

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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

**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, February 5, 2016
8:30 a.m. – 5:00 p.m.**

A. General- Administrator Report

1. Administrator's Report
 - a. CPHS Staffing Changes
 - b. CalProtects System Updates
 - c. CPHS Annual Protocols Report

2. Women, Infants, and Children (WIC) Presentation – Susan Sabatier, Chief, WIC Program, California Department of Public Health

B. Meeting Minutes

December 4, 2015

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

1. Project #: 15-01-1837
Title: Age-Period-Cohort Analysis of Thyroid Cancer in California
PI: Justine Hutchinson, PhD
Co-PI: Sumi Hoshiko, MPH
California Department of Public Health
Richmond, CA

D. New Projects - Full Committee Review Required

1. Project #: 15-12-2358 (Lowe)
Title: Career Pathways Program Evaluation
PI: Randie Chance, PhD
California Department of Justice
Sacramento, CA

2. Project #: 16-01-2366 (Molitor)
Title: You're Stressing Me Out: Adolescent Stress Response to Evaluation from Same-aged Peers and its Effect on Risky Decision Making
PI: Sachiko Donley, PhD
University of California, Irvine
Irvine, CA

3. Project #: 16-01-2369 (Bauer)
Title: Health Resources Services Administration (HRSA) National Vaccine Injury Compensation Program (VICP) Communications Contract
PI: DeVan Hankerson, MA
United States Department of Health and Human Services
Washington, DC

4. Project #: 15-09-2245 (Dickey)
Title: Making the Most of WIC Foods: A Pilot Study to Examine Purchasing Decisions of WIC Participants
PI: Loan Kim, PhD, RD
Co-PI: Shannon Whaley, PhD
Pepperdine University
Malibu, CA

5. Project #: 15-12-2345 (Ruiz)
Title: Rethink Your Drink Revisited: Evaluating the Impact of a Short Educational Intervention to Decrease Sugar-Sweetened Beverage Consumption in High School Aged Minors
PI: Benjamin Schoenberg, BS
William Sansum Diabetes Center
Santa Barbara, CA

6. Project #: 15-12-2356 (Grabau)
Title: Survey of Prison Inmates (SPI)
PI: Timothy Smith, MA
Co-PI: Marcus Berzofsky, DrPH
RTI International
Research Triangle Park, NC

7. Project #: 15-11-2299 (Schaeuble)
Title: Insurance Coverage, Employment Status, and Copayments/Deductibles Faced by Young Women Diagnosed with Breast Cancer
PI: Sujha Subramanian, PhD
RTI International
Triangle Park, NC

8. Project #: 15-12-2344 (Trent)
Title: Asian and Pacific Islander Community Exposures (ACE) Project
PI: Nerissa Wu, PhD
Co-PI: Lauren Joe, MPH
California Department of Public Health
Richmond, 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 #: 15-11-2296 (Grabau/Murphy)
Title: Employee Injury Prevention Project
PI: Andrea Bauchowitz, PhD
Co-PI: Susan Velasquez, PhD
Department of State Hospitals
Sacramento, CA

2. Project #: 16-01-2365 (Molitor/Trent)
Title: Causes of Death in CalPERS Members
PI: Kristal Chichlowska, PhD, MPH
California Public Employee's Retirement System
Sacramento, CA

3. Project #: 15-10-2272 (Ruiz)
Title: Georgia California SEER Genetic Testing Demonstration Project
PI: Dennis Deapen, DrPH
University of Southern California
Los Angeles, CA
Co-PI: Sally Glaser, PhD
California State University East Bay
Fremont, CA

4. Project #: 15-12-2357 (Bauer/Trent)
Title: Investigating Epidemiology and Long-term Outcomes of Infectious Endocarditis
PI: Natalia Egorova, PhD
Mount Sinai
New York, NY
5. Project #: 15-12-2334 (Bauer/Murphy)
Title: Long-term Mortality in Pediatric Gunshot Assault Survivors
PI: Jahan Fahimi, MD, MPH
Co-PI: Ashkon Shaahinfar, MD, MPH
University of California, San Francisco
San Francisco, CA
6. Project #: 15-12-2317 (Schaeuble/Perel)
Title: The Great Recession and Birth Outcomes
PI: Brian Finch, PhD
University of Southern California
Los Angeles, CA
7. Project #: 15-09-2210 (Dickey/Bauer)
Title: Utilizing Electronic Health Records to Measure and Improve Prostate Cancer Care
PI: Tina Hernandez-Boussard, PhD
Stanford University
Stanford, CA
8. Project #: 15-12-2363 (Molitor/Ruiz)
Title: Risk of Second Cancers among People with Aids
PI: Nancy Hessol, MSPH
University of California, San Francisco
San Francisco, CA
9. Project #: 15-11-2298 (Bauer/Trent)
Title: Opioid Use Disorders in Primary Care Settings: Linking EHRs with PDMP and National Death Index Data Systems
PI: Yih-Ing Hser, PhD
University of California, Los Angeles
Los Angeles, CA

