

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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

**AGENDA-Amended**

**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, June 6, 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. IRB Reliance Policy and Procedures Update- (Ruiz)
3. Alternate Members Recruitment -Update (Martinez)
4. Cal Protects
 - a. KSI –Renewal Purchase Order-Approved and Paid-(Martinez)
 - b. Batch 3-CalProtects Issues –Update-(Prefach)
5. Updates
6. Legislation (Rivera/Krishnan)
 - 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
7. Common Rule - California Department of Public Health, Medi-Cal Data Review (Ruiz, Dickey)

B. Approval of Minutes

1. April 4, 2014

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

1. Project #: 12-08-0631 (Bazzano)
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
Tuberculosis Control Branch
California Department of Public Health
Richmond, CA

2. Project #: 13-02-1116 (Lowe)
Title: Champions for Healthy Change
PI: Fred Molitor, PhD
Nutrition Education and Obesity Prevention (NEOP) Branch
Network for a Healthy California
California Department of Public Health
Sacramento, CA

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

1. Project #: 14-01-1479 (Perel)
Title: Wendy's Wonderful Kids Post-Adoption Study: How Are Adopted Foster Youth Faring as Young Adults?
PI: Karin Malm
Child Trends
Bethesda, MD

2. Project #: 14-04-1565 (Molitor)
Title: Mother and Infant Home Visiting Program Evaluation - Strong Start (MIHOPE-Strong Start)
PI: Charles Michalopoulos, PhD
Co-PI: Virginia Knox, PhD
Manpower Demonstration Research Corporation (MDRC)
Oakland, CA

3. Project #: 14-03-1534 (Bazzano)
Title: Randomized Trial to Increase Adherence to Cervical Cancer Screening Guidelines for Young Women
PI: Anna-Barbara Moscicki, MD
University of California, San Francisco
San Francisco, CA

E. Projects With Major Revisions Requiring Full Committee Approval

None

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 #: 13-10-1382 (Perel/Murphy)
Title: A Rigorous System to Determine the Health Impacts of Policies and Programs
PI: Jennifer Ahern, PhD, MPH
University of California, Berkeley
Berkeley, CA

2. Project #: 14-02-1496 (Murphy/Grabau)
Title: Aggression in California Department of State Hospitals
PI: Charles Broderick, PhD
California Department of Mental Health
Sacramento, CA

3. Project #: 14-04-1570 (Dickey/Bauer)
Title: Comparison of Histopathological, Clinical, and Treatment Outcomes, Including but not Limited to SLNB (Sentinell Lymph Node Biopsy) and/or ALND (Axillary Lymph Node Dissection), Between HER2 (Human Epidermal Growth Factor Receptor 2) Positive, ER/PR (Estrogen/Progesterone) Positive, TNBC (Triple Negative Breast Cancer)
PI: Helena Chang
University of California, Los Angeles
Los Angeles, CA

4. Project #: 14-03-1544 (Bazzano/Molitor)
Title: Patterns of Subspecialty Cancer Care and their Association with Survival Among Adolescents and Young Adults (AYAs)
PI: Chelsea Collins, MD
Co-PI: David Freyer
University of Southern California
Los Angeles, CA

5. Project #: 13-09-1355 (Grabau/Perel)
Title: The Effects of Full service Partnership Programs on Emergency Mental Health Services for Youth
PI: Katharan Cordell, MPH
University of California, Berkeley
Berkeley, CA

6. Project #: 14-04-1558 (Bazzano/Dickey)
Title: Using Population-Based Datasets to Generate and Test New Hypotheses for Investigating Preterm Births and Related Adverse Conditions in California
PI: Paul English
California Department of Public Health
Richmond, CA
Co-PI: Gary Shaw, DrPH
Stanford University
Stanford, CA
7. Project #: 14-03-1543 (Palacio/Lowe)
Title: Early Childhood Teaching: Building a Quality Model
PI: Bruce Fuller, PhD
Co-PI: Margaret Bridges, PhD
University of California, Berkeley
Berkeley, CA
8. Project #: 13-12-1445 (Schaeuble/Trent)
Title: The Effect of Air Quality Alerts on Respiratory Hospitalizations
PI: Brandon Heck, BS, BA
University of California, Santa Cruz
Santa Cruz, CA
9. Project #: 13-12-1431 (Dickey/Bauer)
Title: Credit Rationing and the Provision of Healthcare
PI: Jonathan Kalodimos, PhC
University of Washington
Seattle, WA
10. Project #: 13-10-1386 (Schaeuble/Trent)
Title: Predictors of Ambulance Diversion Cascades
PI: Jack Needleman, PhD
Co-PI: Charleen Hsuan, JD
University of California, Los Angeles
Los Angeles, CA
11. Project #: 14-02-1525 (Dickey/Bauer)
Title: Associations Between Obstetrical and Medical Complications of Pregnancy with Demographic and Geographic Factors on Neonatal Outcomes.
PI: Dotun Ogunyemi
University of California, Los Angeles
Los Angeles, CA

