AGENDA – Amended January 23, 2015

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY
400 R Street
Executive Conference Room 300
Sacramento, CA 95811

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

Friday, February 6, 2015
8:30 a.m. – 5:00 p.m.

A. General- Administrator Report
   2. Cal Protects – Update (West)
   3. Updates
   4. Bagley-Keene Act – Jacob Knapp, Legal Counsel

B. Meeting Minutes
   1. October 3 2014
   2. December 5, 2014

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

   1. Project #: 12-10-0788 (Lowe)
      Title: Use of Clofazimine for the Treatment of Multidrug-Resistant (MDR) Tuberculosis in Patients with Limited Therapeutic Options
      PI: Pennan Barry, Ph.D.
      California Department of Public Health
      Richmond, CA
2. 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, Ph.D.
California Department of Public Health
Richmond, CA

3. Project #: 13-01-1058 (Ruiz)
Title: Forteo Post Approval Surveillance Study: Case Series
PI: Alicia Gilsenan, Ph.D.
Co-PI: Elizabeth Andrews, Ph.D.
RTI International
Research Triangle Park, NC

4. Project #: 12-11-0911 (Murphy)
Title: MARBLES (Markers of Autism Risk in Babies - Learning Early Signs)
PI: Irva Hertz-Picciotto, Ph.D.
University of California, Davis
Davis, CA

5. 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

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

1. Project #: 14-12-1807 (Ruiz)
Title: Statewide Youth Tobacco Purchase Survey 2015-2017
PI: David Barker, Ph.D.
Co-PI: Britte Livingston, MA
California State University, Sacramento, Institute for Social Research
Sacramento, CA
<table>
<thead>
<tr>
<th>Project #</th>
<th>Title</th>
<th>PI</th>
<th>Co-PI</th>
<th>University/Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-12-1821</td>
<td>Consumer Engagement to Increase Advance Care Planning-Patient Randomization</td>
<td>Amber Barnato, MD, MPH, MS</td>
<td>Rebecca Sudore, MD</td>
<td>University of Pittsburgh, Pittsburg, PA</td>
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<td>University of California, San Francisco, San Francisco, CA</td>
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<tr>
<td>14-11-1780</td>
<td>Rapid Cycle Polling on Impact of Cal MediConnect on California's Dual Eligible Population Project</td>
<td>Mark DiCamillo, BA, MBA</td>
<td></td>
<td>Field Research Corporation, San Francisco, CA</td>
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<tr>
<td>14-12-1829</td>
<td>Champions for Change Media Campaign Evaluation</td>
<td>Celeste Doerr, Ph.D.</td>
<td></td>
<td>California Department of Public Health, Sacramento, CA</td>
</tr>
<tr>
<td>14-12-1810</td>
<td>Toddlers in Play Study</td>
<td>Jessica Grady, Ph.D.</td>
<td></td>
<td>University of the Pacific, Stockton, CA</td>
</tr>
<tr>
<td>14-12-1809</td>
<td>BT-011 - Pharmacokinetics of Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine) (BAT™) in Pediatric Patients with a Confirmed or Suspected Exposure to Botulinum Toxin.</td>
<td>Jason Richardson, Ph.D.</td>
<td></td>
<td>Emergent BioSolutions Incorporated, Winnipeg, Manitoba, Canada</td>
</tr>
<tr>
<td>14-11-1772</td>
<td>Parents Taking Action: An Educational Program for Latino Parents of Children with Autism and Communication Challenges</td>
<td>Kristina Lopez, PhD, MSW, MS, MA</td>
<td></td>
<td>California State University Long Beach, Long Beach, CA</td>
</tr>
</tbody>
</table>
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 #: 14-10-1750 (Perel)
   Title: Kaiser Permanente Inter-Regional Behavioral Health Suicide Metric for Quality Improvement Benchmarking
   PI: Sumita Bhatia, MPH, MS
   Co-PI: Jean Flores, MPH
   Kaiser Permanente
   Oakland, CA

2. Project #: 14-10-1735 (Ruiz)
   Title: Effect of Birth Method on Post-Natal Health Outcomes of Mothers and Babies
   PI: David Card
   Co-PI: David Evans
   University of California, Berkeley
   Berkeley, CA