10. Project #: 15-12-2338 (Schaeuble/Murphy)
Title: Evaluation of the FY 2011 Bureau of Justice Assistance (BJA) Second Chance Act (SCA) Adult Offender Reentry Demonstration Projects (AORDP)
PI: Pamela Lattimore, PhD
RTI International
Triangle Park, NC
11. Project #: 15-10-2260 (Dickey/Ruiz)
Title: Collection of Confirmed DMD Positive and Presumptive Negative Newborn Screening DBS Specimens (ES01-15002)
PI: Laurie Livshin, MSc
PerkinElmer
Waltham, MA
12. Project #: 15-11-2277 (Murphy/Trent)
Title: Enhanced Drug and Contraband Interdiction Program Evaluation
PI: Magnus Lofstrom, PhD
Co-PI: Brandon Martin, MA
Public Policy Institute of California
San Francisco, CA
13. Project #: 15-10-2271 (Molitor/Trent)
Title: Evaluation of the LA DHS eConsult Program
PI: Ateev Mehrotra, MD, MS, MPH
Co-PI: Michael Barnett, MD, MS
Harvard University
Boston, MA
14. Project #: 15-11-2300 (Bauer/Dickey)
Title: Predicting Pathogenicity of CFTR Mutations Identified by Newborn Screening
PI: Carlos Milla, MD
Stanford University
Palo Alto, CA
15. Project #: 15-12-2362 (Dickey/Ruiz)
Title: Development of Newborn Screen for Niemann-Pick C1 Disease
PI: Daniel Ory, MD
Washington University
St. Louis, MO

16. Project #: 15-11-2285 (Grabau/Schaeuble)
Title: MMPI-2-RF Normative Profiles for Sex Offenders
PI: Klayton Smith, PsyD
Co-PI: Anthony Tarescavage, MA
Department State Hospitals
Coalinga, CA
17. Project #: 15-03-1915 (Palacio/Trent)
Title: Hospital Visits Due to External Causes of Injury: A Time Series Analysis
PI: Peter Tuckel, PhD
Co-PI: William Milczarski, PhD
City University of New York
New York, NY

**F. 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 #: 12-12-1006 (Dickey)
Title: Molecular Epidemiology of Pancreatic Cancer
PI: Paige Bracci, PhD, MS, MPH
University of California, San Francisco
San Francisco, CA
2. Project #: 12-11-0941 (Murphy)
Title: Development of the Brain Basis of Cognitive and Social Behavior in Human Infants
PI: Leslie Carver, PhD
University of California, San Diego
La Jolla, CA
3. Project #: 12-10-0881 (Murphy)
Title: National Children's Study
PI: Christina Chambers, PhD, MPH
University of California, San Diego
La Jolla, CA
Co-PI: Mel Hovell, PhD, MPH
San Diego State University
San Diego, CA

4. Project #: 13-09-1350 (Bazzano)
Title: Los Angeles Mommy and Baby Project Follow Up Project (LAMB Follow-up)
PI: Shin Chao, MPH, PhD
Los Angeles County
Los Angeles, CA
5. Project #: 12-12-0949 (Grabau)
Title: Los Angeles Mommy and Baby (Lamb) Project
PI: Shin Chao, MPH, PhD
Los Angeles County
Los Angeles, CA
6. Project #: 14-03-1550 (Murphy)
Title: The De-escalation of Mass Incarceration: Implementation and Effects of Three Strikes Reform in California
PI: Elsa Chen, PhD
Santa Clara University
Santa Clara, CA
7. Project #: 12-07-0507 (Murphy)
Title: Genome Wide Admixture for Multiple Myeloma in African Americans
PI: Wendy Cozen, DO, MPH
Co-PI: Christopher Haiman, ScD
University of Southern California
Los Angeles, CA
8. Project #: 12-12-0981 (Grabau)
Title: Young Adult Outcomes of Youth Exiting Dependent or Delinquent Care in Los Angeles County
PI: Dennis Culhane, PhD
University of Pennsylvania
Philadelphia, PA
9. Project #: 12-12-0978 (Murphy)
Title: Program Evaluation: The 2011 Medical Record Review of the Family PACT Program
PI: Philip Darney, MD, MSc
University of California, San Francisco
San Francisco, CA
Co-PI: Heike Thiel de Bocanegra, PhD, MPH
California Department of Health Care Services
Sacramento, CA

