

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
(916) 326-3660 FAX (916) 322-2512

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

400 R Street, Room 300
Sacramento, CA 95811

***US Toll-Free Number: 877-581- 9247
Access Code: 963949**

**Friday, April 5, 2013
8:30 a.m. – 5:00 p.m.**

A. General Items

1. CPHS New Staff Member-Introduction (Martinez/Cortes)
2. Cal Protects-Update (Martinez/Prefach)
 - a. PowerPoint Presentation
3. Legislative Update – AB 58 and AB 925 (Martinez)
4. California Cancer Registry – Dr. Arti Parikh-Patel

B. Approval of Minutes

1. October 2011
2. April 2012
3. June 2012
4. August 2012
5. December 2012

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

1. Project #: 12-05-0177 (Lowe)
Title: Kaiser Research Program on Genes, Environment and Health (RPGEH) and Biomonitoring California Adult Cohort Project Biomonitoring Exposures Study (BEST)
PI: Michael Lipsett
California Department of Public Health
Richmond, CA
2. Project #: 12-05-0247 (Perel/Lowe)
Title: Birth Defects Monitoring Program
PI: Shabbir Ahmad, DVM, MS, PhD
Co PI: Melissa Salas, Program Analyst
California Department of Public Health, Center for Family Health
Sacramento, CA

D. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 13-02-1070 (Ruiz, Molitor)
Title: The American Cancer Society Cancer Prevention – 3 Registry Linkage
PI: Alpa Patel, PhD
Co PI: Eric Jacobs, PhD
American Cancer Society
Atlanta, GA

2. Project #: 13-02-1098 (Schaeuble)
Title: Investigating the Link between Walking and Language Development
PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

3. Project# 13-02-1101 (Schaeuble)
Title: Visual Proprioception and Wariness of Heights in Infants
PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

4. Project #: 13-02-1103 (Schaeuble)
Title: Locomotion and Psychological Development in Infancy
PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

5. Project #: 13-02-1113(Schaeuble)
Title: Emotional Communication of Rules to Infants
PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

6. Project #: 13-02-1114 (Molitor)
Title: Maternal and Infant Home Visiting Program Evaluation (MIHOPE)
PI: Virginia Knox, PhD
Co-PI: Charles Michalopoulos, PhD
MDRC
New York, NY

7. Project #: 13-02-1116 (Lowe)
Title: Surveillance of NEOP
PI: Fred Molitor, PhD
California Department of Public Health
Sacramento, CA
8. Project #: 13-02-1135 (Perel)
Title: California Children's Services (CCS) Demonstration Evaluation
PI: Dylan Roby, PhD
Co-PI: Daphna Gans, PhD
University of California, Los Angeles
Los Angeles, CA
9. Project #: 12-08-0678 (Dickey/Ruiz)
Title: Permanency Innovations Initiative (PII) Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
Co-PI: Andrea Sedlak, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
10. Project #: 13-01-1043 (Dinis)
Title: CDPH Focus Groups to Assess Public Knowledge and Attitudes on Climate Changes as a Public Health Issue
PI: Kathy Dervin, MPH
Co PI: Brooke Sommerfeldt, MPH
California Department of Public Health
Richmond, CA
11. Project #: 12-11-0930 (Ruiz/Murphy)
Title: Mortality and Support on On-line Social Media
PI: James Fowler, PhD
University of California San Diego
La Jolla, CA
12. Project# 13-03-1159 (Murphy)
Making the Transition-Socioemotional Adjustment of Youthful Offenders into Adulthood
Elizabeth Cauffman, Ph.D.
Joseph Tatar, MA
University of California, Irvine
Irvine, CA

E. New Projects - Expedited Review Requested

These 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 #: 12-06-0379 (Murphy/Dickey)
Title: Cancer Genetics Research Information System (CGRIS)
PI: Hoda Anton-Culver, PhD
Co-PI: Thomas Taylor, PhD
University of California, Irvine
Irvine, CA

2. Project #: 12-12-0963 (Bazzano/Perel)
Title: Effect of maternal education on adverse birth outcomes
PI: Lela Bachrach, MD, MS
Co-PI: Virginia Bachrach, MD
University of California, Berkeley
Berkeley, CA

