

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
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**AGENDA****COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**

**400 R Street,
Room 101, Sacramento River Room
Sacramento, CA 95811**

***US Toll-Free Number: (877) 581-9247**

Access Code: 963949

Friday, April 4, 2014

8:30 a.m. – 5:00 p.m.

A. General- Administrator Report

1. Reappointment of Members – Secretary Action Request (SAR) Package (Martinez)
2. IRB Reliance Policy Development (Ruiz)
3. Alternate Membership (Lowe)
4. CalProtects
 - a. Determination Approval Letters – Amended for projects during the period of February 2012 to present (Martinez)
 - b. Batch 3-CalProtects Issues – Update (Prefach)
5. Updates
6. Legislation (Rivera)
 - a. AB 2059 Medical Records: Electronic Delivery – Introduced by Assembly Member Muratuschi
 - b. AB 2147 Privacy: Personal Information: Agency Disclosure – Introduced by Assembly Member Melendez
 - c. AB 1683 (Amended 3-12-14) Ken Maddy California Cancer Registry: Disease Reporting – Introduced by Assembly Member Jones

B. Approval of Minutes

1. December 6, 2013
2. February 7, 2014

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

1. Project #: 13-04-1172
Title: National Birth Defects Prevention Study – California Component
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, CA

D. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 14-02-1515
Title: Consumer Engagement to Increase Advance Care Planning
PI: Amber Barnato, MD, MPH, MS
University of Pittsburg
Pittsburg, PA
Co-PI: Rebecca Sudore, MD
University of California, San Francisco
San Francisco, CA

2. Project #: 14-03-1538
Title: The Value in Tapering versus Discontinuing Proton Pump Inhibitors to Minimize its Inappropriate Use
PI: Aileen Laqui
Co-PI: Wing-Sze, Ip
Western University of Health Sciences
Pomona, CA

3. Project #: 14-01-1478
Title: Community-Associated Clostridium Difficile Risk Factor Study
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA

4. Project #: 14-01-1465
Title: California Promoting the Readiness of Minors in Supplemental Security Income (CaPROMISE)
PI: Caren Sax, EdD
San Diego State University
San Diego, CA
Co-PI: Sylvia Hoggat
California Department of Rehabilitation
Sacramento, CA

5. Project #: 14-02-1507
Title: The IMPAACT Study: Improving Physical Activity After Cancer Treatment
PI: Healthier Tarleton, PhD, MS, MPAP
Co-PI: Todd Shoepe, EdD
Loyola Marymount University
Los Angeles, CA

E. Projects With Major Revisions Requiring Full Committee Approval

1. Project #: 12-02-0012
Title: The Neurobehavioral Development of Social Behavior
PI: Nim Tottenham, PhD
Co-PI: Argyrios Ziogas, PhD
University of California, Los Angeles
Los Angeles, 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 #: 13-12-1456
Title: Recidivism Record Collection for the Evaluation of the Bureau of Justice Assistance Second Chance Act (SCA) Adult Demonstration Project
PI: Ronald D'Amico, PhD
Social Policy Research Associates
Oakland, CA
2. Project #: 14-02-1521
Title: Recidivism Record Collection for Participants of the Second Chance Act (SCA) Adult Demonstration Project California Grantees
PI: Ronald D'Amico, PhD
Social Policy Research Associates
Oakland, CA
3. Project #: 13-12-1443
Title: Independent and Multi-Variate Assessment of Novel Markers of Spontaneous Preterm Birth Using Serum-Derived Circulating Microparticles in the Early Gestational Period
PI: Alan Ezrin, PhD
NX Prenatal
Louisville, KY
4. Project #: 13-04-1174
Title: Epidemiology, Outcomes from Treatment, and the Spectrum of Soft Tissue Infection over Time in Hospitalized Patients: a Population Based Description of Inpatients in the State of California
PI: Lisa Ferrigno, MD
Santa Barbara Cottage Hospital
Santa Barbara, CA