10. Project #: 14-12-1829 (Ruiz)
Title: Champions for Change Media Campaign Evaluation
PI: Celeste Doerr, PhD
California Department of Public Health
Sacramento, CA
11. Project #: 12-12-1013 (Grabau)
Title: Applied Statistics for Pattern and Fraud Detection in Health Care Data
PI: Artur Dubrawski, PhD
Carnegie Mellon University
Pittsburgh, PA
12. Project #: 12-10-0873 (Molitor)
Title: Learning to Listen Ahead in English and Spanish
PI: Anne Fernald, PhD
Stanford University
Stanford, CA
13. Project #: 12-11-0893 (Dickey)
Title: Pilot Study of Trends and Risks in Gestational Diabetes
PI: Assiamira Ferrara, MD, PhD
Kaiser Permanente
Oakland, CA
14. Project #: 12-11-0905 (Molitor)
Title: Surveillance of Air Pollution and Related Cardiopulmonary Morbidity in California, 2000-2020
PI: Cynthia Garcia, BA
Co-PI: Hye-Youn Park, PhD
California Air Resources Board
Sacramento, CA
15. Project #: 13-09-1339 (Dickey)
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
16. Project #: 12-06-0426 (Dickey)
Title: Comparative Effectiveness of Treatments for Localized Prostate Cancer (CEASAR Study) - Los Angeles Subcontract
PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA

17. Project #: 12-07-0565 (Dickey)
Title: Disparity in the Quality of Breast Cancer Treatment and Effect on Outcomes – Los Angeles Sub Contract
PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA
18. Project #: 14-08-1682 (Trent)
Title: Comparison of Reverse Shoulder Arthroplasty Versus Total Shoulder Arthroplasty
PI: George Hatch, MD
University of Southern California
Los Angeles, CA
19. Project #: 12-11-0900 (Dickey)
Title: Childhood Autism Risks from Genetics and the Environment (the CHARGE Study)
PI: Irva Hertz-Picciotto, PhD
University of California, Davis
Davis, CA
20. Project #: 12-11-0911 (Murphy)
Title: MARBLES (Markers of Autism Risk in Babies - Learning Early Signs)
PI: Irva Hertz-Picciotto, PhD
University of California, Davis
Davis, CA
21. Project #: 12-11-0931 (Molitor)
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
22. Project #: 12-06-0357 (Molitor)
Title: Ascertainment of Environmental Exposure during Pregnancy
PI: Martin Kharrazi, PhD
California Department of Public Health
Richmond, CA

23. Project #: 12-12-0956 (Dickey)
Title: Replication of Draper Study of Leukemia, Brain Tumors and Distance to Power Lines in California
PI: Leeka Kheifets, PhD
University of California, Los Angeles
Los Angeles, CA
24. Project #: 14-11-1772 (Molitor)
Title: Parents Taking Action: An Educational Program for Latino Parents of Children with Autism and Communication Challenges
PI: Kristina Lopez, PhD, MSW, MS, MA
California State University, Long Beach
Long Beach, CA
25. Project #: 13-02-1084 (Dickey)
Title: Perinatal Regionalization and Quality of Care
PI: Scott Lorch, MD, MSCE
University of Pennsylvania
Philadelphia, PA
26. Project #: 12-11-0910 (Molitor)
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
27. Project #: 13-12-1462 (Grabau)
Title: Racial/Ethnic and Gender Differences in Early Stage Non-small Cell Lung Cancer
PI: Lori Sakoda, MPH, PhD
Kaiser Permanente
Oakland, CA
28. Project #: 12-11-0945 (Dickey)
Title: Central Valley Autism Project, Inc. Early Intensive Behavioral Treatment Outcome Study
PI: Mieke San Julian, MA, BCBA
Central Valley Autism Project, Inc.
Sacramento, CA

29. Project #: 12-11-0924 (Dickey)
Title: Candidate Genes and Congenital Malformations of Neural Crest Cell Origin
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, CA
30. Project #: 13-10-1398 (Molitor)
Title: Birth Defects Study To Evaluate Pregnancy Exposures – California Component
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, CA
31. Project #: 12-10-0801 (Grabau)
Title: Quality of Family Planning Services Delivered by Medi-Cal Providers
PI: Heike Thiel de Bocanegra, PhD, MPH
University of California, San Francisco
San Francisco, CA
32. Project #: 14-08-1694 (Dickey)
Title: Exploring Rural Disparities in Breast Cancer Mortality
PI: Teresa Uyeki, MEd
Co-PI: Elvine-Kreis, Brenda, MA
Humboldt State University
Arcata, CA
33. Project #: 14-11-1779 (Trent)
Title: Effect of Hospital Workload on Hospital Treatment and Outcome
PI: Deepa Wani, MS, MBA
University of South Carolina
Columbia, SC
34. Project #: 12-12-0997 (Molitor)
Title: FoodNet Study of Escherichia coli O157:H7 Infection: Antibiotic Exposure and the Risk of Hemolytic Uremic Syndrome
PI: Katie Wymore, MPH
California Emerging Infections Program
Oakland, CA