3. Project #: 12-12-1024 (Parker/Schaeuble)
Title: Perceptions of Staff Safety and Violence Risk Assessment Decision Making at a Forensic Psychiatric Hospital
PI: Shannon Bader, PhD
Co-PI: Sean Evans, PhD
California Department of Mental Health
Patton, CA

4. Project #: 12-10-0840 (Murphy/Trent)
Title: Ethnic Disparities in Utilization Rates and Complication Rates in Hip & Knee Arthroplasty and Hip Fracture Surgery.
PI: Timothy Brox, MD
Co-PI: Paul Brown, PhD
University of California, San Francisco
Fresno, CA

5. Project #: 13-02-1097 (Lowe/Perel)
Title: An examination of chronic health problems of survivors of adolescent and young adult cancer
PI: Chun Chao, PhD
Kaiser Permanente
Pasadena, CA

6. Project #: 13-02-1092 (Bazzano/Schaeuble)
Title: Subsequent Cancer in Non-Melanoma Skin Cancer Patients
PI: Mary-Margaret Chren, MD
University of California, San Francisco
San Francisco, CA
7. Project #: 13-01-1069 (Parker/Grabau)
Title: CCR-PAMF Linkage: Creating an Anonymized Dataset for Cancer Research
PI: Scarlett Gomez, PhD
Cancer Prevention Institute of California
Fremont, CA
8. Project #: 13-02-1123 (Bazzano/Lowe)
Title: Mutational Profiling of Small Cell Carcinoma of the Ovary, Hypercalcemic Type
PI: Douglas Levine, MD
Co-PI: Gary Leiserowitz
Memorial Sloan-Kettering Cancer Center
New York, NY
9. Project #: 13-01-1068 (Bazzano/Parker)
Title: Evident dampness and mold, fungi identified by DNA-based assays, and respiratory health in CHAMACOS children
PI: Mark Mendell, PhD
California Department of Public Health
Richmond, CA
10. Project #: 12-11-0947 (Dickey/Schaeuble)
Title: Emerging Infections Program Pilot Evaluation of Appropriate Antimicrobial Use in Hospitalized Patients
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA
11. Project #: 12-12-0977 (Dickey/Bazzano)
Title: Establishing a Predictive Model to Differentiate Viral Encephalitis from Acute Demyelinating Encephalomyelitis (ADEM) in Early Presentation among California Children (The EVADE Study)
PI: Poonam Patel, MD
California Department of Public Health
Richmond, CA

12. Project #: 13-01-1064 (Bazzano/Parker)
Title: Demographic and prenatal predictors of maternal health and birth outcomes in San Bernardino County
PI: Pramil Singh, PhD
Co-PI: Jayakaran Job, MD, PhD
Loma Linda University
Loma Linda, CA
13. Project #: 13-02-1118 (Schaeuble/Trent)
Title: Behavior and Driving Safety Study
PI: Garth Utter, MD, MSc
University of California, Davis
Sacramento, CA
14. Project #: 13-02-1094 (Dickey/Schaeuble)
Title: Ibuprofen may decrease and acetaminophen increase the incidence of bronchiolitis
PI: Paul Walsh, MB, BCh, BAO
University of California, Davis
Sacramento, CA

F. Continuing Projects Calendar – Previously approved projects requiring full committee approval

None

G. Projects with major revisions and requiring periodic review

None

H. Projects requiring periodic review only – (including greater than minimal risk). 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 #: 13-03-1152 (Murphy)
Title: Project Number 07-04-52 Family Centered Welfare Research Project – Los Angeles County First approved by CPHS April 2, 2010
PI: Daniel Flaming, PhD
Economic Roundtable
Los Angeles, CA