5. Project #: 13-12-1453
Title: Safety in Childbirth; Estimating Benefits of Risk Appropriate Obstetrical Car
PI: Kimberly Gregory, MD, MPH
Cedars-Sinai Medical Center
Los Angeles, CA
6. Project #: 14-02-1512
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
7. Project #: 14-02-1528
Title: When Do Clients Leave the In-Home Supportive Services Program?
PI: Jennifer Madrid
California State University Sacramento
Sacramento, CA
8. Project #: 14-02-1524
Title: Survey for the Evaluation of the Bureau of Justice Assistance Second Chance Act Adult Demonstration Projects
PI: Carrie Markovitz, PhD
NORC at the University of Chicago
Bethesda, MD
9. Project #: 13-09-1343
Title: The impacts of air pollution in China on health in California
PI: Nicole Ngo, PhD
University of Oregon
Eugene, OR
10. Project #: 14-02-1466
Title: Social Context Through the Maternal Life Course and Birth Outcomes
PI: Michelle Pearl, PhD
Sequoia Foundation
Richmond, CA 94804

11. Project #: 14-02-1495
Title: Exploring the variability of Prenatal Screening Serum Analytes by Maternal and Fetal Characteristics
PI: Sona Saha, PhD, MPH
California Department of Public Health
Richmond, CA
Co-PI: Jennifer Adibi, ScD
Department of Epidemiology, University of Pittsburg
Pittsburg, PA
12. Project #: 13-12-1463
Title: Komen Community Profiles for Ten California Counties
PI: David Stinchcomb, MS
Westat, Inc
Rockville, MD
13. Project #: 13-12-1440
Title: What is the Value of Correctional Vocational Education? An examination of Recidivism and Post-Release Labor Market Outcomes
PI: Emily Weisburst, MA
University of Texas
Austin, TX
14. Project #: 14-01-1483
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 94804
15. Project #: 13-11-1427
Title: Reading Instructional Approaches in Juvenile Correctional Facilities: A National Survey of Teacher-Reported Practices, Challenges, and Recommendations
PI: Min-Chi Yan, MA
University of Wisconsin-Madison
Madison, WI

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

2. Project #: 12-10-0840
Title: Ethnic Disparities in Utilization Rates and Complication Rates in Hip & Knee Arthroplasty and Hip Fracture Surgery
PI: Timothy Brox, MD
University of California, San Francisco
Fresno, CA
Co-PI: Paul Brown, PhD
University of California, Merced
Merced, CA

3. Project #: 12-12-0988
Title: The Association Between Gestational Age at Delivery, Race/Ethnicity, Hospital Characteristics, and Perinatal Outcomes.
PI: Yvonne Cheng, MD, PhD
University of California, San Francisco
San Francisco, CA
Co-PI: Aaron Caughey, MD, PhD
Oregon Health and Science University
Portland, OR

4. Project #: 13-02-1095
Title: Patterns of Inheritance of Autism Spectrum Disorders
PI: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA

5. Project #: 13-02-1119
Title: Memory Processes in Childhood (project number: 09-08-01)
PI: Simona Ghetti, PhD
University of California, Davis
Davis, CA

6. Project #: 13-03-1149
Title: Assessing the Quality and Effectiveness of the California Problem Gambling Treatment System
PI: Timothy Fong, MD
University of California, Los Angeles
Los Angeles, CA
7. Project #: 13-01-1069
Title: CCR-PAMF Linkage: Creating an Anonymized Dataset for Cancer Research
PI: Scarlett Gomez, PhD
Cancer Prevention Institute of California
Fremont, CA
8. Project #: 13-03-1140
Title: Surveillance of HIV Risk & Prevention Behaviors of Men Who Have Sex with Men, Injection Drug Users, and Heterosexuals; San Diego, California
PI: Juliana Grant, MD, MPH
California Department of Public Health
Sacramento, CA
9. Project #: 13-02-1134
Title: Life Course Energy Balance and Breast Cancer Risk in Black/White Women Under 50
PI: Ann Hamilton, PhD
University of Southern California
Los Angeles, CA
10. Project #: 13-02-1084
Title: Perinatal Regionalization and Quality of Care
PI: Scott Lorch, MD, MSCE
University of Pennsylvania
Philadelphia, PA
11. Project #: 12-12-1016
Title: Tracking the Well-Being of Children in California
PI: Mark Mather, PhD
Population Reference Bureau
Washington, DC

