

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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AGENDA
COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY

400 R Street, Room 300
Sacramento, CA 95811

Friday, June 5, 2009
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. Revisions to Policies and Procedures
 - i. Term of the Chair
 - ii. Full Committee review of projects
 - b. Office of Human Research Protection request for comments on guidance on genetic information
 - c. Status of SB13 Work Group
 - d. Status of web-based application system
2. CPHS membership
 - a. Recruitment
 - b. Reappointment of members
3. Determination of research vs. public health practice
4. California Cancer Registry and OSHPD Data Linkage – release of OSHPD data (Dr. Lowe)

B. Approval of Minutes

August 1, 2008, February 4, 2009 and March 13, 2009 Meeting Minutes

C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval**Projects with major revisions and requiring periodic review**

1. Project No. 08-06-02 (Reviewer – Ruiz/Lowe)
Project Title: "Causes of Testicular Cancer and Cryptorchidism"
Principal Investigator: Victoria Cortessis, PhD
USC
Los Angeles, CA

Projects requiring periodic review only – (including moderate risk)
Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.

2. Project No. 07-06-52 (Harris)
Project Title: “Updating State Level Smoking Attributable Costs Related to Pregnancy: Maternal Smokers in California in 2003/2004”
Principal Investigator: E. Kathleen Adams, PhD
Emory University, School of Public Health
Atlanta, GA

3. Project No. 05-06-53 (Mihordin)
Project Title: “Determinants of Intrapartum Obstetrical Quality”
Principal Investigator: Jennifer Bailit, MD, MPH
Metrohealth Medical Center
Cleveland, OH

4. Project No. 08-06-61 (Kirkish)
Project Title: “The geographic distribution and political significance of name choice among parents from different racial backgrounds”
Principal Investigator: Alexandra Bass
University of Chicago
Chicago, IL

5. Project No. 05-06-55 (Harris)
Project Title: “National Evaluation of the Robert Wood Johnson Foundation’s Urban Health Initiative”
Principal Investigator: John Billings, JD
New York University
New York, NY

6. Project No. 04-06-62 (Harris)
Project Title: “California Welfare Reform Impact Study”
Principal Investigator: Henry Brady, PhD
UC Berkeley
Berkeley, CA

7. Project No. 05-06-56 (Ruiz)
Project Title: “Chronic Disease Morbidity and Mortality in the San Joaquin Valley: A Longitudinal Study”
Principal Investigator: John A. Capitman, PhD
California State University, Fresno
Fresno, CA

8. Project No. 03-06-57 (Mihordin)
Project Title: "The Link Between Infant and Adult Health"
Principal Investigator: David Card, PhD
UC Berkeley
Berkeley, CA

9. Project No. 05-06-02 (Harris)
Project Title: "Methods Development for Exposure-Related Behaviors"
Principal Investigator: Joseph S. Carey, MD
UC Los Angeles
Los Angeles, CA

10. Project No. 95-06-04 (Murphy)
Project Title: "Office of Statewide Health Planning and Development
1992-2010 Confidential Hospital Discharge Data"
Principal Investigator: Dinnie Chao
CDPH
Sacramento, CA

11. Project No. 94-06-12 (Ruiz)
Project Title: "Study of Infant Sleeping Position and SIDS Risk"
Principal Investigator: Li De-Kun, MD, PhD
Kaiser Permanente
Oakland, CA

12. Project No. 96-06-07 (Mihordin)
Project Title: "The Nature of Psychopathy Among Forensic Patients
and Prefrontal Functioning"
Principal Investigator: Annette Ermshar, PhD
DMH Patton State Hospital
Patton, CA

13. Project No. 02-06-05 (Murphy)
Project Title: "California WISEWOMAN Study: Heart of the Family
(Corazon de la Familia)"
Principal Investigator: Maureen Farrell, RN, FNP, MHA
CDPH
Sacramento, CA

