this project will be infants born between August 2005 and May 2009 that participated in the CDPH NSP.

VSAC Discussion: We will need a copy of the data use agreement. We will notify the requestors that they will not receive SSN

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VSAC Recommendation: Approved with stipulation:

1. The requestor will be told that social security numbers cannot be released on birth files.
 2. Request a copy of the data use agreement from the requestor.
-

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Project Title: Enhancement of Surveillance of Vaccine Preventable Diseases Using California Hospital Discharge Data

Principle Investigator(s): Robert Shechter, MD; Kathy Harriman, PhD, RN

Project Type: Continuing Surveillance

CPHS Approval: Not Required

Project No.: N/A

Expiration: February 4, 2011

File(s) Requested: Ad Hoc Birth Data File

Requested Identifiers: Monthly BID Files and Baseline

Personal Contact: No

Identifiers Released: No

History:

Summary: The California Immunization Registry currently consists of nine regional registries whose members are most local health departments. Registries are confidential databases that capture and consolidate all of a child's immunization information, allowing private and public providers to identify and vaccinate needy children, and providing a complete record for parents. Health and Safety Code Section 120440 governs the operation of the registry, specifying measures for the secure sharing of immunization information to help protect children against vaccine-preventable disease.

County-specific birth data have been helpful to the county-level registries in (1) estimating the population of young children in a county and (2) allowing rapid population of demographic fields for records of children in the registry. However, the data available to any single county are insufficient to the current multi-county regional registries. To bridge this gap, Immunization (IZ) Branch is requesting access of BID files. Under this request, VSS would provide monthly BID files to the IZ Branch. The files would include the child's name, sex, birth date, and plurality (single, twin, etc.); city and county of birth; date of death, if any; parent's names and birth dates; informant's relationship to child; and local registration district and number.

VSAC Discussion: The committee expressed interest in obtaining the results, which could be requested in the VSAC approval letter. Linette said there is a placeholder on site to post results on the Internet.

VSAC Recommendation: Approved

Vital Statistics Advisory Committee (VSAC)
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Project Title: California Parkinson's Disease Registry Pilot Project Research:
Use of Medicare Data to Assess Registry Data Collection Efficiency

Principle Investigator(s): Caroline M. Tanner, MD, PhD

Project Type: New Research

CPHS Approval: Approved

Project No.: 09-06-54

Expiration: June 4, 2010

File(s) Requested: 2006, 2007, 2008 Death Statistical Master File

Requested Identifiers: Name, Certificate Number, Social Security Number

Personal Contact: No

Identifiers Released: No

History: No

Summary: Investigators are requesting access to California death data files in order to (1) ensure accuracy of registry-derived annual prevalence estimates of PD by removing deceased cases; and (2) determine the number of cases who were alive during part of a prevalence year but not ascertained in other sources.

A population-based registry will allow a more accurate assessment of the total number of people with PD. Registry data can also be used to detect clusters of disease, to determine if particular groups or sub-groups are at higher risk for developing the disease and to identify trends in disease rates over time. In the future, registry data will provide an important platform for research into many aspects of PD, including its possible causes (e.g., environmental exposures), natural history, efficacy of interventions and patterns of health care utilization and needs.

The registry pilot project involves collection of data about, but no direct contact with, persons with PD/parkinsonism who reside in one of the four designated reporting counties (Santa Clara, Kern, Fresno, Tulare). During the registry pilot project, data had been collected on cases prevalent during the time from of 2006 through 2009.

Death data will be linked to the California PD Registry dataset as part of a capture-recapture validation study previously approved by CPHS. Personal identifiers including name, date of birth, and SSN are needed for precise case matching and de-duplication procedures. Address information will confirm residence in one of the four designated registry reporting counties.

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VSAC Recommendation: Approve with stipulation:

1. The requestor will be asked to provide us with a data use agreement.
 2. Data will be released upon CPHS approval.
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Project Title: Maternal Age-Specific Prevalence Rates of Chromosome Abnormalities by Race/Ethnicity in the Kaiser Health Plan in Northern and Southern California and Portland

Principle Investigator(s): Joseph Terdiman, MD, PhD

Project Type: Continuing Research

CPHS Approval: Approved

Project No.: 98-08-03

Expiration: August 6, 2010

File(s) Requested: 2008 Birth Statistical Master File, 2006 Birth Cohort File, 2007 Fetal Death Statistical Master File

Requested Identifiers: Name, Certificate Number, Address, Social Security Number

Personal Contact: No

Identifiers Released: No

History: Previous Data Request

Summary: The objective of this proposal is to determine maternal age-specific prevalence rates of cytogenetic (chromosomal) abnormalities among various race/ethnic groups in the Kaiser Health Plan using the Kaiser Permanente Interregional Genetics Database and the birth and fetal death records from California and Oregon.

Data on live births and spontaneous and induced terminations of pregnancies will be obtained from the Kaiser Health Plan and matched to the California and Oregon birth tapes to determine race/ethnicity. The data will be combined into a single dataset for analysis. Two groups of cytogenetic abnormalities will be considered: (1) karyotypes associated with minor abnormalities or no known phenotypic changes, and (2) karyotypes associated with major morphological abnormalities or maternal biochemical markers. Since current reliable reference rates of cytogenetic abnormalities are only available for individuals of European origin, results from this proposed study will enable more accurate genetic counseling, especially of minorities, and provide possible leads to biological and other factors, apart from maternal age, that affect rates of chromosome abnormalities in the population.

VSAC Discussion: Debbie C wanted to know if the data was on tape. The data are on CD but in the future, it will be available electronically.

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VSAC Recommendation: Approved with stipulation: The requestor will be told that social security numbers cannot be released on birth or cohort files.

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Items for discussion

- **Flowchart of VSAC**

A flowchart demonstrating the flow of a request to VSAC was presented to the committee. Peter mentioned that VSAC should have a flowchart for all of the various functions that occur to the request prior to and after VSAC reviews

A box will be added to inform committee members of the Committee's recommendations.

- **Destroying or returning vital statistics data**

The approval letter will include language requiring the destruction and or return of data.

- **Revisions to the data request application**

Due to the volume, it was brought up the potential of splitting the review of protocols by birth and death.

- **Distribution of SSN to Researchers**

Linette discussed federal statute which restricts the use of SSN. Without a clear understanding of this statute at this time, we will stop releasing SSN on data until we continue to analyze the meaning of this statute. This only applies to the Birth Statistical Master File and the Birth Cohort files.