

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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

**AGENDA (Amended)****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, December 7, 2012
8:30 a.m. – 5:00 p.m.**

A. General Items

1. Welcome -New CPHS Members –Drs. Grabau and Trent (Murphy)
2. CPHS Staff Update (Martinez/Cortes)
3. CalProtects-Update (Molitor/Martinez)
4. Death Data Projects (Ruiz, Lowe)
5. Amendment and Continuing Review Forms (Lowe)

B. Approval of Minutes

1. August 2012
2. October 2012

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

1. Project # 12-06-0361 (Molitor)
Title: An Evaluation of the Transition of Seniors and Persons with Disabilities to Mandatory Medi-Cal Managed Care
PI Carrie Graham, Ph.D.
University of California, Berkeley
Berkeley, CA
2. Project 11-10-36 (Lowe/Murphy)
Title: Low Income Health Program Evaluation
PI: Gerald Kominski, Ph.D.
University of California, Los Angeles
Los Angeles, CA

D. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: **12-08-0658** (Molitor)
Title: Personal Responsibility and Education Program (PREP) Evaluation
PI: Claire Brindis, Ph.D.
University of California, San Francisco
San Francisco, CA

2. Project #: **12-10-0837** (Ruiz)
Title: Prenatal Environmental Determinants of Inter-Generational Risk Supplement Study (PEDIGREE Moms)
PI: Barbara Cohn, PhD
Co-PI: Mary Beth Terry, PhD
Berkeley, CA

3. Project #: **12-10-0810** (Perel)
Title: California Youth Transitions to Adulthood Study (CALYOUTH)
PI: Mark Courtney, PhD
University of Chicago
Chicago, IL

4. Project #: **12-09-0749** (Parker)
Title: Cancer Epidemiology in Adventists - A Low Risk Group
PI: Gary Fraser, MD, PhD
Loma Linda University
Loma Linda, CA

5. Project #: **12-10-0792** (Schaeuble)
Title: Long-term Outcomes in Duarte Galactosemia
PI: Judith Fridovich-Keil, PhD
Emory University
Atlanta, GA

6. Project #: **12-08-0696** (Takahashi)
Title: Understanding the Workplace Interactions of Young Adult Cancer Survivors with Occupational and Environmental Health Professionals
PI: Dawn Stone
Fullerton, CA

7. Project #: **12-10-0841** (Lowe)
Title: Outcome evaluation of the Bedsider Program Reminder System to Improve Contraceptive Continuation and Prevent Unplanned Pregnancy
PI: Heike Thiel de Bocanegra, PhD, MPH
California Department of Health Care Services
Sacramento, CA

8. Project# **12-05-0259** (Lowe)
Novo Nordisk Medullary Thyroid Carcinoma Surveillance Study: A
Case-Series Registry
PI: Gretchen Dieck, MD
Co-PI: Jerome Hershman, MD
United BioSource Corporation
Blue Bell, PA

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.

9. Project #: **12-10-0786** (Murphy/Takahashi)
Title: California Parolee Reentry Evaluation
PI: Shannon Carey, PhD
NPC Research
Portland, OR
10. Project #: **12-10-0821** (Bazzano/Molitor)
Title: Short Inter-Pregnancy Intervals and Risk of Autism Spectrum Disorders
PI: Lisa Croen, PhD
Co-PI: Ousseny Zerbo, PhD
Kaiser Permanente
Oakland, CA
11. Project #: **12-07-0512** (Takahashi/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, PhD
Patton State Hospital
Patton, CA
12. Project #: **12-09-0735** (Takahashi/Bazzano)
Title: BRCA1 Mutation Status from Tumor Pathology
PI: Ann Hamilton, PhD
University of Southern California
13. Project #: **12-09-0736** (Bazzano/Takahashi)
Title: Use of Cancer Registry Data By USC Clinical Investigators
PI: Ann Hamilton
University of Southern California