14. Project No. 05-06-57 (Kirkish)
Project Title: "Population-based Incidence of Common Medical and
Obstetrical Complications by Age and Race/Ethnicity"
Principal Investigator: Kimberly D. Gregory, MD, MPH
UCLA
Los Angeles, CA

15. Project No. 05-06-58 (Kirkish)
Project Title: "Are Current Quality Indicators Applicable to Maternal Health"
Principal Investigator: Kimberly D. Gregory, MD, MPH
UCLA
Los Angeles, CA
16. Project No. 05-06-59 (Kirkish)
Project Title: "Multiple Gestations: Risks of Antepartum Admissions; and Maternal and Neonatal Risks by Method of Delivery"
Principal Investigator: Kimberly D. Gregory, MD, MPH
UCLA
Los Angeles, CA
17. Project No. 06-06-52 (Mihordin)
Project Title: "Contributions of Intellectual Functioning, Psychiatric Diagnosis, and History of Neurological Injury on TOMM Performance"
Principal Investigator: Leslie Hall, PhD
DMH
Vacaville, CA
18. Project No. 00-06-06 (Lowe)
Project Title: "Epidemiologic Study of Congenital Hypothyroidism, Thyroid Stimulating Hormone (TSH) and Perchlorate in Drinking Water in California"
Principal Investigator: Michael A. Kelsh, PhD, MPH
Exponent
Menlo Park, CA
19. Project No. 05-06-61 (Kirkish)
Project Title: "Nurse Unionization and Patient Outcomes"
Principal Investigator: Alexandre Mas, PhD
UC Berkeley
Berkeley, CA
20. Project No. 07-06-04 (Ruiz-English and Spanish)
Project Title: "Pesticide and Gene Interactions and Breast Cancer in Hispanic Farm Workers"
Principal Investigator: Paul K. Mills, PhD, MPH
Public Health Institute
Fresno, CA
21. Project No. 04-06-01 (Murphy)
Project Title: "The California PKU Late Treatment Project"
Principal Investigator: Kathryn Moseley, MS, RD
Childrens Hospital Los Angeles
Los Angeles, CA

22. Project No. 06-06-03 (Ruiz)

Project Title: "FoodNet Case-Control Study of Selected Salmonella Sterotypes"

Principal Investigator: Dawn Norton, PhD
CDPH
Oakland, CA

23. Project No. 05-06-03 (Ruiz-English & Spanish)

Project Title: "Controls for a Molecular Epidemiology Study of Infant Leukemia"

Principal Investigator: Julie A. Ross, PhD
University of Minnesota
Minneapolis, MN

24. Project No. 07-06-54 (Ruiz)

Project Title: "Lower Extremity Vascular Procedure Rates and Outcomes in California"

Principal Investigator: Min-Woong Sohn, PhD
Northwestern University
Chicago, IL

25. Project No. 03-04-56 (Lowe)

Project Title: "Proposal to Continue Research on the Developmentally Disabled"

Principal Investigator: David Strauss, PhD, FASA
UC Riverside
Riverside, CA

26. Project No. 03-06-06 (Mihordin)

Project Title: "Community Knowledge and Attitudes of Rabies Control and Willingness to Pay for an Oral Rabies Vaccination Program in Skunks in California"

Principal Investigator: Ben Sun, DVM, MPVM
CDPH
Sacramento, CA

27. Project No. 00-06-02 (Ruiz)

Project Title: "Responses to Short-Term Fluctuations in Particulate Air Pollution in Asthmatic Children: Implications for Asthma Natural History; Characterization of Asthmatic Children's Air Pollution Exposure in Fresno, California"

