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, April 3, 2015
8:30 a.m. – 5:00 p.m.

A. General- Administrator Report
   1. Reappointment of Members – Secretary Action Request (SAR) Package (Martinez)
   2. Adverse Event Summary – Update (West)
   3. Updates
   4. Case Studies Report (Grabau)
   5. Mark Resnick, Ph.D., Department of State Hospitals Appeal

B. Meeting Minutes
   February 6, 2015

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

   1. Project #: 12-04-0119 (Ruiz)
      Title: Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis
      PI: Pamala Kirley, M.P.H.
      California Emerging Infections Program
      Oakland, CA
2. Project #: 14-01-1465 (Perel)
   Title: California Promoting the Readiness of Minors in Supplemental Security Income (CaPROMISE)
   PI: Caren Sax, Ed.D.
       San Diego State University
       San Diego, CA
   Co-PI: Sylvia Hoggat
       California Department of Rehabilitation
       Sacramento, CA

3. Project #: 12-08-0678 (Dickey)
   Title: Permanency Innovations Initiative (PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
   PI: Curtis Shepard, Ph.D.
       L.A. Gay & Lesbian Center
       Los Angeles, CA
   Co-PI: George Gable, M.S., M.A.
       Westat
       Rockville, MD

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

1. Project #: 15-02-1879 (Bazzano)
   Title: Variations in Needs After Colorectal Cancer Diagnosis
   PI: Ulrike Boehmer, Ph.D.
       Boston University
       Boston, MA

2. Project #: 12-05-0170 (Dickey)
   Title: Original Proposal Title: Causes of Testicular Cancer and Cryptorchidism; Updated Protocol Title: Causes of Germ Cell Tumors and Related Conditions
   PI: Victoria Cortessis, Ph.D.
       University of Southern California
       Los Angeles, CA

3. Project #: 15-02-1888 (Schaeuble)
   Title: Acceptance and Commitment Therapy in Newly Diagnosed Breast Cancer Patients
   PI: Thereasa Cronan, Ph.D.
       San Diego State University
       San Diego, CA
4. Project #: 15-02-1858 (Lowe)
   Title: SRI Demographic Questions for California Breast Cancer Research
   PI: Scarlett Gomez, Ph.D.
   Cancer Prevention Institute of California
   Fremont, CA

5. Project #: 15-01-1853 (Molitor)
   Title: Evaluation of Cal MediConnect
   PI: Carrie Graham, Ph.D.
   University of California, San Francisco
   San Francisco, CA
   Co-PI: Stephen H. Kaye, Ph.D.
   University of California, San Francisco
   San Francisco, CA

6. Project #: 14-11-1798 (Trent)
   Title: Cohort Mortality Study of Workers Exposed to Tungsten Carbide with a Cobalt Binder-Phase 3
   PI: Gary Marsh, M.S., Ph.D.
   University of Pittsburgh
   Pittsburgh, PA

7. Project #: 12-07-0529 (Ruiz)
   Title: Childhood Cancer Record Linkage Project
   PI: Catherine Metayer, M.D., Ph.D.
   University of California, Berkeley
   Berkeley, CA
   Co-PI: Joseph Wiemels, Ph.D.
   University of California, San Francisco
   San Francisco, CA

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

9. Project #: 14-12-1814 (Bauer)
   Title: Culture and Shared Decision-Making for Breast Cancer Treatment
   PI: Judy Wang, Ph.D.
   Georgetown University
   Washington, DC
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 #:** 15-01-1852 (Bauer/Dickey)
   **Title:** Preventable Hospitalization Rates Among California’s Medi-Cal Population
   **PI:** Andrew Bindman, M.D.
   University of California, San Francisco
   San Francisco, CA

2. **Project #:** 14-11-1773 (Bauer/Dickey)
   **Title:** Impact of Health Insurance on Long-term Health and Mortality
   **PI:** Bernard Black, J.D.
   Northwestern University
   Chicago, IL

3. **Project #:** 14-12-1818 (Perel/Bazzano)
   **Title:** The Long-Term Outcomes of Individuals with Developmental Disabilities: Profiles and Trajectories
   **PI:** North Cooc, Ed.D.
   University of Austin, Texas
   Austin, TX

4. **Project #:** 15-02-1899 (Lowe/Perel)
   **Title:** Long Term Frozen Stability of Markers of Inborn Errors of Metabolism (IEM) and Lysosomal Storage Disorders (LSD) in Neonatal Dried Blood Spots
   **PI:** Jason Cournoyer, Ph.D.
   Diagnostics R&D
   Waltham, MA

5. **Project #:** 15-03-1906 (Murphy/Grabau)
   **Title:** Language and Criminality: Pragmatic Choice and Parole Outcome
   **PI:** Melissa Crimmins, M.A.
   California Department of Corrections and Rehabilitation
   Lancaster, United Kingdom

