

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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

**AGENDA - ADDENDUM****COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**

400 R Street, Room 300
Sacramento, CA 95811

***US Toll-Free Number: 877-581- 9247
Access Code: 963949**

**Friday, June 7, 2013
8:30 a.m. – 5:00 p.m.**

A. General Items

1. Administrative Updates – L. Martinez
 - a. CPHS Staff schedule
 - b. CPHS Committee Binder Contents Announcement
 - c. CPHS Meeting Minutes Update
 - d. Full Committee Tabled Projects
 - e. Physical Safeguard Language Update
 - f. Final Reports (Completed Protocols) Publications
2. Legislative Update – AB 58 and AB 926 (Martinez)
3. Bagley-Keene Open Meeting Act Presentation – Jacob Knapp, OSHPD Senior Staff Counsel)

B. Approval of Minutes

1. August 2011
2. December 2011
3. February 2012

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

1. Project #: 12-08-0678 (Dickey/Ruiz)
Title: Permanency Innovations Initiative (PII) Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, Ph.D.
Co PI: Andrea Sedlak, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
2. Project #: 12-05-0244 (Lowe)
Title: National Survey of Youth in Custody - 2
PI: David Cantor, PhD
Westat
Rockville, MD

D. Full Committee Projects Requiring Further Discussion

1. Project# 12-10-0810 (Lowe, Dinis)
Title: California Youth Transitions to Adulthood Study (CALYOUTH)
PI: Mark Courtney, Ph.D.
University of Chicago
Chicago, Illinois

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 13-02-1099 (Bazzano)
Title: North American Wilms
PI: Rayjean Hung, PhD, MS
Mount Sinai Hospital
Toronto, ON Canada
2. Project #: 13-02-1114 (Molitor)
Title: Maternal and Infant Home Visiting Program Evaluation (MIHOPE)
PI: Virginia Knox, PhD
Co PI: Charles Michalopoulos, PhD
MDRC
New York, NY
3. Project# 13-03-1162
Title: Looking Back and Leaning Forward: A 20-Year Impact Analysis of
Unity Care Group, Inc.
PI: Megan Holston, MA
Unity Care Group, Inc.
San Jose, CA
4. Project #: 13-04-1182
Title: Perceptions of STDs and Youth in California (Youth Sexual Health
Needs Assessment)
PI: Claire Brindis, DrPH
University of California, San Francisco
San Francisco, CA
5. Project #: 13-04-1176
Title: Measuring the Quality of Cancer Care at the MD Group Level in CA
PI: Gail Rusin, MBA
Integrated Healthcare Association
Oakland, CA

6. Project #: 12-11-0930 (Ruiz/Murphy)
Title: Mortality and Support on On-line Social Media
PI: James Fowler, PhD
University of California San Diego
La Jolla, 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 #: 13-03-1161 (Ruiz/Lowe)
Title: Retrospective Review of Positron Emission Tomography for a Cancer indication at Radiological Associates of Sacramento
PI: Benjamin Franc, MD
Sacramento, CA
2. Project #: 12-07-0536 (Lowe/Grabau)
Title: COMPARATIVE EVALUATION OF STROKE TRIAGE ALGORITHMS FOR EMERGENCY MEDICAL DISPATCHERS (MeDS): Prospective Cohort Study
PI: Prasanthi Govindarajan
University of California, San Francisco
San Francisco, CA
3. Project #: 13-03-1144 (Schaeuble/Murphy)
Title: Realignment and Recidivism
PI: Timm Grattet, PhD
Co-PI: Magnus Lofstrom, PhD
Public Policy Institute of California
Sacramento, CA
4. Project #: 13-03-1153
Title: Crime in Metropolitan America: Patterns and Trends across the Southern California Landscape
PI: John Hipp, PhD
University of California, Irvine
Irvine, CA

5. Project #: 13-03-1143 (Molitor/Trent)
Title: Grant Proposal title: Breast Cancer Family Registry Cohort Protocol
project title: CCR Linkage with the Northern California Breast
Cancer Family Registry Cohort
PI: John Esther, PhD
Cancer Prevention Institute of California
Fremont, CA

