

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
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**ADDENDUM AGENDA****COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**

400 R Street,
Sacramento River Room
Sacramento, CA 95811

***US Toll-Free Number: 888-636-3807**

Access Code: 963949

Friday, August 1, 2014

8:30 a.m. – 5:00 p.m.

A. General- Administrator Report

1. Reappointment of Members-Secretary Action Request (SAR) Package-Update (Martinez)
2. Cal Protects
 - a. Batch 3 & 4 -CalProtects Issues –Update (West)
3. Updates
4. Legislation (Rivera)
 - a. AB 1683 Ken Maddy California Cancer Registry, Introduced by Assembly Member Jones
 - b. AB 2059 Medical Records: Electronic Delivery, Introduced by Assembly Member Muratuschi
 - c. AB 2147 State Government Internet Website: Information Practices, Introduced by Assembly Member Melendez
5. Continuing Renewals/Amendments/Full Committee Reviews (Dickey)
6. GNB Release of Data/Specimens (Lowe)

B. Approval of Minutes

1. April 4, 2014
2. June 5, 2014

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

1. Project #: 12-10-0819 (Lowe)
Title: Maternal and Infant Health Assessment (MIHA)
PI: Paula Braveman, MD, MPH
University of California, San Francisco
San Francisco, CA

2. Project #: 13-08-1333 (Lowe)
Title: Understanding the Relation between Child Sleep Habits and Functional Outcomes
PI: Angela Lukowski, PhD
University of California, Irvine
Irvine, CA

D. New Projects Calendar
New Projects - Full Committee Review Required

1. Project #: 14-05-1595 (Trent)
Title: Evaluation of Cleaning and Custodial Workers' Exposures to Organic Compounds from Cleaning Activities: A Field Study
PI: Kai-Chung Cheng, PhD
Co-PI: Wenhao Chen, PhD
California Department of Public Health
Richmond, CA

2. Project #: 14-06-1631 (Schaeuble/Molitor)
Title: Neural Assays and Longitudinal Assessment of Infants at Very High Risk for ASD
PI: Scott Johnson, PhD
Co-PI: Mirella Dapretto, PhD
University of California, Los Angeles
Los Angeles, CA

3. Project #: 14-06-1610 (Murphy)
Title: Exosomal miRNA, Metabolites, and Candidate Factors in Saliva of Schizophrenic Patients
PI: Wolff Kirsch, MD
Loma Linda University
Loma Linda, CA
Co-PI: William Britt, PhD, ABN
Patton State Hospital
Redlands, CA

4. Project #: 14-03-1540 (Molitor)
Title: Formaldehyde Sampling in California Mobile Homes
PI: Stephanie Parent, MA
Co-PI: Qunfang Zhang, PhD
California Air Resources Board
Sacramento, CA
5. Project #: 14-06-1614 (Palacio)
Title: A Pilot Study of Analyzing Emerging Environmental Contaminants and Their Secondary Metabolites in Human Blood and Urine
PI: Jianwen She, PhD
Co-PI: Wei Zou
California Department of Public Health
Richmond, CA
6. Project #: 14-02-1507 (Schaeuble)
Title: The IMPAACT Study: Improving Physical Activity After Cancer Treatment
PI: Heather Tarleton, PhD, MS, MPAP
Co-PI: Todd Shoepe, EdD
Loyola Marymount University
Los Angeles, CA
7. Project #: 14-06-1624 (Bazzano)
Title: Pregnancy Assistance Fund Feasibility and Design Study (PAF FADS)
PI: Susan Zief, PhD
Co-PI: Matthew Stagner
Mathematica Policy Research
Princeton, NJ

E. Projects With Major Revisions Requiring Full Committee Approval

1. Project #: 12-05-0176 (Dickey)
Title: California Health Interview Survey
PI: Ninez Ponce, PhD
Co-PI: David Grant, PhD
University of California, Los Angeles
Los Angeles, CA

F. 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 #: 14-05-1593 (Lowe/Palacio)
Title: Sudden Cardiac Arrest Registry for Orange County, CA
PI: Anjan Batra, MD
University of California, Irvine
Irvine, CA

2. Project #: 14-04-1567 (Molitor/Trent)
Title: Predictors of School Based Health Centers
PI: Melina Bersamin, PhD
Prevention Research Center
Oakland, CA

3. Project #: 14-06-1630 (Schaeuble/Grabau)
Title: Enhanced Observation and Restraint Usage Patterns in a State Hospital System
PI: Charles Broderick, PhD

4. Project #: 14-03-1533 (Ruiz/Molitor)
Title: Retrospective Study to Investigate the Incidence and Risk Factors for Early Postpartum Anemia after Cesarean Delivery
PI: Alexander Butwick, MBBS, FRCA, MS
Stanford University
Stanford, CA
Co-PI: Gabriel Escobar, MD
Kaiser Permanente
Oakland, CA

5. Project #: 13-07-1302 (Lowe/Palacio)
Title: Return on Investment: The Cost Offsets Associated with Supported Housing in Los Angeles
PI: Dennis Culhane
University of Pennsylvania
Philadelphia, PA

6. Project #: 14-04-1566 (Ruiz/Molitor)
Title: Restaurant Program Lower Income Area Panel Survey
PI: Arie Kapteyn, PhD
University of Southern California
Los Angeles, CA

