AGENDA

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
400 R Street
Sacramento River Room, 130
Sacramento, CA 95811

*US Toll-Free Number: 888-636-3807
Access Code: 963949

Friday, June 5, 2015
8:30 a.m. – 5:00 p.m.

A. General- Administrator Report
   1. Administrators Report (Martinez)
   2. Legislation Update (Rivera)

B. Discussion Items
   1. California Department of Public Health Vital Statistics Advisory Committee
      Presentation – Laura Lund and Colin Chew
   2. Case Studies Discussion/Presentation (Grabau)
   3. Data Sharing Discussion/Presentation (Lowe)

C. Meeting Minutes
   February 6, 2015
   April 3, 2015

D. Projects with Reported Adverse Events/Deviations
   (CPHS will decide if any action on these projects is necessary)
   1. Project #: 12-05-0259 (Lowe)
      Title: Medullary Thyroid Carcinoma Surveillance Study: A Case-Series
      Registry
      PI: Gretchen Dieck, PhD
      United BioSource Corporation
      Blue Bell, PA
2. Project #: 14-07-1651 (Schaeuble)
   Title: Evaluation of the Permanency Innovation Initiative: California Partners for Permanency II
   PI: George Gabel, MS, MA
       Westat
       Rockville, MD

3. 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

4. Project #: 12-08-0678 (Ruiz)
   Title: Permanency Innovations Initiative (PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
   PI: Curtis Shepard, PhD
       LA Gay & Lesbian Center
       Los Angeles, CA
   Co-PI: George Gabel, MS, MA
       Westat
       Rockville, MD

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 15-04-1996 (Grabau)
   Title: Activity and Psychological Development
   PI: Joseph Campos, PhD
       University of California, Berkeley
       Berkeley, CA
   Co-PI: David Anderson, PhD
       San Francisco State University
       San Francisco, CA

2. Project #: 15-04-1972 (Lowe)
   Title: Criminogenic Risk Factors Among Forensic Psychiatric Inpatients
   PI: Darci Delgado, PsyD
       California Department of Mental Health
       Vacaville, CA
3. Project #: 14-05-1691 (Bazzano)
   Title: Predictors of Recurrent Breast Tumors in Women with DCIS
   PI: Karla Kerlikowske, MD
   University of California, San Francisco
   San Francisco, CA

4. Project #: 15-04-1998 (Bauer)
   Title: Joy Luck Academy: A Randomized Controlled Trial
   PI: Qian Lu, MD, PhD
   Department of Psychology, University of Houston
   Houston, TX

5. Project #: 15-04-1970 (Palacio)
   Title: Preparing a Computerized Tool for Preventing Prenatal Drinking for a Larger Trial
   PI: Madhabika Nayak, PhD
   Public Health Institute
   Emeryville, CA

6. Project #: 15-02-1857 (Schaeuble)
   Title: Evaluating a Pilot Mobile Health Program
   PI: Sasigant O’Neil, MS
   Co-PI: Keith Kranker, PhD
   Mathematica Policy Research
   Cambridge, MA

7. Project #: 15-04-1950 (Dickey)
   Title: The UCSF and UNMC Dementia Care Ecosystem: Using Innovative Technologies to Personalized and Deliver Coordinate
   PI: Leslie Wilson, PhD
   University of California, San Francisco
   San Francisco, CA

8. Project #: 15-03-1917 (Trent)
   Title: Foam Replacement and Environmental Exposure Study (FREES)
   PI: Nerissa Wu, PhD
   California Department of Public Health
   Richmond, CA
   Co-PI: Deborah Bennett, PhD
   University of California, Davis
   Davis, CA
9. Project #: 15-04-1961 (Murphy)
   Title: Assessing Prison Volunteer Programs to Determine What Works
   PI: Peter York, MSW
   Algorhythm
   Garnet Valley, PA
   Co-PI: Sharon Farrell, PhD

    Title: California Student Tobacco Survey
    PI: Shu-Hong Zhu, PhD
    University of California, San Diego
    San Diego, 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 #: 14-09-1723 (Dickey/Molitor)
   Title: Innovative Approaches for Studying Gestational Weight Gain
   PI: Barbara Abrams, DrPH, RD
   University of California, Berkeley
   Berkeley, CA