6. Project #: 13-04-1173 (Perel/Murphy)
Title: Advanced Illness Management (AIM) Pilot Program: Cost and
Utilization of Care Among AIM Enrollees and Controls
PI: Joshua Liberman, PhD
Research, Development and Dissemination Sutter Health
Concord, CA

1. Project #: 13-04-1200 (TBD)
Title: Birth Certificate and Fetal Death Certificate Data Matching for the
Post-Licensure Rapid Immunization Safety Monitoring (PRISM)
Program
PI: Chunfu Liu
HealthCore, Inc.
Alexandria, VA

2. Project #: 13-05-1207 (Murphy/Perel)
Title: Investigation of Racial/Ethnic Differences in Placental Weight and
Birth Weight
PI: Latha Palaniappan, MS
Co-PI: Kristen Azar, RN, MSN/MPH
Palo Alto Medical Foundation Research Institute
Palo Alto, CA

3. Project #: 12-12-0957
Title: Genomic Analysis of Multiple Primary Tumors
PI: Susan Ramus, PhD
Co-PI: Wendy Cozen, D.O. MPH
University of Southern California
Los Angeles, CA

4. Project #: 12-12-0984 (Lowe/Grabau)
Title: Comparative effectiveness and safety of commonly used beta
blockers
PI: Jaekyu Shin, PharmD
University of California, San Francisco
San Francisco, CA

5. Project #: 13-02-1073 (Molitor/Trent)
Title: First 5 Kern Evaluation
PI: Jianjun Wang, PhD
California State University Bakersfield
Bakersfield, CA

6. Project #: 12-08-0651 (Murphy/Schaeuble)
Title: Recidivism Analysis of the Evaluation of the Re-integration of Ex-Offenders (RExO) Program
PI: Andrew Wiegand, PhD
Social Policy Research Associates
Oakland, CA

7. Project #: 13-02-1125 (Dickey/Schaeuble)
Title: Epidemiology and expenditures of infant health in California
PI: Paul Wise, MD, MPH
Stanford University
Stanford, CA

G. Continuing Projects Calendar – Previously approved projects requiring full committee approval

None

H. Projects with major revisions and requiring periodic review

None

I. 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 #: 12-04-0074 (Lowe/Grabau)
Title: Unclaimed Children Revisited: California Case Study
PI: Yumiko Aratani, PhD
Columbia University
New York, NY

2. Project #: 12-04-0061 (Lowe/Grabau)
Title: The California Teachers Study
PI: Leslie Bernstein, PhD
Co-PI: Dennis Deapen, DrPH
University of Southern California
Los Angeles, CA

3. Project #: 12-05-0244 (Lowe/Grabau)
Title: National Survey of Youth in Custody - 2
PI: David Cantor, PhD
Westat
Rockville, MD
4. Project #: 12-04-0079 (Murphy)
Title: Retrospective Evaluation of Outcomes of PET Scanning Using the National Oncologic PET Registry (NOPR)
PI: William Carpenter, PhD
University of North Carolina
Chapel Hill, NC
5. Project #: 12-03-0042 (Dickey)
Title: Cancer Incidence and Cancer Mortality in the World Trade Center Health Registry
PI: James Cone, MD
New York City Department of Health and Mental Hygiene (NYCDOHMH)
Long Island, NY
6. 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
7. Project #: 12-04-0147 (Dickey)
Title: Joint Contributions of the Supplemental Nutrition Assistance Program, Unemployment Insurance, and Cash Assistance to California's Social Safety Net
PI: Caroline Danielson, PhD
Co-PI: Jane Mauldon, PhD
Public Policy Institute of California
San Francisco, CA
8. Project #: 12-04-0053 (Lowe/Grabau)
Title: RealAge Collaboration – Prediction of Mortality Risk Using Online Health and Health Interest Data
PI: James Fowler, PhD
University of California, San Diego
La Jolla, CA