14. Project #: **12-10-0812** (Bazzano/Takahashi)
Title: HPV Typing of Invasive Cancers: Monitoring the Impact of a Prophylactic HPV Vaccine on HPV Types in Cervical and Laryngeal Cancer: Using Tissues from Central Cancer Registries
PI: Brenda Hernandez, PhD, MPH
University of Hawaii
Honolulu, HI
15. Project #: **12-05-0245** (Lowe/Perel)
Title: Hospitalization Patterns and Emergency Department Use During Transition Period: Analysis of Experience for Those with Chronic Illnesses
PI: Jenna Jones, MPH
University of California, Los Angeles
Los Angeles, CA
16. Project #: **12-08-0602** (Takahashi/Parker)
Title: Investigation of the Factors that Affect Outcomes of Cancer Patients throughout San Diego County and California.
PI: Santosh Kesari, MD, PhD
Co-PI: Katrina Flores
University of California, San Diego
San Diego, CA
17. Project #: **12-07-0513** (Molitor/Dickey)
Title: Geographic Distribution and Spatial Analysis of Human Typhus Cases in California
PI: Anne Kjemtrup, DVM, PhD
California Department of Public Health
18. Project #: **12-10-0865** (Murphy/Schaeuble)
Title: Effect of Agricultural Pesticides on Adverse Birth Outcomes
PI: Ashley Larsen, MS
UC Santa Barbara
Santa Barbara, CA
19. Project #: **12-10-0866** (Molitor/Perel)
Title: Establish a Prospective Cohort Study From a Series of Population Controls
PI: Eunjung Lee, PhD
University of Southern California
Los Angeles, CA
20. Project #: **12-09-0754** (Lowe/Perel)
Title: MMPI-2 Profile of Sex Offenders: Is There a Valid One?
PI: Marlon Lorenzo, BS Psychology
California Department of Mental Health
Coalinga, CA

21. Project #: **12-09-0757** (Lowe/Takahashi)
Title: Normal and Abnormal Spatial Vision in Infants and Form and Motion Integration
PI: Anthony Norcia
Stanford University
Stanford, CA
22. Project #: **12-10-0857** (Bazzano/Takahashi)
Title: A Retrospective Study and Comparative Analysis of Predictive Factors Associated with Clinical Trial Accrual Patterns at Moores Cancer Center, UC San Diego
PI: Erin Reid, MD, MS
Co-PI: Kristine Ortwine, MPH
University of California, San Diego
San Diego, CA
23. Project #: **12-09-0756** (Ruiz/Lowe)
Title: Cedars-Sinai Medical Center Internal Quality Assurance Tracking Process
PI: Alfredo Trento, MD
Co-PI: Lawrence Czer
Cedars-Sinai Medical Center
Los Angeles, CA
24. Project #: **12-10-0805** (Molitor/Perel)
Title: CA State Death Data Linkage to Stanford EHR
PI: Susan Weber, PhD
Stanford University
Stanford, CA
- Project# 12-10-0829 (TBD)
Epidemiological and Biostatistical Component of the Pratt & Witney Cohort Study
Gary Marsh, M.S., Ph.D.
University of Pittsburgh
Pittsburgh, PA

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

None.

F. Projects with major revisions and requiring periodic review

None.

**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.**

25. Project #: **12-09-0698** (Molitor)
Title: Follow-up of Infants Born to Pregnant Women with Confirmed or Probable 2009 H1N1 Influenza with Symptom Onset from April 1 through December 31, 2009
PI: Meileen Acosta, MPH
Solano County Health and Social Services
Fairfield, CA
26. Project #: **12-10-0777** (Bazzano)
Title: CHIS Smoker Follow-Up Study
PI: Wael Al-delaimy
University of California, San Diego
La Jolla, CA
27. Project #: **12-10-0842** (Murphy)
Title: Evaluation of Measure Y Re-Entry Employment Research Application
PI: Patricia Bennett, PhD
Resource Development Associates
Oakland, CA
28. Project #: **12-10-0819** (Dinis)
Title: Maternal and Infant Health Assessment (MIHA)
PI: Paula Braveman, MD, MPH
University of California, San Francisco
San Francisco, CA
29. Project #: **12-10-0836** (Lowe)
Title: Perinatal Profiles
PI: Ray Catalano, PhD
University of California, Berkeley
Berkeley, CA
30. Project #: **12-10-0817** (Murphy)
Title: Father Involvement Initiative
PI: Philip Cowan, PhD
Co-PI: Carolyn Cowan, PhD
University of California, Berkeley
Berkeley, CA