12. Project #: 13-10-1366 (Molitor/Trent)
Title: The Children's Data Network / California Children's Services Archive
PI: Emily Putnam-Hornstein, PhD
Co-PI: Jacquelyn McCroskey, DSW
University of Southern California
Los Angeles, CA
13. Project #: 14-05-1591 (Ruiz/Lowe)
Title: Analysis of the Impact of California's 1115 Bridge to Reform Waiver on Medi-Cal Seniors and People with Disabilities: A Partnership with LA Care Health Plan
PI: Lhasa Ray, MD, MS
University of California, Los Angeles
Los Angeles, CA
14. Project #: 14-02-1499 (Ruiz/Bazzano)
Title: Decreasing Access to Trial of Labor After Cesarean: What is the Impact on Patients?
PI: Melissa Rosenstein, MD, MAS
Co-PI: Miriam Kuppermann, PhD, MPH
University of California, San Francisco
San Francisco, CA
15. Project #: 14-03-1535 (Grabau/Perel)
Title: The Role of Integrated Care in Reducing Hospitalizations and Health Care Spending
PI: Eric Schmidt, MS
Pacific Graduate School of Psychology
Palo Alto, CA
16. Project #: 14-01-1472 (Molitor/Trent)
Title: Gestational Vitamin D and Relationship with Autism Spectrum Disorders
PI: Jaime Sconberg, BA
University of California, Davis
Davis, CA
17. Project #: 14-02-1492 (Schaeuble/Perel)
Title: Does public reporting of quality measures impact patient choice
PI: Deepa Wani, MS
University of South Carolina
Florence SC

18. Project #: 14-01-1477 (Perel/Murphy)
Title: Differential Responses to Measured and Perceived Pollution
PI: Corey White
Co-PI: Olivier Deschenes, PhD
University of California, Santa Barbara
Santa Barbara, CA
19. Project #: 14-02-1503 (Bazzano/Schaeuble)
Title: Neighborhood deprivation and the utilization of preconception care/postpartum care in Los Angeles
PI: Lujing Zhan
University South Carolina
Columbia, SC
20. Project #: 13-11-1414 (Perel/Schaeuble)
Title: Impact of New Medicare Readmission Policy on Hospital Readmissions for All Patients
PI: David Zingmond, PhD, MD
Co-PI: Jose Escarce, PhD, MD
University of California, Los Angeles
Los Angeles, CA

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 #: 13-02-1101 (Schaeuble)
Title: Visual Proprioception and Wariness of Heights in Infants
PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA
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 #: 12-03-0042 (Dickey)
Title: Cancer Incidence and Cancer Mortality in the World Trade Center Health Registry
PI: James Cone, MD
New York City Department of Health and Mental Hygiene
Island City, NY

4. Project #: 12-05-0177 (Ruiz)
Title: Kaiser Research Program on Genes, Environment and Health (RPGEH) and Biomonitoring California Adult Cohort Project Biomonitoring Exposures Study (BEST)
PI: Michael DiBartolomeis
California Department of Public Health
Richmond, CA
5. Project #: 12-04-0125 (Dickey/Fowler)
Title: Political Engagement Before and After the Death of a Spouse
PI: James Fowler, PhD
University of California, San Diego
La Jolla, CA
6. Project #: 12-04-0065 (Lowe)
Title: The Utility of the MacArthur Competency Assessment Tool-Criminal Adjudication (MacCAT-CA) in a Forensic Inpatient Setting
PI: David Glassmire, PhD
Patton State Hospital
Patton, CA
7. Project #: 12-07-0536 (Lowe)
Title: Comparative Evaluation of Stroke Triage Algorithms for Emergency Medical Dispatchers (MeDS): Prospective Cohort Study
PI: Prasanthi Govindarajan
University of California, San Francisco
San Francisco, CA
8. Project #: 12-08-0644 (Bauer)
Title: WIC ITFPS-2: Feeding My Baby – A National WIC Study
PI: Gail Harrison
University of California, Los Angeles
Los Angeles, CA
9. Project #: 12-05-0181 (Dickey)
Title: A Study of Primary and Secondary Prevention Behavior Practiced Among 5-Year Survivors of Colorectal Cancer
PI: Nikki Hawkins, PhD
Centers for Disease Control and Prevention
Atlanta, GA

10. Project #: 12-04-0097 (Molitor/Trent)
Title: Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer (WECARE)
PI: Esther John, PhD
Cancer Prevention Institute of California
Fremont, CA
11. Project #: 12-04-0095 (Molitor/Trent)
Title: Study of Infant Sleeping Position and SIDS Risk
PI: De-Kun Li, PhD, MD
Kaiser Foundation Research Institute
Oakland, CA
12. Project #: 12-04-0126 (Dickey)
Title: The Utility of the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) in a State Hospital
PI: Stephen Nitch, PhD
Co-PI: Dominique Kinney, PhD
California Department of Mental Health
Patton, CA
13. Project #: 12-06-0455 (Dickey/Bauer)
Title: Evaluation of the Association Between Geographic Distribution and Clustering of Exemptions and Outbreak of Vaccine Preventable Diseases
PI: Saad Omer, PhD, MPH, MBBS
Emory University
Atlanta, GA
14. Project #: 12-04-0062 (Dickey/Bauer)
Title: Pilot Study to Test Laboratory Components of the CECBP
PI: Myrto Petreas, PhD, MPH
California Department of Toxic Substances Control
Berkeley, CA
15. 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