9. 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
10. Project #: 12-04-0157 (Molitor/Trent)
Title: The California Maternal Data Center: Establishing a Statewide Data Center for Use in Rapid-Cycle Maternity Care Improvement Projects
PI: Jeffrey Gould, MD, MPH
Co-PI: Elliott Main, MD
Stanford University
Stanford, CA
11. 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
12. Project #: 12-04-0045 (Lowe/Grabau)
Title: California Coronary Artery Bypass Graft Outcomes Reporting Program (CCORP)
PI: Holly Hoegh, PhD
California Office of Statewide Health Planning and Development
Sacramento, CA
13. Project #: 12-04-0064 (Murphy)
Title: Effect of Drug Resistance on Transmissibility and Pathogenicity of M. tuberculosis
PI: Philip Hopewell, MD
San Francisco General Hospital
San Francisco, CA
Co-PI: Jennifer Flood, MD, MPH
California Department of Public Health
Richmond, CA

14. Project #: 12-05-0209 (Lowe/Grabau)
Title: Measuring Your Health (MY-Health): Validation Study of Health Outcomes Measures
PI: Theresa Keegan, PhD
Cancer Prevention Institute of California
Fremont, CA
Co-PI: Rosemary Cress, DrPH
Public Health Institute
Sacramento, CA
15. Project #: 12-04-0132 (Murphy)
Title: San Francisco Mammography Registry: A Research Resource
PI: Karla Kerlikowske, MD
University of California, San Francisco
San Francisco, CA
16. Project #: 12-04-0123 (Ruiz)
Title: Investigation of Factors that Affect Patterns of Care and Survival for Brain and Central Nervous System Cancer Patients Throughout San Diego County and California
PI: Santosh Kesari
Co-PI: Katrina Flores, MPH
University of California, San Diego
La Jolla, CA
17. Project #: 12-04-0119 (Ruiz)
Title: Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis
PI: Pamala Kirley, MPH
California Emerging Infections Program
Oakland, CA
18. Project #: 12-04-0102 (Lowe/Grabau)
Title: Research Program in Medication Use and Outcomes in Pregnancy
PI: De-Kun Li, MD, PhD
Kaiser Foundation Research Institute
Oakland, CA
19. Project #: 12-05-0177 (Molitor/Trent)
Title: Kaiser Research Program on Genes, Environment and Health (RPGEH) and Biomonitoring California Adult Cohort Project Biomonitoring Exposures Study (BEST)
PI: Michael Lipsett
California Department of Public Health
Richmond, CA

20. Project #: 12-03-0044 (Lowe/Grabau)
Title: Aggregated Complication Measure for Neonatal Quality of Care
PI: Scott Lorch, MD, MSCE
University of Pennsylvania
Philadelphia, PA
21. Project #: 12-03-0036 (Dickey)
Title: Trial Participation for Cancer Patients
PI: Anup Malani, JD, PhD
University of Chicago
Chicago, IL
22. Project #: 12-04-0144 (Murphy)
Title: In-school Survey and Evaluation of Tobacco Use Prevention Education (TUPE) programs - 2003-2004
PI: William McCarthy, PhD
Co-PI: Barbara Dietsch, PhD
WestEd
San Francisco, CA
23. Project #: 12-05-0205 (Molitor/Trent)
Title: The effectiveness of a risk screening instrument in identifying patients at risk of aggression: The use of the COVR in a psychiatric hospital
PI: Barbara McDermott, PhD
University of California, Davis
Sacramento, CA
24. Project #: 12-04-0146 (Molitor)
Title: Categorization of Infant-Directed Speech
PI: David Moore, PhD
Claremont Colleges
Claremont, CA
25. Project #: 12-04-0126 (Dickey)
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