Principal Investigator: Ira Tager, MD, MPH
UC Berkeley
Berkeley, CA

28. Project No. 05-06-63 (Mihordin)
Project Title: "Fall Injury Study Collaboration"
Principal Investigator: Roger Trent, PhD
CDPH
Sacramento, CA
29. Project No. 04-06-06 (Kirkish)
Project Title: "Partners in Care for Children"
Principal Investigator: Bonnie T. Zima, MD, MPH
UCLA
Los Angeles, CA
30. Project No. 03-06-58 (Harris)
Project Title: "Race, Ethnicity, and Access to Care for Newborns"
Principal Investigator: Laurence C. Baker
Stanford University
Stanford, CA
31. Project No. 95-06-09 (Kirkish)
Project Title: "The California Teachers Study"
Principal Investigator: Leslie Bernstein, PhD
CDPH
Sacramento, CA
32. Project No. 05-06-02 (Harris)
Project Title: "Methods Development for Exposure-related Behaviors"
Principal Investigator: Irva Hertz-Picciotto, PhD
UCD School of Medicine
Davis, CA
33. Project No. 97-06-09 (Ruiz-English and Spanish)
Project Title: "National Birth Defects Prevention Study-
California Component"
Principal Investigator: Gary Shaw, DrPH
CDPH CA Birth Defects Monitoring Program
Berkeley, CA
34. Project No. 05-08-54 (Harris)
Project Title: "The California Family Resource"
Principal Investigator: Raymond White, PhD
Ernest Gallo Clinic & Research Center
Emeryville, CA
35. Project No. 96-06-08 (Mihordin)
Project Title: "Organochlorine Compounds and Menstrual Cycle Function"
Principal Investigator: Gayle C. Windham, PhD
CDPH
Oakland, CA

36. Project No. 05-06-06 (Kirkish)

Project Title: "Evaluation of Diabetes Lifestyle Intervention Program"
Principal Investigator: Ari Zeldin, MD, FAAP
Westside Regional Center
Culver City, CA

Projects with revisions only

Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.

37. Project No. 00-04-04 (Reviewer - Dickey)

Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA

D. Second Review Calendar – Projects not previously approved that require full committee review

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project No. 09-06-01 (Reviewer – Harris-English, Dinis-Spanish)

Project Title: "Socioeconomic Influences on Young Adults with Hematopoietic Cancer: The SEQOL Study"

Principal Investigator: Hoda Anton-Culver, PhD
UC Irvine
Irvine, CA

Erin Kent, MS
UC Irvine
Irvine, CA

2. Project No. 09-06-02 (Reviewer - Ward)

Project Title: "Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer"

Principal Investigator: Esther John, PhD, MSPH
NCCC
Fremont, CA

3. Project No. 09-06-03 (Reviewer - Murphy)

Project Title: "Impact of an Online Support System on Health Related Quality of Life among Men Diagnosed with Prostate Cancer"

Principal Investigator: Jerry Lee, PhD
Loma Linda University
Loma Linda, CA

4. Project No. 09-06-04 (Reviewer - Murphy)
Project Title: "Genome-wide Association Study of Prostate Cancer in African Americans"
Principal Investigator: Kristine Monroe, PhD
USC
Los Angeles, CA
5. Project No. 09-06-05 (Reviewer - Mihordin)
Project Title: "Human Resource Management in the Public Mental Health System"
Principal Investigator: Richard Scheffler, PhD
UC Berkeley
Berkeley, CA
6. Project No. 09-06-06 (Reviewer - Ruiz)
Project Title: "Measuring the Quality of Decisions in Breast Cancer: A Cancer Genetics Network Pilot"
Principal Investigator: Argyrios Ziogas, PhD
UC Irvine
Irvine, CA
7. Project No. 09-06-07 (Reviewer – Mihordin-English, Dinis-Spanish)
Project Title: "Clostridium difficile Infection Surveillance Through the Emerging Infections Program"
Principal Investigator: Bela Matyas, MD, MPH
CDPH
Richmond, CA
8. Project No. 09-06-08 (Reviewer – Lowe/Dinis)
Project Title: "Early Social Development of Toddler Twins"
Principal Investigator: Theodore Jacob, PhD
Family Research Center
VA Palo Alto Health Care System
Menlo Park, CA

New Projects - Expedited Review Requested, but which may require full committee review. Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.