2. Project #: 13-02-1088 (Parker)
Title: The Path to Language and Literacy: A Cross-Linguistic Longitudinal Approach
PI: Margaret Friend, MA, PhD
San Diego State University
San Diego, CA
3. Project #: 13-02-1115 (Murphy)
Title: Cognitive Function after Breast Cancer Treatment
PI: Patricia Ganz, MD
University of California, Los Angeles
4. Project #: 13-02-1119 (Dickey)
Title: Memory Processes in Childhood
PI: Simona Ghetti, PhD
University of California, Davis
Davis, CA
5. Project #: 13-02-1124 (Parker/Grabau)
Title: Ultrafine Particle Exposure and Respiratory Outcomes among Bicycle Commuters
PI: Susan Gilbreath, PhD
Co-PI: Poh-Sin Yap, PhD
California Air Resources Board
Sacramento, CA
6. Project #: 13-01-1056 (Murphy)
Title: Forteo Patient Registry
PI: Alicia Gilsenan, PhD
Co-PI: Elizabeth Andrews, PhD
RTI International
RTP, NC
7. Project #: 13-02-1134 (Dickey/Dinis)
Title: Life Course Energy Balance and Breast Cancer Risk in Black/White Women Under 50
PI: Ann Hamilton, PhD
University of Southern California
8. Project #: 12-12-1016 (Murphy)
Title: Tracking the Well-Being of Children in California
PI: Mark Mather, PhD
Washington, DC

9. Project #: 12-06-0455 (Dickey/Lowe)
Title: 'Evaluation of the Association between Geographic Distribution and Clustering of Exemptions and Outbreak of Vaccine Preventable Diseases
PI: Saad Omer, MBBS, MPH, PhD
Emory University
Atlanta, GA
10. Project #: 13-03-1137 (Lowe)
Title: Quality Reporting and Patient Volume in California Hospitals
PI: John Romley, PhD
Co-PI: Allison Cuellar
University of Southern California
Los Angeles, CA

I. 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.

11. Project #: 12-08-0631 (Bazzano/Ruiz)
Title: Predictors of long-term outcomes in California children with central nervous system (CNS) tuberculosis (TB)
PI: Pennan Barry, MD, MPH
Co-PI: Alexandra Duque-Silva, MD
California Department of Public Health
Richmond, CA
12. Project #: 12-08-0631 (Lowe/Perel)
Title: Impact of economic factors on health outcomes at birth
PI: Suzanne Bostwick
Co-PI: Ricardo Basurto-Davila, PhD, MSc
Department of Public Health
Los Angeles, CA
13. Project #: 12-08-0588 (Dinis/Lowe)
Title: Vaccine Safety Datalink (VSD) Study
PI: Steven Jacobsen, MD, PhD
Kaiser Permanente
Pasadena, CA

14. Project #: 12-10-0861 (Perel/Lowe)
Title: Evaluating the effects of exposure to air pollution on adverse birth outcomes in Southern California
PI: Beate Ritz, MD, PhD
Co-PI: Ondine von Ehrenstein
University of California, Los Angeles
Los Angeles, CA

15. Project #: 13-01-1027 (Bazzano)
Title: Formative Evaluation of the Adolescent Family Life Plan, Positive Youth Development, My Life Plan (AFLP-PYD-MLP) Program
PI: Kathleen Tebb, PhD
University of California, San Francisco
San Francisco, CA

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

No reports.

K. 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).

No reports.

L. Exemption Request

1. Project #: 13-01-1122 (Ruiz/Lowe)
Title: Linkage of Medi-Cal Administrative Data to California Birth Cohort Files
PI: Aldona Herrndorf, MPH
California Department of Health Care Services

2. Project #: 13-01-1102 (Ruiz/Lowe)
Title: Linkage of Medi-Cal Administrative Data to California Death Statistical Master File
PI: Aldona Herrndorf, MPH
California Department of Health Care Services

M. Next Meeting

The next CPHS meeting is scheduled for Friday, June 7, 2013 in Sacramento.

N. 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 (5) 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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If interested, please call the telephone number and enter the access below when prompted.

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Access Code: 963949

If you have any questions or comments, please contact CPHS at 916-326-3660 or cphs-mail@oshpd.ca.gov.

California Health and Human Services Agency
Committee for the Protection of Human Subjects
400 R Street, Room 359
Sacramento, CA 95811
Phone: (916) 326-3660
Fax: (916) 322-2512
Lucila Martinez, Administrator
Lucila.Martinez@oshpd.ca.gov
cphs-mail@oshpd.ca.gov
CPHS website: www.oshpd.ca.gov/boards/cphs