26. Project #: 12-04-0062 (Dickey)
Title: Pilot Study to Test Laboratory Components of the CECBP
PI: Myrto Petreas, PhD, MPH
California Department of Toxic Substances Control
Berkeley, CA
27. Project #: 13-04-1172 (Lowe/Grabau)
Title: National Birth Defects Prevention Study – California Component
PI: Gary Shaw, DrPH
Co-PI: Suzan Carmichael, PhD
Stanford University
Stanford, CA
28. Project #: 12-05-0198 (Dickey)
Title: Trends and Outcomes in the Treatment of Thoracic Aortic Dissection in California, 1992 – 2007
PI: Min-Woong Sohn, PhD
Northwestern University
Chicago, IL
29. 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
30. Project #: 12-04-0067 (Dickey)
Title: California EHS-Net Food and Water Safety Risk Factors Associated with Mobile Food Vehicles Study
PI: Susan Strong
California Department of Public Health
Sacramento, CA
31. Project #: 12-02-0012 (Dickey/Ruiz)
Title: The Neurobehavioral Development of Social Behavior
PI: Nim Tottenham, PhD
University of California, Los Angeles
Los Angeles, CA
32. Project #: 12-03-0029 (Ruiz)

Title: The Effect of Speed Limits on Infant Health, Accidents and Travel Time

PI: Arthur van Benthem, PhD
Stanford University
Stanford, CA

33. Project #: 12-04-0105 (Ruiz)

Title: "The Impact of Lower Extremity Orthopedic Surgery on the Lives of Children with Cerebral Palsy

PI: Stephanie Yu, MSPT, PCS
Department of Public Health
El Monte, CA

J. Projects with Revisions Only

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 #: 13-02-1098 (Schaeuble)

Title: Investigating the Link Between Walking and Language Development

PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

2. Project #: 13-02-1101 (Schaeuble)

Title: Visual Proprioception and Wariness of Heights in Infants

PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

3. Project #: 13-02-1103 (Schaeuble)

Title: Locomotion and Psychological Development in Infancy

PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

4. Project #: 13-02-1113 (Schaeuble)

Title: Emotional communication of rules to infants

PI: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

5. Project #: 12-08-0644 (Bazzano/Molitor)

- Title: WIC ITFPS-2: Feeding My Baby – A National WIC Study
PI: Gail Harrison
University of California, Los Angeles
Los Angeles, CA
6. Project #: 12-08-0605 (Dickey/Molitor)
Title: Maternal and Infant Environmental Exposure Project (also known as Chemicals in Our Bodies Project)
PI: Michael Lipsett, MD
California Department of Public Health
Richmond, CA
7. Project #: 12-08-0611 (Dickey/Ruiz)
Title: Health Benefits of Expressive Writing among Chinese Breast Cancer Survivors
PI: Qian Lu
University of Houston
Houston, TX
8. Project #: 12-05-0176 (Dickey/Ruiz)
Title: California Health Interview Survey
PI: Ninez Ponce, PhD
Co-PI: David Grant, PhD
University of California, Los Angeles
Los Angeles, CA
9. Project #: 12-08-0678 (Dickey/Murphy)
Title: Permanency Innovations Initiative(PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
Co-PI: Andrea Sedlak, PhD
Westat
Rockville, MD
10. Project #: 12-04-0161 (Murphy)
Title: Probabilistic Inference and Categorization Development in Infants
PI: Fei Xu, PhD
University of California, Berkeley
Berkeley, CA

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

No reports.

L. 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).

No reports.

M. Exemption Request

1. Project #: 13-05-1220 (Lowe)
Title: Evaluation of the Garrett Lee Smith Suicide Prevention Program
PI: David Barker, PhD
California State University Sacramento
Sacramento, CA

2. Project #: 13-05-1206(Lowe)
Title: Comprehensive Approaches to Raising Educational Standards (CARES) Plus Program, Round 2: First 5 California Government Program Evaluation
PI: David Dodds, PhD, MPH
Co-PI: Robert Dean, MA
California Children and Families Commission
Sacramento, CA

3. Project #: 13-05-1218 (Lowe)
Title: Evaluation of Cyclic Variations in Adaptive Conditioning (CVAC) device for use in the performance and recovery of Oracle Sailing team athletes
PI: Ryan West, MS
Professional Sailing Team OTUSA
San Francisco, CA

M. Next Meeting

The next CPHS meeting is scheduled for Friday, August 2, 2013 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.

US Toll-Free Number: 877-581-9247

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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