35. Project #: 12-11-0895 (Murphy)
Title: Expanding the Role of Medicaid in Cancer Care for the Uninsured
PI: David Zingmond, MD, PhD
University of California, Los Angeles
Los Angeles, CA
36. Project #: 13-10-1369 (Molitor)
Title: Impact of Co-Morbid Illness in Individuals with Chronic HIV/AIDS Infection
PI: David Zingmond, MD, PhD
Co-PI: William Cunningham, MD, MPH
University of California, Los Angeles
Los Angeles, CA

G. Projects With Major Revisions Requiring Periodic 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 #: 12-05-0177 (Molitor)
Title: Kaiser Research Program on Genes, Environment and Health (RPGEH) and Biomonitoring California Adult Cohort Project Biomonitoring Exposures Study (BEST)
PI: Michael DiBartolomeis, PhD
California Department of Public Health
Richmond, CA
2. Project #: 12-11-0927 (Murphy)
Title: Collection of Gene Mutations for Laboratory Quality Assurance
PI: Lisa Feuchtbaum, DrPH, MPH
California Department of Public Health
Richmond, CA
3. Project #: 14-05-1584 (Molitor)
Title: SEER Pharmacy Data Linkage Pilot
PI: Sally Glaser, PhD
Cancer Prevention Institute of California
Fremont, CA
Co-PI: Dennis Deapen, DrPH
University of Southern California
Los Angeles, CA

4. Project #: 12-04-0073 (Molitor)
Title: Factors Associated with the Closure of Emergency Services & Impact on Patient Outcomes; Effect of Employment on Emergency Department Utilization
PI: Renee Hsia, MD, MSc
University of California, San Francisco
San Francisco, CA
5. Project #: 14-10-1747 (Murphy)
Title: Understanding Memory and Generalization Abilities in Children
PI: Angela Lukowski, PhD
Co-PI: Helen Mijojevich, MA
University of California, Irvine
Irvine, CA
6. Project #: 12-08-0596 (Dickey)
Title: California Maternal, Child and Adolescent Health Report
PI: Lisa Nicholas, MD
University of California, Los Angeles
Los Angeles, CA
7. 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

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

None

I. 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

J. Exemption/Determination Requests

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 #: 15-12-2341 (Ruiz)
Title: Architectural Design of High Security Psychiatric Hospitals - A Survey of Current Practices
PI: Andrea Bauchowitz, PhD
Department of State Hospitals
Patton, CA
2. Project #: 15-12-2328 (Ruiz)
Title: SNP Discovery and Characterization of the Human Beta-Globin Gene for Non-Invasive Prenatal Testing for Beta-Hemoglobinopathies
PI: Katie Carlberg, MD
UCSF Benioff Children's Hospital
Oakland, CA
3. Project #: 15-12-2353 (Ruiz)
Title: PREdiction of Sudden Cardiac Death in MulTiethnic Communities (P.R.E.S.T.O.) Study
PI: Sumeet Chugh, MD
Cedars-Sinai Medical Center
Los Angeles, CA
4. Project #: 15-12-2361 (Bauer)
Title: Shoo the Flu - Flu Surveillance Impact Evaluation
PI: Erica Pan, MD, MPH
Alameda County Department of Public Health
Oakland, CA
5. Project #: 15-12-2336 (Ruiz)
Title: Molecular Epidemiology of Pediatric Germ Cell Tumors
PI: Jenny Poynter, PhD
University of Minnesota
Minneapolis, MN
6. Project #: 15-11-2313 (Ruiz)
Title: Impact of Pulse Oximetry Screening
PI: Rie Sakai-Bizmark, MD, MPH, PhD
LA BioMed at Harbor-UCLA Medical Center
Torrance, CA

7. Project #: 15-12-2322 (Ruiz)
Title: Rethink Your Drink Revisited: Evaluating the Impact of a Short Educational Intervention to Decrease Sugar-Sweetened Beverage Consumption in Latino Adolescents
PI: Benjamen Schoenberg, BS
William Sansum Diabetes Center
Santa Barbara, CA
8. Project #: 15-07-2142 (Ruiz)
Title: Evaluating Outcomes Related to the Prenatal and Newborn Screening Programs
PI: Juan Yang, PhD
Co-PI: Lisa Feuchtbaum, DrPH, MPH
California Department of Public Health
Richmond, CA

K. Public Comments

L. Next Meeting

The next CPHS meeting is scheduled for Friday, April 1, 2016 in Sacramento.

M. 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 CPHS encourages public attendance and participation at 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: **888-636-3807** Access Code: **963949**

If you have any questions or comments, please contact:

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 Main e-mail: cphs-mail@oshpd.ca.gov

CPHS Website: www.oshpd.ca.gov/boards/cphs