7. Project #: 14-06-1617 (Lowe/Murphy)
Title: Decision-making Factors Influencing the Wearing of Body Armor: A National Study
PI: Bruce Taylor, PhD
NORC, University of Chicago
Bethesda MD

8. Project #: 14-05-1577 (Dickey/Bauer)
Title: Mapping ALS Hotspots and Environmental Exposures
PI: Nathan Torbick, PhD
Applied GeoSolutions
Newmarket, NH
Co-PI: Paul English
California Department of Public Health
Richmond, CA

9. Project #: 14-06-1620 (Schaeuble/Ruiz)
Title: Health Care Costs and Treatment Patterns of Patients Diagnosed with Schizophrenia and Bipolar Disorders
PI: Huseyin Yuce, PhD
City University of New York
Brooklyn, NY

G. 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 #: 12-06-0462 (Murphy)
Title: Racial Differences and Trends in Fertility Timing, Fertility-Stopping Decisions, and Prenatal Care
PI: Jason Abrevaya, PhD
University of Texas
Austin, TX

2. Project #: 12-05-0273 (Murphy)
Title: Situational, Interpersonal and Individual Factors Related to Patient Aggression in a State Hospital
PI: Shannon Bader, PhD
Co-PI: Sean Evans, PhD
Patton State Hospital
Patton, CA

3. Project #: 12-05-0237 (Murphy)
Title: Identification of Characteristics Common Among Repetitive Aggressors in a State Hospital
PI: Shannon Bader, PhD
Co-PI: Benjamin Rose, PsyD
Patton State Hospital
Patton, CA
4. Project #: 13-06-1241 (Murphy/Dickey)
Title: Evidence-Based Practices by Community Substance Use Treatment Providers: Parolee Outcomes
PI: Jo Brocato, PhD
California State University Long Beach
Long Beach, CA
5. Project #: 12-05-0191 (Murphy)
Title: Molecular Epidemiology of Lung Cancer
PI: Chu Chen, PhD
Fred Hutchinson Cancer Research Center
Seattle, WA
6. Project #: 12-11-0930 (Murphy)
Title: Mortality and Support on Online Social Media
PI: James Fowler, PhD
University of California, San Diego
La Jolla, CA
7. Project #: 12-04-0165 (Murphy)
Title: Cancer Prevention Study-II (CPS-II): Registry Linkage with the California Cancer Registry
PI: Susan Gapstur, PhD
American Cancer Society
Atlanta GA
8. Project #: 12-05-0261 (Murphy)
Title: Immune Response Genes and Young Adult Hodgkin Lymphoma: Greater Bay Area Extension
PI: Sally Glaser, PhD
Cancer Prevention Institute of California
Fremont, CA

9. Project #: 12-06-0431 (Dickey/Lowe)
Title: Improving Cancer Screening Among Breast and Colorectal Cancer Survivors and their Relatives through the Los Angeles County Cancer Surveillance Program
PI: Beth Glenn, PhD
University of California, Los Angeles
Los Angeles, CA
Co-PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA
10. Project #: 12-06-0359 (Molitor)
Title: Identification and Characterization of CFTR Mutations among Nonwhite Patients with Cystic Fibrosis to Improve the Clinical Sensitivity of Neonatal Screening and Diagnostic Testing
PI: Martin Kharrazi, PhD
California Department of Public Health
Richmond, CA
11. Project #: 12-06-0351 (Murphy)
Title: Medi-Cal Disease Management Pilot Program Evaluation
PI: Gerald Kominsk
University of California, Los Angeles
Los Angeles, CA
12. Project #: 12-06-0469 (Murphy)
Title: Specific Treatment Parameters and Treatment Outcomes of Multidrug-resistant Tuberculosis: An Individual Patient Data (IPD) Meta-Analysis
PI: Dick Menzies
McGill University
Montreal, PQ, Canada
Co-PI: Jennifer Flood
California Department of Public Health
Richmond, CA
13. Project #: 12-06-0319 (Murphy)
Title: Racial and Ethnic Differences in Causes of Mortality
PI: Latha Palaniappan, MD, MS
Palo Alto Medical Foundation Research Institute
Palo Alto, CA

H. Projects with major revisions and requiring periodic review

1. Project #: 13-01-1056 (Murphy)
Title: Forteo Patient Registry
PI: Alicia Gilsean, PhD
Co-PI: Elizabeth Andrews, PhD
RTI International
Research Triangle Park, NC

2. Project #: 12-08-0644 (Molitor)
Title: WIC ITFPS-2: Feeding My Baby – A National WIC Study
PI: Gail Harrison
University of California, Los Angeles
Los Angeles, CA

3. Project #: 12-04-0132 (Murphy/Lowe)
Title: San Francisco Mammography Registry: A Research Resource
PI: Karla Kerlikowske, MD
University of California, San Francisco
San Francisco, CA

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

None

J. 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).

None

K. Exemption/Determination Requests

1. Project #: 14-06-1606 (Ruiz/Lowe)
Title: LA County CHDP Program Operational Support
PI: Alan Tomines, MD
LA County Department of Public Health
El Monte, CA

2. Project #: 14-06-1634 (Ruiz/Lowe/Dickey)
Title: Healthier U Program Evaluation
PI: Seth Leibson, BA
University of California, Berkeley
Berkeley, CA

L. Public Comments

M. Next Meeting

The next CPHS meeting is scheduled for Friday, October 3, 2014 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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If you have any questions or comments, please contact CPHS at 916-326-3660 or cphs-mail@oshpd.ca.gov.

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