6. **Project #:** 15-02-1897 (Bazzano/Dickey)
   **Title:** Program Evaluation and Dissemination of Prenatal Screening in California
   **PI:** Lisa Feuchtbaum, Dr.P.H, M.P.H.
   California Department of Public Health
   Sacramento, CA
7. Project #: 15-02-1898 (Bazzano/Dickey)
   Title: Program Evaluation and Dissemination for Newborn Screening in California
   PI: Lisa Feuchtbaum, Dr.P.H., M.P.H.
       California Department of Public Health
       Sacramento, CA

8. Project #: 14-10-1767 (Murphy/Palacio)
   Title: Neighborhood Effects and Preterm Birth Among Asian American Subgroups (different from proposal title)
   PI: Mistry Gage, M.P.H.
       University of Illinois
       Chicago, IL
   Co-PI: Kristin Rankin, M.S.P.H., Ph.D.
          University of Illinois
          Chicago, IL

9. Project #: 14-10-1764 (Murphy/Trent)
   Title: CARET Biorepository and Data Enhancement Project
   PI: Gary Goodman, M.D.
       Fred Hutchinson Cancer Research Center
       Seattle, WA
   Co-PI: Mark Thornquist, Ph.D.
          Fred Hutchinson Cancer Research Center
          Seattle, WA

10. Project #: 15-02-1871 (Murphy/Palacio)
    Title: California's Conditional Release Program (CONREP) Study
    PI: Patricia Gray, M.A.
        Santa Rosa, CA

11. Project #: 15-02-1895 (Palacio/Molitor)
    Title: Long-term Impacts of California Student Aid Commission's Cal Grant Entitlement Program
    PI: Oded Gurantz, M.S.
        Stanford University
        Stanford, CA

12. Project #: 15-02-1859 (Ruiz/Dickey)
    Title: Strong Start for Mothers and Newborns Evaluation
    PI: Ian Hill, M.P.A., M.S.W.
    Co-PI: Lisa Dubay, Ph.D.
           Urban Institute
           Washington, DC
<table>
<thead>
<tr>
<th>Project #</th>
<th>Title</th>
<th>PI</th>
<th>Co-PI</th>
<th>Institution</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-12-1805</td>
<td>Impact of Foster Care on Child Well Being</td>
<td>Jason Huang, M.A.</td>
<td>Atul Gupta, M.A.</td>
<td>Stanford University</td>
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<tr>
<td>15-01-1841</td>
<td>SIBO-Cancer Link</td>
<td>Shehnaz Hussain, Ph.D.</td>
<td></td>
<td>Cedars-Sinai Medical Center</td>
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<tr>
<td>14-09-1714</td>
<td>Evaluation of Long-term Pediatric and Neonatal Surgery Resource Utilization and Outcomes in California</td>
<td>Howard Jen, M.D.</td>
<td></td>
<td>Tufts University</td>
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<td>14-10-1732</td>
<td>Insurer-Hospital Dependence and Physician Treatment Decisions</td>
<td>William Johnson, M.A.</td>
<td>Amalia Miller, Ph.D.</td>
<td>University of Virginia</td>
</tr>
<tr>
<td>15-02-1885</td>
<td>CARE for Children with Medical Complexity</td>
<td>Carlos Lerner, M.D., MPhil</td>
<td></td>
<td>University of California, Los Angeles</td>
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<tr>
<td>15-02-1894</td>
<td>Health and Economic Toll of Tobacco on CA’s LGB Community</td>
<td>Wendy Max, Ph.D.</td>
<td>Hai-Yen Sung, Ph.D.</td>
<td>University of California, San Francisco</td>
</tr>
</tbody>
</table>
20. Project #: 12-08-0609 (Bazzano/Perel)
   Title: Autism, Autoimmunity and the Environment
   PI: Craig Newschaffer, Ph.D.
       AJ Drexel Autism Institute
       Philadelphia, PA

21. Project #: 14-11-1800 (Murphy/Palacio)
   Title: Why Inmates Disaffiliate from their Gangs?
   PI: Olesya Novozhilova
       California State University, Sacramento
       Sacramento, CA

22. Project #: 15-02-1872 (Molitor/Lowe)
   Title: Ovarian Cancer Patients Pathology Report Review
   PI: Malcolm Pike, Ph.D.
       University of Southern California
       Los Angeles, CA

23. Project #: 14-07-1649 (Molitor/Trent)
   Title: Building De-Identified Data Sets and Conducting
          Exploratory Analysis for the California Home Visiting Program
   PI: Kristen Rogers, Ph.D.
   Co-PI: Jennifer Gregson, MPH, Ph.D.
          California Department of Public Health
          Sacramento, CA