3. Project #: 14-03-1550 (Murphy)
   Title: The De-Escalation of Mass Incarceration: Implementation and Effects of Three Strikes Reform in California
   PI: Elsa Chen, Ph.D.
   Santa Clara University
   Santa Clara, CA

4. Project #: 14-11-1799 (Ruiz)
   Title: Exogenous Shocks In Utero and Infant Health: Evidence from California
   PI: Shin-Yu Chou, Ph.D.
   Co-PI: Muzhe Yang, Ph.D.
   Department of Economics, Lehigh University
   Bethlehem, PA

5. Project #: 14-11-1790 (Murphy)
   Title: Illustrative Cases to Support the Cal-VAT Guidelines
   PI: Laura Dardashti, MD
   California Department of Mental Health
   Sacramento, CA
6. Project #: 14-02-1488 (Molitor)
   Title: The Effect of the Supplemental Security Income Children's Program
   on Health Care Utilization of Enrolled Children and Families
   (different title)
   PI: Manasi Deshpande, Ph.D. Candidate
   Massachusetts Institute of Technology
   Cambridge, MA

7. Project #: 14-05-1581 (Molitor)
   Title: Quality of Care for Patients with Kidney and Ureteral Stones in
   California
   PI: Christopher Elliott, MD, Ph.D.
   Stanford University
   Mountain View, CA

8. Project #: 13-08-1323 (Grabau)
   Title: The Relationship Between the Rorschach Performance
   Assessment System Cognitive Processing Scales and
   Neuropsychological Status in a Conditional Release Offender
   Population
   PI: Shay Groenewold, Ph.D. student
   Alliant International University
   Vista, CA

9. Project #: 15-01-1837 (Trent)
   Title: Age-Period-Cohort Analysis of Thyroid Cancer in California
   PI: Justine Hutchinson, Ph.D.
   Co-PI: Sumi Hoshiko, MPH
   California Department of Public Health
   Richmond, CA

10. Project #: 14-11-1777 (Bauer)
    Title: Measuring the Attributable Mortality of Healthcare-Associated
    Infections in the United States
    PI: Joelle Nadle, MPH
    California Emerging Infections Program
    Oakland, CA

11. Project #: 14-12-1832 (Lowe)
    Title: A Good Name is Worth its Weight in Salary: A Study of Federal
    Employee Names and Salary
    PI: Shawn Pope, Ph.D.
    Stanford University
    Stanford, CA
12. Project #: 14-08-1694 (Dickey)
   Title: Exploring Rural Disparities in Breast Cancer Mortality
   PI: Teresa Uyeki, M.S.Ed
   California Center for Rural Policy, Humboldt State University
   Arcata, CA
   Co-PI: Brenda Elvine-Kreis, MA
   Breast and GYN Health Project
   Arcata, CA

13. Project #: 14-11-1779 (Trent)
   Title: Effect of Hospital Workload on Hospital Treatment and Outcome
   PI: Deepa Wani
   University of South Carolina
   Columbia, SC

14. Project #: 14-11-1791 (Lowe)
   Title: The Effect of Workplace Hours Requirements on Female
   Occupational and Fertility Choices: Evidence from Medical
   Residents
   PI: Melanie Wasserman, Ph.D. Candidate
   Co-PI: David Autor, Ph.D.
   Massachusetts Institute of Technology
   Cambridge, MA

15. Project #: 14-10-1744 (Bauer)
   Title: Evaluation of the Health Care Innovation Awards: Community
   Resource Planning, Prevention, and Monitoring (HCIA)
   PI: Allison Witman, Ph.D.
   RTI International
   Research Triangle Park, NC

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 #: 12-10-0783 (Dickey)
      Title: PM 2.5-Cardiovascular Disease Associations: Use of Modeled
      Hierarchical Bayesian vs. Ambient Monitoring Exposure Data
      PI: John Balmes, MD, MPH
      University of California, Berkeley
      Berkeley, CA
      Co-PI: Paul English, Ph.D., MPH
      California Department of Public Health
      Richmond, CA
2. Project #: 12-10-0842 (Murphy)
   Title: Evaluation of Measure Y Re-Entry Employment Research Application
   PI: Patricia Bennett, Ph.D.
   Resource Development Associates
   Oakland, CA