31. Project #: **12-10-0843** (Murphy)
Title: Use of Linked Data Bases to Assess Selected Quality Indicators for Maternal and Infant Health
PI: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA
32. Project #: **12-10-0773** (Murphy)
Title: Effects of Neighborhood Cultural Context on Infant Mortality and Birth Weight in Los Angeles County
PI: Lisa DeCamp, MD, MSPH
Co-PI: Narayan Sastry
John Hopkins University
33. Project #: **12-10-0849** (Molitor)
Title: Health Insurance and Financial Protection
PI: Carlos Dobkin, PhD
University of California, Santa Cruz
Santa Cruz, CA
34. Project #: **12-10-0815** (Bazzano)
Title: Investigations of Language Learning and Social Cognition in Infants and Children
PI: Michael Frank
Stanford University
Stanford, CA
35. Project #: **12-10-0799** (Murphy)
Title: Occurrence and Distribution of Autism in California
PI: Irva Hertz-Picciotto, PhD
University of California, Davis
Davis, CA
36. Project #: **12-09-0724** (Dickey)
Title: Mental Health Services and Client Outcomes
PI: Wei-Chin Hwang, PhD
Claremont Colleges
Claremont, CA
37. Project #: **12-11-0894** (Bazzano)
Title: Maternal and Infant Health Outcomes Among Women with Preexisting Morbidity in California
PI: Maria Jocson, MD, MPH
Co-PI: Michael Curtis, PhD
California Department of Public Health

38. Project #: **12-04-0168** (Takahashi)
Title: Culture, Social Support & Quality of Life: Asian American Breast Cancer Survivors
PI: Marjorie Kagawa-Singer, PhD, MA, MN, RN, FAAN
Co-PI: Qian Lu, MD, PhD
University of California, Los Angeles
Los Angeles, CA
39. Project #: **12-11-0904** (Dinis)
Title: Patient Involvement in Choice of Physician and Hospital for Breast Cancer
PI: Nancy Keating, MD, MPH
Harvard University
Boston, MA
40. Project #: **12-10-0784** (Murphy)
Title: Low Income Health Program (LIHP) Evaluation
PI: Gerald Kominski
University of California, Los Angeles
Los Angeles, CA
41. Project #: **12-08-0663** (Ruiz/Lowe)
Title: The California Pregnancy-Associated Mortality Review
PI: Elizabeth Lawton, MHS
Co-PI: Patrick Fox, PhD
California Department of Public Health
42. Project #: **12-10-0853** (Murphy)
Title: Severe Community-Onset Staphylococcus aureus Infection Surveillance through Active Bacterial Core Surveillance/Emerging Infections Program
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA
43. Project #: **12-10-0772** (Murphy)
Title: NIH-AARP Diet and Health Study
PI: Yikyung Park, ScD
National Cancer Institute
Rockville, MD
44. Project #: **12-09-0733** (Takahashi)
Title: Preliminary Study of Reproductive Health Impacts in Nail and Hair Care Workers
PI: Thu Quach, PhD
Cancer Prevention Institute of California
Berkeley, CA