2. Project #: 14-10-1731 (Dickey/Bazzano)
   Title: Effect of Maternal Education on Adverse Birth Outcomes
   PI: Lela Bachrach, MD, MS
   University of California, Berkeley
   Berkeley, CA
   Co-PI: Virginia Bachrach, MD

3. Project #: 15-03-1927 (Schaeuble/Perel)
   Title: Social Patterns in Naming Practices in the United States, 1990-2006
   PI: Phech Colatat, PhD
   Washington State University in St. Louis
   St Louis, MO
   Co-PI: Tristan Botelho, SM
   Massachusetts Institute of Technology
   Cambridge, MA
4. Project #: 15-04-1976 (Ruiz/Trent)
   Title: Understanding the geographic origins of Emergency Department and Trauma Center Patients within South Los Angeles
   PI: Michael Cousineau, PhD
       University of Southern California
       Los Angeles, CA

5. Project #: 15-03-1913 (Ruiz/Dickey)
   Title: Impact of Life Course Socioeconomic Status on the Ovarian Reserve
   PI: Paul English, PhD
       California Department of Public Health
       Richmond, CA
   Co-PI: Maria Bleil, PhD
       University of Washington
       Seattle, WA

6. Project #: 15-04-1990 (Ruiz/Trent)
   Title: Imaging Intensity as a Measure of Cancer Care Efficiency
   PI: Benjamin Franc, MD, MS
       University of California, San Francisco
       San Francisco, CA

7. Project #: 15-04-1978 (Lowe/Trent)
   Title: Reuters Request for Death Certificate Data
   PI: Selam Gebrekidan, MS
       Thomson Reuters
       New York, NY

8. Project #: 15-03-1942 (Murphy/Palacio)
   Title: Understanding Prison Violence
   PI: Jonathan Kurzfeld, MS
       University of California, Riverside
       Riverside, CA
   Co-PI: Gregory DeAngelo, PhD

   Title: The Metabolomics of Inborn Errors of Metabolism: A Pilot Study
   PI: Wai-Nang Lee, MD
       Los Angeles Biomedical Research Institute
       Torrance, CA
   Title: Collection of Confirmed Positive Specimens for Evaluation in a Clinical Study to Establish Screening Performance of the PerkinElmer NeoBase2 Non-Derivatized MSMS Test System for Inborn Errors of Metabolism. The proposal title is different as it describes the actual clinical study. (Pivotal Study to Establish Screening Performance for the NeoBase2 Non-Derivatized MSMS Test System)
   PI: Laurie Livshin, MSc
   Clinical and Regulatory Affairs, PerkinElmer
   Waltham, MA

    Title: Collection of Confirmed x-ALD Positive Specimens for Evaluation in a Clinical Study to Establish Screening Performance of the PerkinElmer NeoBase2 Non-Derivatized MSMS Test System for x-ALD. The proposal title is different as it describes the actual clinical study. (Pivotal Study to Establish Screening Performance for the NeoBase2 Non-Derivatized MSMS Test System)
    PI: Laurie Livshin, MSc
    Clinical and Regulatory Affairs, PerkinElmer
    Waltham, MA

12. Project #: 14-10-1748 (Dickey/Bauer)
    Title: Assessment of Health Care Spending in California Patients with Liver Disease
    PI: Mindie Nguyen, MD, MAS
    Stanford University
    Palo Alto, CA

13. Project #: 15-03-1901 (Molitor/Dickey)
    Title: Evaluation of Prototype’s Initiatives to Address the Needs of Children and Mothers in Residential Treatment Services
    PI: Michael Rodi, PhD
    Children and Family Futures
    Lake Forest, CA

14. Project #: 15-04-1958 (Trent/Palacio)
    Title: Analyses of Adverse Events Underreporting by Hospitals in California
    PI: Patrick Romano, MD, MPH
    Co-PI: David Chin, PhD
    University of California, Davis
    Sacramento, CA
15. Project #: 15-04-1977 (Molitor/Ruiz)
   Title: CARE for Children with Medical Complexity
   PI: Christy Sandborg, MD
   Co-PI: Michael-Anne Browne, MD
   Stanford University
   Palo Alto, CA

16. Project #: 15-03-1937 (Murphy/Lowe)
   Title: A Right-Based Approach to Sound Canteen and Care Packaging Policy/Program Development for the Prison Population in the State of California
   PI: Georgena Wiley, FNP-BC, DNP
   San Diego, CA