12. Project #: 13-01-1068
Title: Evident Dampness and Mold, Fungi Identified by DNA-based Assays, and Respiratory Health in CHAMACOS Children
PI: Mark Mendell, PhD
California Department of Public Health
Richmond, CA
13. Project #: 13-02-1108
Title: A Retrospective Study of the Morbidities Suffered by Survivors of Pediatric Cancer Therapy
PI: Lisa Mueller, MD
Kaiser Permanente
Los Angeles, CA
14. Project #: 12-11-0947
Title: Emerging Infections Program Pilot Evaluation of Appropriate Antimicrobial Use in Hospitalized Patients
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland CA
15. Project #: 13-02-1124
Title: Ultrafine Particle Exposure and Respiratory Outcomes among Bicycle Commuters
PI: Hye-Youn Park, MPH, PhD
Co-PI: Cynthia Garcia
California Air Resources Board
Sacramento, CA
16. Project #: 13-02-1071
Title: Effectiveness of a Large Prenatal Tobacco Reduction Program
PI: Michelle Pearl, PhD
Sequoia Foundation
Richmond, CA
Co-PI: Martin Kharrazi, PhD
California Department of Public Health
Richmond, CA
17. Project #: 13-02-1093
Title: National Survey of Child and Adolescent Well-Being II (NSCAW II)
PI: Heather Ringeisen, PhD
RTI International
Research Triangle Park, NC

18. Project #: 13-02-1109
Title: Kaiser Permanente Northern California Family Linkage Project
PI: Neil Risch, PhD
Kaiser Foundation Research Institute
Oakland, CA
19. Project #: 13-01-1027
Title: Formative Evaluation of the Adolescent Family Life Plan, Positive Youth Development, My Life Plan (AFLP-PYD-MLP) Program
PI: Kathleen Tebb, PhD
University of California, San Francisco
San Francisco, CA
20. Project #: 13-02-1094
Title: Ibuprofen may decrease and acetaminophen increase the incidence of bronchiolitis Proposal
PI: Paul Walsh, MB BCh BAO
University of California, Davis
Sacramento CA

H. Projects with major revisions and requiring periodic review

1. Project #: 12-06-0297
Title: Linking Birth Certificate Data to the Southern California Children's Health Study Cohort Data
PI: Frank Gilliland, MD, PhD
Co-PI: Carrie Breton, ScD
University of Southern California
Los Angeles, CA
2. Project #: 12-08-0596
Title: California Maternal, Child and Adolescent Health Report
PI: Lisa Nicholas, MD
University of California, Los Angeles
Los Angeles, CA
3. Project #: 12-04-0126
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

4. Project #: 12-05-0176
Title: California Health Interview Survey
PI: Ninez Ponce, PhD
Co-PI: David Grant, PhD
University of California, Los Angeles
Los Angeles, CA

5. Project #: 13-10-1365
Title: Personal Exposure to Ultrafine Particles Study
PI: Jeffery Williams, PhD
Co-PI: Qunfang Zhang, PhD
California Air Resources Board
Sacramento, 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 #: 13-12-1452
Title: Severity of Disease and Economic Impact of Pertussis in Adolescents 14-17 Years of Age
PI: Aiden Varan, MPH
Co-PI: Kathleen Winter, MPH
San Diego County
San Diego, CA

2. Project #: 14-02-1502
Title: The Value in Tapering versus Discontinuing Proton Pump Inhibitors to Minimize its Inappropriate Use
PI: Aileen Laqui
Co-PI: Wing-Sze, Ip
Western University of Health Sciences
Pomona, CA

L. Public Comments

M. Next Meeting

The next CPHS meeting is scheduled for Friday, June 6, 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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