45. Project #: **12-09-0732** (Bazzano)
Title: Persistent Organic Pollutants and Breast Cancer Risk: Chemicals
Old and New
PI: Peggy Reynolds, PhD
Co-PI: Myrto Petreas, PhD
Cancer Prevention Institute of California
Berkeley, CA
46. Project #: **12-09-0729** (Takahashi)
Title: Regional Variations in Breast Cancer Rates in California
PI: Peggy Reynolds, PhD
Cancer Prevention Institute of California
Berkeley, CA
47. Project #: **12-11-0916** (Lowe)
Title: High Medicaid Hospitals and Postoperative Cancer Outcomes in
California
PI: Kim Rhoads, MD, MPH
Stanford University
Stanford, CA
48. Project #: **12-10-0861** (Takahashi)
Title: Evaluating the Effects of Exposure to Air Pollution on Adverse Birth
Outcomes in Southern California
PI: Beate Ritz, MD, PhD
University of California, Los Angeles
Los Angeles, CA
49. Project #: **12-10-0831** (Bazzano)
Title: Residential Proximity to Agricultural Pesticides and Autism
Spectrum Disorder—A Follow-Up Study
PI: Eric Roberts, MD, PhD
Richmond, CA
50. Project #: **12-08-0697** (Molitor/Ruiz)
Title: Genetics of Breast Cancer Risk in Latinas
PI: Elad Ziv, MD
University of California, San Francisco
San Francisco, CA

H. 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.

51. Project #: **12-08-0632** (Parker)
Title: Evaluation of First 5 California's Child Signature Program
PI: David Dodds, PhD, MPH
Co-PI: Robert Dean, MA
California Children and Families Commission
Sacramento, CA
52. Project #: **12-06-0393** (Ruiz/Lowe)
Title: Development of State-wide Perinatal Quality Improvement Metrics with OSHPD PDD/Birth Certificate Linked Data
PI: Jeffrey Gould, MD, MPH
Stanford University
Stanford, CA
53. Project #: **12-06-0287** (Ruiz/Dickey)
Title: Physician Induced Demand: Evidence from Patients with MDs
PI: Erin Johnson, PhD
Co-PI: Michal Rehavi, PhD
Massachusetts Institute of Technology
54. Project #: **12-04-0072** (Ruiz/Molitor)
Title: Firefighter Occupational Exposures (FOX) Project
PI: Michael Lipsett
California Department of Public Health
Richmond, CA
55. Project #: **12-04-0103** (Dinis/Lowe)
Title: Visual Processing and Later Cognitive Effects in Infants with Fragile X Syndrome
PI: Susan Rivera, PhD
University of California, Davis
Davis, CA
56. Project #: **12-08-0678** (Dickey)
Title: Permanency Innovations Initiative (PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
Co-PI: Andrea Sedlak, PhD
LA Gay & Lesbian Center
Los Angeles, CA

57. Project #: **12-07-0580** (Ruiz/Bazzano)
Title: Can Medicaid Benefits Reduce Access Disparities for Ethnic Minority Children & Youth
PI: Lonnie Snowden, PhD
University of California, Berkeley
Berkeley, CA

58. Project #: **12-05-0213** (Murphy/Lowe)
Title: Evaluation of First 5 California's Child Signature Program
PI: Margaret Wrensch, PhD
Co-PI: John Wiencke, PhD
University of California, San Francisco
San Francisco, CA

59. Project #: **12-08-0631** (Bazzano)
Title: Predictors of Long-term Outcomes in California Children with Central Nervous System (CNS) Tuberculosis (TB)
PI: Pennan Barry, MD, MPH
Co-PI: Alexandra Duque-Silva, MD
California Department of Public Health
Richmond, CA

60. 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

61. Project#: **12-11-0902** (Ruiz)
California Behavioral Risk Factor Survey
Kurt Snipes, Ph.D.
California Department of Public Health

62. Project# **12-11-0933** (Ruiz)
Title: California Women's Health Survey
Kurt Snipes, Ph.D.
California Department of Public Health

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

No reports.

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).

No reports.

K. Exemption Request

No report

L. Next Meeting

The next CPHS meeting is scheduled for February 1, 2013 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 encourages public attendance and participation at its meetings. CPHS also established a toll-free telephone number for the public to monitor or participate in the meetings. If interested, please call the telephone number and enter the access code 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.

California Health and Human Services Agency
Committee for the Protection of Human Subjects

400 R Street, Room 359

Sacramento, CA 95811

Phone: (916) 326-3660

Fax: (916) 322-2512

Lucila Martinez

Administrator

Lucila.Martinez@oshpd.ca.gov

cphs-mail@oshpd.ca.gov

CPHS website: www.oshpd.ca.gov/boards/cphs