16. Project #: 12-05-0184 (Lowe)
Title: Pre- and Post-Natal Air Pollution Exposure and Early Childhood Respiratory Disease in the UCLA Environment and Pregnancy Outcomes Study (EPOS) Cohort
PI: Beate Ritz, PhD, MD
Co-PI: Ondine von Ehrenstein
University of California, Los Angeles
Los Angeles, CA
17. Project #: 12-04-0148 (Molitor/Trent)
Title: Early Language and Social Cognition
PI: Rose Scott, PhD
University of California, Merced
Merced, CA
18. Project #: 13-01-1064 (Grabau)
Title: Demographic and Prenatal Predictors of Maternal Health and Birth Outcomes in San Bernardino County
PI: Pramil Singh, DrPH
Co-PI: Jayakaran Job, DrPH, MD
Loma Linda University
Loma Linda, CA
19. Project #: 12-04-0067 (Dickey/Bauer)
Title: California EHS-Net Food and Water Safety Risk Factors Associated with Mobile Food Vehicles Study
PI: Susan Strong
California Department of Public Health
Sacramento, CA
20. Project #: 12-04-0140 (Ruiz)
Title: California Parkinson's Disease Registry Pilot Project Research: Use of Medicare Data to Assess Registry Data Collection Efficiency
PI: Caroline Tanner, PhD, MD
The Parkinson's Institute
Sunnyvale, CA
Co-PI: Beate Ritz, PhD, MD
University of California, Los Angeles
Los Angeles, CA
21. Project #: 12-02-0012 (Dickey)
Title: The Neurobehavioral Development of Social Behavior
PI: Nim Tottenham, PhD
University of California, Los Angeles
Los Angeles, CA

22. Project #: 13-02-1073 (Molitor/Trent)
Title: First 5 Kern Evaluation
PI: Jianjun Wang, PhD
California State University Bakersfield
Bakersfield, CA
23. Project #: 13-02-1125 (Dickey/Bauer)
Title: Epidemiology and Expenditures of Infant Health in California
PI: Paul Wise, MD, MPH
Stanford University
Stanford, CA
24. Project #: 13-04-1170 (Lowe)
Title: Re-Operations for Thyroid and Parathyroid Disease in California
PI: Michael Yeh, MD
University of California, Los Angeles
Los Angeles, CA

H. Projects with major revisions and requiring periodic review

1. Project #: 12-08-0631 (Bazzano)
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
2. Project #: 14-02-1512 (Dickey)
Title: Understanding Racial and Ethnic Disparities Resulting from the Concentration of Major Cancer Surgeries in High-Volume Hospitals
PI: Katherine Harris, PhD
MedStar Health Research Institute
Hyattsville, MD
Co-PI: Waddah Al-Refaie, MD, FACS
Georgetown University Hospital
Washington, DC
3. Project #: 12-08-0611 (Dickey/Ruiz)
Title: Health Benefits of Expressive Writing Among Chinese Breast Cancer Survivors
PI: Qian Lu
University of Houston
Houston, TX

4. Project #: 12-11-0906 (Molitor)
Title: Using Population-Based Datasets to Generate and Test New Hypotheses for Investigating Preterm Births and Related Adverse Conditions in California
PI: Gary Shaw, DrPH
Co-PI: Paul Wise, MD, MPH
Stanford University
Stanford, CA

5. Project #: 13-10-1398 (Molitor/Trent)
Title: Birth Defects Study To Evaluate Pregnancy ExposureS – California Component
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, CA

6. Project #: 14-01-1483 (Perel/Lowe)
Title: Biomonitoring California - Using Banked Specimens to Enhance Our Understanding of Chemical Exposure in California
PI: Nerissa Wu, PhD, MPH
Co-PI: Michael DiBartolomeis, PhD, DABT
California Department of Public Health
Richmond, 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 Request

1. Project #: 14-04-1556 (Lowe)
Title: CHCF Healthcare Antitrust Enforcement
PI: Lisa Maiuro, PhD, MSPH
Health Management Associates
Sacramento, CA

2. Project #: 14-04-1562 (Ruiz)
Title: Evaluation of Hepatitis Treatment and Outcomes Among Medi-Cal Population
PI: Kathleen Winter, MPH
Co-PI: Darryl Kong, MPH
California Department of Public Health
Richmond, CA

L. Public Comments

M. Next Meeting

The next CPHS meeting is scheduled for Friday, August 1, 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.

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.

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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.

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