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

25. Project #: 15-01-1835 (Ruiz/Dickey)
   Title: Measured Parameters in MidPregnancy Blood Specimens and
          Risks of Selected Adverse Pregnancy Outcomes
   PI: Gary Shaw, Dr.P.H.
   Co-PI: Suzan Carmichael, Ph.D.
          Stanford University
          Stanford, CA
26. Project #: 14-10-1768 (Dickey/Bauer)
   Title: Impact of Surgery and Adjuvant Treatment on Thyroid, Parathyroid, Adrenal, and Neuroendocrine Tumors
   PI: Michael Yeh, M.D.
   Co-PI: Masha Livhits, M.D.
   University of California, Los Angeles
   Los Angeles, CA

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 #: 12-06-0379 (Murphy)
   Title: Cancer Genetics Research Information System (CGRIS)
   PI: Hoda Anton-Culver, Ph.D.
   Co-PI: Argyrios Ziogas, Ph.D.
   University of California, Irvine
   Irvine, CA

2. Project #: 12-10-0840 (Murphy)
   Title: Ethnic Disparities in Utilization Rates and Complication Rates in Hip & Knee Arthroplasty and Hip Fracture Surgery.
   PI: Timothy Bronx, M.D.
   University of California, San Francisco
   San Francisco, CA
   Co-PI: Paul Brown, Ph.D.
   University of California, Merced
   Merced, CA

3. Project #: 13-03-1159 (Murphy)
   Title: Making the Transition: Socioemotional Adjustment of Youthful Offenders into Adulthood
   PI: Elizabeth Cauffman, Ph.D.
   Co-PI: Joseph Tatar, Ph.D.
   University of California, Irvine
   Irvine, CA
4. Project #: 12-12-0988 (Murphy)  
Title: The Association Between Gestational Age at Delivery, Race/Ethnicity, Hospital Characteristics, and Perinatal Outcomes  
PI: Yvonne Cheng, M.D., Ph.D  
University of California, Davis  
Davis, CA  
Co-PI: Aaron Caughey, M.D., Ph.D.  
Oregon Health and Science University  
Portland, OR

5. Project #: 13-02-1115 (Murphy)  
Title: Cognitive Function after Breast Cancer Treatment  
PI: Patricia Ganz, M.D.  
University of California, Los Angeles  
Los Angeles, CA

6. Project #: 13-01-1056 (Murphy)  
Title: Forteo Patient Registry  
PI: Alicia Gilsenan, Ph.D.  
Co-PI: Elizabeth Andrews, Ph.D.  
RTI International  
Research Triangle Park, NC

7. Project #: 13-01-1069 (Grabau)  
Title: CCR-PAMF Linkage: Creating an Anonymized Dataset for Cancer Research  
PI: Scarlett Gomez, Ph.D.  
Cancer Prevention Institute of California  
Fremont, CA

8. Project #: 13-03-1140 (Murphy)  
Title: Surveillance of HIV Risk & Prevention Behaviors of Men Who Have Sex with Men, Injection Drug Users, and Heterosexual  
PI: Juliana Grant, M.D., M.P.H.  
California Department of Public Health  
Sacramento, CA

9. Project #: 12-10-0785 (Murphy)  
Title: Understanding the Relation Between Sleep and Memory in Infants  
PI: Angela Lukowski, Ph.D.  
University of California, Irvine  
Irvine, CA
10. Project #: 12-12-1016 (Murphy)
   Title: Tracking the Well-Being of Children in California
   PI: Mark Mather, Ph.D.
   Co-PI: Beth Jarosz, M.A.
   Population Reference Bureau
   Washington, DC

11. Project #: 13-02-1077 (Schaeuble)
    Title: Longitudinal Study of Hospital Outcomes for California’s Children
    PI: Olivia Geraldine, M.D., M.P.H.
    Co-PI: Linda Remy, M.S.W., Ph.D.
    University of California, San Francisco
    San Francisco, CA

12. Project #: 13-02-1124 (Grabau)
    Title: Ultrafine Particle Exposure and Respiratory Outcomes Among Bicycle Commuters
    PI: Hye-Youn Park, M.P.H., Ph.D.
    Co-PI: Cynthia Garcia, BA
    California Air Resources Board
    Sacramento, CA

G. Projects With Major Revisions Requiring Periodic Review

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

2. Project #: 13-01-1027 (Molitor)
   Title: Formative Evaluation of the Adolescent Family Life Plan, Positive Youth Development, My Life Plan (AFLP-PYD-MLP) Program
   PI: Kathleen Tebb, Ph.D.
   University of California, San Francisco
   San Francisco, 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

1. Project #: 15-03-1909 (Ruiz)
   Title: California Student Tobacco Survey
   PI: Shu-Hong Zhu, Ph.D.
   University of California, San Diego
   San Diego, CA

K. Public Comments

L. Next Meeting
   The next CPHS meeting is scheduled for Friday, June 5, 2015 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.

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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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Committee for the Protection of Human Subjects
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