

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
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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

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

**Friday, February 7, 2014
8:30 a.m. – 5:00 p.m.**

A. General Items

1. CPHS Administration
 - a. CPHS New Members- (Ruiz, Murphy)
 - b. Alternate Members (Ruiz, Lowe)
2. CalProtects
 - a. Adverse Event Reporting Language-Approval Letters June 2012-June 2013 (Martinez)
 - b. Batch 3 Issues -Update
3. CPHS Legislation –No report

B. Approval of Minutes

1. December 6, 2013

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

1. Project #: 13-02-1134 (Dickey/Ruiz)
Title: Life Course Energy Balance and Breast Cancer Risk in Black/White Women Under 50
PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA
2. Project #: 12-06-0283 (Dickey)
Title: Reach for Health
PI: Ruth Patterson, PhD
University of California, San Diego
La Jolla, CA

3. Project #: 12-07-0500 (Lowe, Ruiz)
Title: Evaluation of the Permanency Innovation Initiative: California Partners for Permanency
PI: Andrea Sedlack, PhD
Westat, Inc.
Rockville, MD

D. Full Committee Projects Requiring Further Discussion

None

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 14-01-1464 (Dinis)
Title: Epigenetic Risk Factors in Women with Breast Cancer: A Family Case-Control Study
PI: Mildred Gonzales, RN, MSN
Azusa Pacific University
Alhambra, CA
2. Project #: 14-01-1471 (Lowe)
Title: A Frequency-Based EEG Measure of Attention in Infants
PI: David Moore, PhD
Claremont Colleges
Claremont, CA
3. Project #: 13-10-1383 (Perel)
Title: Understanding Cancer Survivor's Information Needs and Information-Seeking Behaviors for Complementary and Alternative Medicine (CAM)
PI: Lou Ann Scarton, MS
University of Utah
Salt Lake City, UT
4. Project #: 13-10-1398 (Grabau)
Title: Birth Defects Study To Evaluate Pregnancy ExposureS – California Component
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, 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 #: 13-11-1426
Title: Oil Refining and Health
PI: Patrick Baylis
University of California, Berkeley
Oakland, CA

2. Project #: 13-11-1422
Title: San Joaquin County Local Arrest Study
PI: Campbell Bullock, MA
San Joaquin Data Co-Op
Stockton, CA

3. Project #: 13-04-1191
Title: Obstetric Management and Outcomes in California 2005-2012
PI: Aaron Caughey, MD, PhD
Co-PI: Blair Darney, PhD, MPH
Oregon Health and Science University
Portland, OR

4. Project #: 13-12-1428
Title: Chronic Disease in California, 2007-2016
PI: Shannon Conroy, PhD, MPH
California Department of Public Health
Sacramento, CA

5. Project #: 13-04-1174
Title: Epidemiology, Outcomes from Treatment, and the Spectrum of Soft Tissue Infection over Time in Hospitalized Patients: A Population Based Description of Inpatients in the State of California
PI: Lisa Ferrigno, MD
Santa Barbara Cottage Hospital
Santa Barbara, CA

6. Project #: 13-12-1459
Title: Sickle Cell Disease Primary Care Provider Survey
PI: Lisa Feuchtbaum, DrPH, MPH
Co-PI: Ning Rosenthal, MD, PhD
California Department of Public Health
Richmond, CA

7. Project #: 13-11-1424
Title: Merger of Welcome Baby Data with Medi-Cal Data
PI: Tood Franke, PhD
Co-PI: Embry Howell, PhD
University of California, Los Angeles
Los Angeles, CA
8. Project #: 13-09-1339
Title: The Laborist: Is this Model of Care Associated with Better Patient Outcomes?
PI: Kimberly Gregory, MD, MPH
Cedars-Sinai Medical Center
Los Angeles, CA
9. Project #: 12-06-0277
Title: HCG and Sex Ratios in California Births
PI: Martin Kharrazi, PhD
Co-PI: Michelle Pearl, PhD
California Department of Public Health
Richmond, CA
10. Project #: 13-09-1343
Title: The Impacts of Air Pollution in China on Health in California
PI: Nicole Ngo, PhD
University of Oregon
Eugene, OR
11. Project #: 14-01-1467
Title: Risk Factors at Birth and Receipt of Early Intervention Services: An Analysis of Linked Data from Orange County
PI: Emily Putnam-Hornstein, PhD
University of Southern California
Los Angeles, CA
12. Project #: 13-12-1439
Title: Public vs. Private Provision of Ambulance Services
PI: Liam Rose
University of California, Santa Cruz
Spreckels, CA
13. Project #: 13-11-1403
Title: Use of Beta Blockers in Medi-Cal Beneficiaries
PI: Jaekyu Shin, PharmD
University of California, San Francisco
San Francisco, CA

