

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
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**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, February 1, 2013
8:30 a.m. – 5:00 p.m.**

A. General Items

1. Farewell to Dr. Takahashi (Ruiz)
2. CPHS Staff Update (Martinez/Cortes)
3. CalProtects-Update (Martinez/Dhaliwal)
 - a. Powerpoint Presentation
4. SB-13 Information (Dickey)
5. Legislative Update – AB 58 (Martinez)

B. Approval of Minutes

1. June 2012
2. August 2012
3. October 2012
4. October 2011

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

1. Project #: 12-05-0177 (Lowe)
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
2. Project #: 07-06-05 (Dinis/Murphy)
Title: Evaluation of First 5 California's CARES Program
PI: Judith Cantrell (Dodds)
California Children and Families

3. Project #: 12-10-0785 (Ruiz/Murphy)
Title: Low Income Health Program Evaluation
PI: Gerald Kominski
University of California, Los Angeles

D. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 12-11-0898 (Molitor/Trent)
Title: Long-Term Follow-up of the Family and Cancer Therapy Selection (FACTS) Study Participants
PI: Scott Ramsey, M.D., Ph.D.
Fred Hutchinson Cancer Research Center
Seattle, WA
2. Project #: 12-12-1007 (Schaeuble)
Title: Colorectal Cancer Family Epigenetic Study Program
PI: S. Pamela Shiao, Ph.D.
Azusa Pacific University
Azusa, CA
3. Project #: 12-10-0871 (Parker/Grabau)
Title: Cognitive Impairment: Is There a Role for Cognitive Assessment in the Treatment of Sexually Violent Predators?
PI: Allen Azizian, Ph.D.
California Department of Mental Health
Coalinga, CA
4. Project #: 12-12-1008 (Dickey)
Title: Utilization of Mental Health Services Among Individuals with Developmental Disabilities: Parents' and Caregivers' Perspectives
PI: Alicia Bazzano, M.D., Ph.D.
Co-PI: Erica Schuster
Westside Regional Center
Culver City, CA
5. Project #: 12-12-1020 (Murphy)
Title: From Utility to Significance: Exploring Ecological Connection, Ethics and Personal Transformation Through a Gardening and Environmental Literacy Program within San Quentin Prison
PI: Melissa Benham, MS
Co-PI: Rachel O'Malley
San Jose State University
San Jose, CA

6. Project #: 12-12-0965 (Lowe)
Title: Consequences of Devolution: Effectiveness, Efficiency, and Equity of Care in California's County-Based Public Mental Health Care System
PI: Lonnie Snowden, Ph.D.
Co-PI: Megan Vanneman
University of California, Berkeley
Berkeley, CA
7. Project #: 12-12-0951 (Perel)
Title: Method Comparison of Drug Concentration Levels in Oral Fluid Determined by Lin-Zhi International Homogeneous Enzyme Immunoassay (EIA) Versus Liquid Chromatography/ Mass Spectrometry or Gas Chromatography /Mass Spectrometry (LCMS/GCMS)
PI: Julie Tai, Ph.D.
Co-PI: Amy Lu, Ph.D.
Sunnyvale, CA
8. Project #: 13-01-1027 (Bazzano)
Title: Formative Evaluation of the Adolescent Family Life Plan, Positive Youth Development, My Life Plan (AFLP-PYD-MLP) Program
PI: Kathleen Tebb
University of California, San Francisco
San Francisco, CA

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.

9. Project #: 12-10-0783 (TBD)
Title: PM 2.5-Cardiovascular Disease Associations: Use of Modeled Hierarchical Bayesian vs. Ambient Monitoring Exposure Data
PI: John Balmes, M.D., MPH
University of California, Berkeley
Berkeley, CA
10. Project #: 12-08-0596 (Dickey/Molitor)
Title: California Maternal, Child and Adolescent Health Report
PI: Angela Chen, M.D.
University of California, Los Angeles
Los Angeles, CA

11. Project #: 12-11-0930 (Schaeuble/Dinis)
Title: Mortality and Support on Online Social Media
PI: James Fowler, Ph.D.
University of California, San Diego
La Jolla, CA
12. Project #: 13-01-1031 (TBD)
Title: Establish a Prospective Cohort Study from a Series of Population Controls
PI: Eunjung Lee, Ph.D.
University of Southern California
Los Angeles, CA
13. Project #: 12-10-0801 (Parker/Grabau)
Title: Quality of Family Planning Services Delivered by Medi-Cal Providers
PI: Heike Thiel de Bocanegra, Ph.D., MPH
California Department of Health Care Services
Sacramento, CA
14. Project #: 12-12-1022 (TBD)
Title: Camp Lejeune Health Survey
PI: Perri Ruckart, MPH
Centers for Disease Control and Prevention
Atlanta, GA

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

None

G. Projects with major revisions and requiring periodic review

None

H. 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.

- 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

2. Project #: 12-08-0619 (Lowe)
Title: Impact of Maternal and Child Health Funding on Health Outcomes
PI: Suzanne Bostwick
Los Angeles County
Los Angeles, CA