3. Project #: 12-12-1006 (Dickey)
   Title: Molecular Epidemiology of Pancreatic Cancer
   PI: Paige Bracci, Ph.D., MS, MPH
   University of California, San Francisco
   San Francisco, CA

4. Project #: 12-11-0941 (Murphy)
   Title: “Development of the Brain Basis of Cognitive and Social Behavior in Human Infants”
   PI: Leslie Carver, Ph.D.
   University of California, San Diego
   San Diego, CA

5. Project #: 12-10-0881 (Murphy)
   Title: National Children’s Study
   PI: Christina Chambers, Ph.D., MPH
   University of California, San Diego
   San Diego, CA
   Co-PI: Mel Hovell, Ph.D., MPH
   San Diego State University
   San Diego, CA

6. Project #: 12-12-0949 (Grabau)
   Title: Los Angeles Mommy and Baby (Lamb) Project
   PI: Shin Chao, Ph.D.
   Los Angeles County
   Los Angeles, 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, Sc.D.
   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, Ph.D.
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: Phillip Darney, MD, MSc
University of California, San Francisco
San Francisco, CA
Co-PI: Heike Thiel de Bocanegra, Ph.D., MPH
California Department of Health Care Services
Sacramento, CA

10. Project #: 12-11-0893 (Dickey)
Title: Pilot Study of Trends and Risks in Gestational Diabetes
PI: Assiamira Ferrara, MD, Ph.D.
Kaiser Permanente
Oakland, CA

11. Project #: 12-12-0986 (Perel)
Title: The Utility of the SIRS and MFAST in a Forensic Inpatient Setting
PI: David Glassmire, Ph.D.
Patton State Hospital
Patton, CA

12. 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

13. Project #: 12-06-0426 (Dickey)
Title: Comparative Effectiveness of Treatments for Localized Prostate Cancer (CEASAR Study) - LOS ANGELES SUBCONTRACT
PI: Ann Hamilton, Ph.D.
University of Southern California
Los Angeles, CA
14. Project #: 12-07-0565 (Dickey)
   Title: Comparative Effectiveness of Treatments for Localized Prostate Cancer (CEASAR Study) - LOS ANGELES SUBCONTRACT
   PI: Ann Hamilton, Ph.D.
       University of Southern California
       Los Angeles, CA

15. Project #: 12-11-0900 (Dickey)
   Title: Childhood Autism Risks from Genetics and the Environment (the CHARGE Study)
   PI: Irva Hertz-Picciotto, Ph.D.
       University of California, Davis
       Davis, CA

16. Project #: 12-11-0911 (Murphy)
    Title: MARBLES (Markers of Autism Risk in Babies - Learning Early Signs)
    PI: Irva Hertz-Picciotto, Ph.D.
        University of California, Davis
        Davis, CA

17. Project #: 12-11-0927 (Murphy)
    Title: Collection of CFTR Mutations for Laboratory Quality Assurance
    PI: Martin Kharrazi, Ph.D.
        California Department of Public Health
        Richmond, CA

18. Project #: 12-12-0956 (Dickey)
    Title: Replication of Draper Study of Leukemia, Brain Tumors and Distance to Power Lines in California
    PI: Leeka Kheifets, Ph.D.
        University of California, Los Angeles
        Los Angeles, CA

19. Project #: 12-08-0596 (Dickey)
    Title: California Maternal, Child and Adolescent Health Report
    PI: Lisa Nicholas, Ph.
        University of California, Los Angeles
        Los Angeles, CA

20. Project #: 13-12-1462 (Grabau)
    Title: Racial/Ethnic and Gender Differences in Early Stage Non-Small Cell Lung Cancer
    PI: Lori Sadoka, MPH, Ph.D.
        Kaiser Permanente
21. Project #: 12-11-0945 (Dickey)
   Title: Central Valley Autism Project, Inc. Early Intensive Behavioral Treatment Outcome Study
   PI: Mieke San Julian, MA
       Central Valley Autism Project Incorporated
       Sacramento, CA