14. Project #: 13-12-1462
Title: Racial/ethnic and Gender Differences in Early Stage Non-Small Cell Lung Cancer
PI: Lori Sakoda, MPH, PhD
Kaiser Permanente
Oakland, CA
15. Project #: 13-12-1463
Title: Komen Community Profiles for Ten California Counties
PI: David Stinchcomb
Westat, Inc.
Rockville, MD
16. Project #: 13-12-1440
Title: What is the Value of Correctional Vocational Education? An Examination of Recidivism and Post-Release Labor Market Outcomes
PI: Emily Weisburst, MA
Co-PI: Sandra Black
University of Texas
Austin, TX
17. Project #: 12-05-0219
Title: Multigenerational Familial and Environmental Risk for Autism (MINERvA) Network--California Population
PI: Gayle Windham, PhD
Co-PI: Martin Kharrazi, PhD
California Department of Public Health
Richmond, CA
18. Project #: 13-11-1427
Title: Reading Instructional Approaches in Juvenile Correctional Facilities: A National Survey of Teacher-Reported Practices, Challenges, and Recommendations
PI: Min-Chi Yan
University of Wisconsin
Madison, WI
19. Project #: 13-12-1436
Title: Maternal Influenza Infection During Pregnancy and Risk of Autism Spectrum Disorder
PI: Ousseny Zerbo, PhD
Co-PI: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA

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

None

H. Projects with major revisions and requiring periodic review

1. Project #: 12-05-0191
Title: Molecular Epidemiology of Lung Cancer
PI: Chu Chen, PhD
Fred Hutchinson Cancer Research Center
Seattle, WA
2. Project #: 13-06-1252
Title: The Challenge of Individualizing Treatments for Patients with Breast Cancer, Program Project Grant: Los Angeles Subcontract
PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA
3. Project #: 13-02-1116
Title: Champions for Healthy Change
PI: Fred Molitor, PhD
California Department of Public Health
Sacramento, CA
4. Project #: 12-10-0770
Title: Exploring the Variability of Prenatal Screening Serum Markers by Maternal and Fetal Factors
PI: Sona Saha, PhD, MPH
California Department of Public Health
Richmond, CA
Co-PI: Jennifer Adibi, ScD
University of California, San Francisco
5. Project #: 12-12-1018
Title: Out-of-Hospital Sudden Cardiac Death - Records Review
PI: Zian Tseng, MD, MAS
University of California, San Francisco
San Francisco, CA

6. Project #: 13-11-1425
Title: California Environmental Protection Agency's CalEnviroScreen:
Low Birth Weight Indicator
PI: Roberta Weilling, MS, MPH
Co-PI: Rose Cendak
Office of Environmental Health Hazard Assessment
Oakland, CA

**I. 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 #: 12-12-0949
Title: Los Angeles Mommy and Baby (Lamb) Project
PI: Shin Chao, PhD
Los Angeles County
Los Angeles, CA
2. Project #: 12-10-0821
Title: Short Inter-Pregnancy Intervals and Risk of Autism Spectrum
Disorders
PI: Lisa Croen, PhD
Co-PI: Ousseney Zerbo, PhD
Kaiser Permanente
Oakland, CA
3. Project #: 12-12-0981
Title: Young Adult Outcomes of Youth Exiting Dependent or Delinquent
Care in Los Angeles County
PI: Dennis Culhane, PhD
University of Pennsylvania
Philadelphia, PA
4. Project #: 12-12-0962
Title: The Utility of the MMPI-2, MMPI-2-RF, and PAI in a State
Psychiatric Hospital
PI: David Glassmire, PhD
Patton State Hospital
Patton, CA
5. Project #: 12-12-0986
Title: The Utility of the SIRS and MFAST in a Forensic Inpatient Setting
PI: David Glassmire, PhD
Patton State Hospital
Patton, CA

6. Project #: 12-11-0931
Title: Effects of Increased Economic Resources on Weight-Related Health: A Quasi-Experimental Study
PI: Jessica Jones-Smith, PhD, MPH, RD
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD
7. Project #: 12-11-0910
Title: Comparative Effectiveness of Integration of Care Programs at Improving Metabolic Screening and Treatment of People with Severe Mental Illness
PI: Christina Mangurian, MD
University of California, San Francisco
San Francisco, CA
8. Project #: 12-10-0801
Title: Quality of Family Planning Services Delivered by Medi-Cal Providers
PI: Heike Thiel de Bocanegra, PhD, MPH
University of California, San Francisco
Sacramento, CA

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

None

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).

None

L. Exemption Request

1. Project #: 14-01-1481
Title: Economic and Health Burden of Chronic Disease in California
PI: Paul Brown, PhD
Co-PI: Mariaelena Gonzalez, PhD
University of California, Merced
Merced, CA

M. Public Comments

N. Next Meeting

The next CPHS meeting is scheduled for Friday, April 4, 2014 in Sacramento.

O. 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.

The Committee for the Protection of Human Subjects (“CPHS”) encourages public attendance and participation at CPHS meetings. Additionally, CPHS established a toll-free telephone number for members of the public to monitor or participate in any CPHS meeting.

If interested, please call the telephone number and enter the access below when prompted.

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

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

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