Project #: 12-12-0970 (Dickey)
Title: Healthy City Direct Technical Assistance and Healthcity.org Online
Mapping and Analysis
PI: Erin Coleman, MURP
Los Angeles, CA
4. Project #: 12-12-0958 (Lowe)
Title: A Diverse Autism Registry for Effectiveness Studies
PI: Lisa Croen, Ph.D.
Kaiser Permanente
Oakland, CA
5. Project #: 12-12-0981 (Parker/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
6. Project #: 12-12-1013 (Parker)
Title: Applied Statistics for Pattern and Fraud Detection in Health Care
Data
PI: Artur Dubrawski, Ph.D.
Carnegie Mellon University
Pittsburgh, PA
7. Project #: 12-11-0940 (Ruiz)
Title: Quality of Care in Hysterectomy and Urogynecologic Procedures in
the State of California
PI: Christopher Elliot, M.D., Ph.D.
Stanford University
Stanford, CA

Project #: 12-12-1003 (Murphy)
Title: Gestational Diabetes: Diagnostic Criteria and Outcomes
PI: Assiamira Ferrara, M.D., Ph.D.
Kaiser Permanente Division of Research
Oakland, CA

9. Project #: 12-12-0983 (Ruiz/Dickey)
Title: SRI Demographic Questions for California Breast Cancer Research
PI: Scarlett Gomez, Ph.D.
Cancer Prevention Institute of California
Fremont, CA
10. Project #: 12-07-0565 (Dickey)
Title: Disparity in the Quality of Breast Cancer Treatment and Effect on Outcomes-Los Angeles Subcontract
PI: Ann Hamilton, Ph.D.
University of Southern California
11. 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
12. 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
13. Project #: 12-12-0950 (Schaeuble)
Title: LEGACY: A Cohort of Youth in Families from the Breast Cancer Family Registry
PI: Esther John, Ph.D.
Cancer Prevention Institute of California
Fremont, CA
14. 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
15. 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

16. Project #: 12-12-0985 (Murphy)
Title: Reproductive Outcomes among Female Flight Attendants
PI: Christina Lawson, Ph.D.
National Institute of Occupational Safety and Health
Cincinnati, OH
17. Project #: 12-12-0990 (Parker/Grabau)
Title: The Prison University Project Evaluation Study
PI: Amy Lerman, Ph.D.
Woodrow Wilson School of Public and International Affairs
Princeton, NJ
18. 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
19. Project #: 12-11-0927 (Lowe/Bazzano)
Title: The Development of Object Representation in Infancy
PI: Lisa Oakes, Ph.D.
University of California, Davis
Davis, CA
20. Project #: 12-12-1002 (Lowe)
Title: Exploratory Spatial Data Analysis of Community Environmental Risk Factors for Teen Pregnancy and Adverse Birth Outcomes
PI: Ikuho Yamada, Ph.D.
Center for Spatial Information Science, University of Tokyo
Tokyo, Japan
21. Project #: 12-11-0895 (Murphy)
Title: Expanding the Role of Medicaid in Cancer Care for the Uninsured
PI: David Zingmond, M.D., Ph.D.
University of California, Los Angeles
Los Angeles, CA

I. 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 #: 12-09-0705 (Ruiz)
Title: Evaluating the Effectiveness of a 13-Valent Pneumococcal Conjugate Vaccine among Children
PI: Mirasol Apostol, M.P.H.
California Emerging Infections Program
Oakland, CA
2. Project #: 12-11-0893 (Dickey)
Title: Pilot Study of Trends and Risks in Gestational Diabetes
PI: Assiamira Ferrara, M.D., Ph.D.
Kaiser Permanente
Oakland, CA
3. Project #: 12-05-0177 (Molitor/Ruiz)
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
4. Project #: 12-05-0176 (Dickey/Ruiz)
Title: California Health Interview Survey
PI: Ninez Ponce, Ph.D.
Co-PI: David Grant, Ph.D.
University of California, Los Angeles
Los Angeles, CA
5. Project #: 12-07-0500 (Lowe)
Title: Evaluation of the Permanency Innovation Initiative: California Partners for Permanency
PI: Andrea Sedlak, Ph.D.
6. Project #: 12-06-0389 (Lowe/Molitor)
Title: Mortality and Morbidity Predictors of Neonates with Surgical Conditions: Health Services Research Using Linked PDD/Cohort File of OSHPD Database
PI: Jeffrey Upperman, M.D.
Co-PI: Rita Burke, Ph.D., MPH
Children's Hospital of Los Angeles
Los Angeles, CA

7. Project #: 12-08-0655 (TBD)
Title: Culture and Breast Cancer Survivorship
PI: Judy Wang, Ph.D.
Georgetown University
Washington, CA
8. Project #: 12-08-0692 (Molitor/Trent)
Title: California Late Impact of Phototherapy Study (CLIPS)
PI: Andrea Wickremasinghe, M.D.
University of California, San Francisco
San Francisco, CA
9. Project #: 12-04-0127 (Molitor/Trent)
Title: Improving the Reporting of Race, Ethnicity, and Language in California
PI: David Zingmond, M.D., Ph.D.
University of California, Los Angeles
Los Angeles, CA

J. Second Review Calendar – Projects not previously approved that require full committee review
No reports.

K. 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.

L. Exemption Request

1. Project #: 13-01-1038 (Ruiz)
Title: Assessment of the Validity of the Birth Certificate Pregnancy Complication Code for Maternal Hepatitis B Infection, 2009-2010
PI: Catheryn Salibay, MPH
California Department of Public Health

M. Next Meeting

The next CPHS meeting is scheduled for April 5, 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.

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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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