17. Project #: 14-07-1637 (Bauer/Ruiz)
   Title: Learning about Hospital Substitution Patterns from Natural Experiments
   PI: Nathan Wilson, PhD
   Johns Hopkins University
   Washington, DC
   Co-PI: Ted Rosenbaum, PhD
   Federal Trade Commission
   Washington, DC

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 #: 12-05-0170 (Dickey)
   Title: Causes of Germ Cell Tumors and Related Conditions
   PI: Victoria Cortessis, PhD
   University of Southern California
   Los Angeles, CA

2. Project #: 12-05-0177 (Ruiz/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, DABT
   California Department of Public Health
   Richmond, CA
3. Project #: 12-04-0125 (Dickey)
   Title: Political Engagement Before and After the Death of a Spouse
   PI: James Fowler, PhD
   University of California, San Diego
   La Jolla, CA

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

5. 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

6. 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

7. Project #: 12-04-0095 (Molitor/Trent)
   Title: Study of Infant Sleeping Position and SIDS Risk
   PI: De-Kun Li, MD, PhD
   Kaiser Foundation Research Institute
   Oakland, CA

8. Project #: 12-03-0036 (Dickey)
   Title: Trial Participation for Cancer Patients
   PI: Anup Malani, JD, PhD
   University of Chicago
   Chicago, IL

9. Project #: 12-06-0455 (Dickey)
   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
10. Project #: 13-10-1366 (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

11. Project #: 14-03-1535 (Grabau)  
Title: The Role of Integrated Care in Reducing Hospitalizations and Health Care Spending  
PI: Eric Schmidt, MS  
Pacific Graduate School of Psychology  
San Jose, CA

12. Project #: 12-04-0148 (Molitor/Trent)  
Title: Early Language and Social Cognition  
PI: Rose Scott, PhD  
University of California, Merced  
Merced, CA

13. Project #: 12-04-0141 (Dickey)  
Title: Perchlorate and Thyroid Hormones in Pregnancy and Infants in Southern California  
PI: Craig Steinmaus, MD, MPH  
University of California, Berkeley  
Berkeley, CA  
Co-PI: Martin Kharrazi, PhD  
California Department of Public Health  
Richmond, CA

14. Project #: 12-02-0012 (Dickey/Ruiz)  
Title: The Neurobehavioral Development of Social Behavior  
PI: Nim Tottenham, PhD  
Columbia University  
New York, NY

15. Project #: 12-04-0067 (Dickey)  
Title: California EHS-Net Food and Water Safety Risk Factors Associated with Mobile Food Vehicles Study  
PI: Jeanne-Marie Weathers, BS  
California Department of Public Health  
Sacramento, CA
16. Project #: 13-04-1176 (Dickey)
   Title: Measuring the Quality of Cancer Care at the MD Group Level in CA
   PI: Ann Woo, PharmD
        Integrated Healthcare Association
        Oakland, CA
   Co-PI: Kathleen Foley, PhD
           Truven Health Analytics
           Newtown, PA

H. Projects With Major Revisions Requiring Periodic Review

1. 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, MD
        McGill University
        Montreal, PQ, Canada
   Co-PI: Pennan Barry,
           California Department of Public Health
           Richmond, CA

2. Project #: 12-06-0326 (Lowe/Ruiz)
   Title: The Development of Object Representation in Infancy
   PI: Lisa Oakes, PhD
   Co-PI: Steven Luck, PhD
          University of California, Davis
          Davis, CA

3. Project #: 15-02-1875 (Dickey)
   Title: Cost Containment in WIC: Lessons from the California WIC Vendor Market
   PI: Maya Rossin-Slater, PhD
   Co-PI: Heather Royer, PhD
          University of California, Santa Barbara
          Santa Barbara, CA

4. Project #: 12-10-0772 (Murphy)
   Title: NIH-AARP Diet and Health Study
   PI: Rashmi Sinha, PhD
    National Cancer Institute
    Rockville, MD
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**  
None

L. **Public Comments**

M. **Next Meeting**  
The next CPHS meeting is scheduled for Friday, August 7, 2015 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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**US Toll-Free Number:** 888-636-3807 **Access Code:** 963949

If you have any questions or comments, please contact:  
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