1. Project No. 09-06-51 (Kirkish)
Project Title: "Quality of Human Representation In the Rorschach Protocols of Mentally Ill Offenders"
Principal Investigator: Lindsey Alvis, MS
DMH
Vacaville, CA

2. Project No. 09-06-64 (Murphy)
Project Title: "Cancer Genetics Research Information System (CGRIS)"
Principal Investigator: Hoda Anton-Culver, PhD
UC Irvine
Irvine, CA

3. Project No. 09-06-63 (Mihordin)
Project Title: "Sterilizations in California State Hospitals, 1910s to 1950s"
Principal Investigator: Miroslava Chavez-Garcia, PhD
UC Davis
Davis, CA

4. Project No. 09-06-52 (Harris)
Project Title: "Secondary Analysis of Maternal and Infant Health
Assessment Survey Data"
Principal Investigator: Phillip Darney, MD, MSC
UC San Francisco
San Francisco, CA

5. Project No. 09-06-58 (Murphy)
Project Title: "Moving to Opportunity for Fair Housing Demonstration
Program 10 Year Evaluation"
Principal Investigator: Lawrence Katz,
Harvard University
Cambridge, MA

6. Project No. 09-06-53 (Ruiz)
Project Title: "Characterization of Readmission in California and an
Estimation of the Impact of Post-Discharge complications on
the Sensitivity of the AHRQ Qis"
Principal Investigator: Kathryn McDonald, MM
Stanford University
Stanford, CA

7. Project No. 09-06-60 (Ward)
Project Title: "An Assessment of how vulnerability indicators affect the
association between adverse birth outcomes and air
pollution and traffic exposures"
Principal Investigator: Rachel Morello-Frosch, PhD, MPH
UC Berkeley
Berkeley, CA

8. Project No. 09-06-55 (Harris)
Project Title: "Hospital Characteristics and the Quality of Cancer Care and
Outcomes in California"
Principal Investigator: Kim Rhoads, MD, MPH, MS
Stanford University
Stanford, CA

9. Project No. 09-06-54 (Mihordin)

Project Title: "California Parkinson's Disease Registry Pilot Project
Research: Use of Medicare Data to Assess Registry Data
Collection Efficiency"

Principal Investigator: Caroline Tanner, MD, PhD
The Parkinson's Institute
Sunnyvale, CA

10. Project No. 09-06-61 (Ruiz)

Project Title: "The Impact of lower extremity orthopedic surgery on the
lives of children with cerebral palsy"

Principal Investigator: Stephanie Yu, MSPT, PCS
California Children's Services
Long Beach, CA

11. Project No. 09-06-62 (Ward)

Project Title: "Linkage of California Hospital Discharge Records with State
Vital Statistics Records with Evaluation of Sources of Bias"

Principal Investigator: David Zingmond, MD, PhD
UCLA
Los Angeles, CA

F. Projects with Request for CPHS to Rely on Another Institutional Review Board (IRB) (CPHS will decide on whether to rely on another IRB for approval of these projects)

G. Projects with Reported Adverse Events (CPHS will decide if any action on these projects is necessary)

H. Exemption Request

1. Project No. 05-06-04 (Reviewer – Lowe/Ruiz)

Project Title: "Medical Monitoring Project"

Principal Investigator: Mark Damesyn, DrPH
CDPH Office of AIDS
Sacramento, CA

I. Next Meeting

The next CPHS meeting is scheduled for August 7, 2009 in Sacramento.

J. Adjournment

NOTE: Action may be taken on any items listed in this agenda.

To request any background materials prior to the meeting please contact cphs-mail@oshpd.ca.gov.

Pursuant to the Americans with Disabilities Act, the meeting is accessible to people with mobility impairments. Please contact CPHS, cphs-mail@oshpd.ca.gov or 916-326-3660, at least five working days in advance of the meeting to make arrangements for persons who require additional reasonable accommodations or have special needs. CPHS will ensure that it makes every effort to fulfill the request.

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