22. 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

23. Project #: 12-11-0924 (Dickey)
   Title: Candidate Genes and Congenital Malformations of Neural Crest Cell Origin
   PI: Gary Shaw, Ph.D.
   Co-PI: Suzan Carmichael, Ph.D.
       Stanford University
       Stanford, CA

24. Project #: 12-12-0953 (Schaeuble)
   Title: Parkinson’s Registry Investigation of Diagnosis and Etiology (PRIDE) Study
   PI: Caroline Tanner, MD, Ph.D.
   Co-PI: Samuel Goldman, MD, MPH
       University of California, San Francisco
       San Francisco, CA

25. Project #: 12-10-0801 (Grabau)
   Title: Quality of Family Planning Services Delivered by Medi-Cal Providers
   PI: Heike Thiel de Bocanegra, Ph.D., MPH
       University of California, San Francisco
       San Francisco, CA

26. Project #: 12-11-0895 (Murphy)
   Title: Expanding the Role of Medicaid in Cancer Care for the Uninsured
   PI: David Zingmond, MD, Ph.D.
       University of California, Los Angeles
       Los Angeles, CA
G. Projects With Major Revisions Requiring Periodic Review

1. Project #: 14-02-1512 (Martinez)
   Title: Understanding Racial and Ethnic Disparities Resulting from the Concentration of Major Cancer Surgeries in High-Volume Hospitals
   PI: Waddah Al-Refaie, MD, FACS
       Med-Star Health Research
       Washington DC

2. Project #: 12-07-0512 (Schaeuble)
   Title: Validation of Embedded Malingering Indices in the Wechsler Adult Intelligence Scale-Fourth Edition (WAIS-IV) in a Forensic Psychiatric Inpatient Population
   PI: David Glassmire, Ph.D.
       Patton State Hospital
       Patton, CA

3. Project #: 13-06-1252 (Palacio)
   Title: The Challenge of Individualizing Treatments for Patients with Breast Cancer, Program Project Grant: Los Angeles Subcontract
   PI: Ann Hamilton, Ph.D.
       University of Southern California
       Los Angeles, CA

4. Project #: 12-10-0784 (Ruiz)
   Title: Low Income Health Program (LIHP) Evaluation
   PI: Gerald Kominski
       University of California, Los Angeles
       Los Angeles, CA

5. 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 Hoggatt
       California Department of Rehabilitation
       Sacramento, CA

6. Project #: 14-01-1477 (Perel)
   Title: Differential Responses to Measured and Perceived Pollution
   PI: Corey White
   Co-PI: Oliver Deschenes, Ph.D.
       University of California, Santa Barbara
Santa Barbara, 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 #: 14-11-1793 (Lowe)
   Title: Program Evaluation and Dissemination of Prenatal and Newborn Screening in California
   PI: Lisa Feuchtbbaum, Ph.D., MPH
   Co-PI: Laura Jelliffe, Ph.D.
   California Department of Public Health
   Richmond, CA

2. Project #: 14-12-1833 (Ruiz)
   Title: Assessment of Health Care Spending in California Patients with Liver Disease
   PI: Mindie Nguyen, MD, MAS
   Stanford University
   Palo Alto, CA

3. Project #: 15-01-1840 (Ruiz)
   Title: Disparities in Cervical Cancer Outcomes: Race, Socioeconomic Status and the Healthcare System
   PI: Kristine Penner, MD, MPH
   Co-PI: Robert Bristow, MD, MBA
   University of California, Irvine
   Irvine, CA

4. Project #: 14-12-1828 (Ruiz)
   Title: Hospital Response to Medicaid Payment Changes in California
   PI: Preethi Rao, Doctoral Candidate
   University of Pennsylvania
   Philadelphia, PA

K. Public Comments

L. Next Meeting
   The next CPHS meeting is scheduled for Friday, April 3, 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.

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: 888-636-3807  
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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Committee for the Protection of Human Subjects  
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