

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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**AGENDA****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, October 5, 2012
8:30 a.m. – 5:00 p.m.**

A. General Items

1. CPHS Staff Update (Lucila/James)
2. CPHS SAR Update (Lucila)
3. CPHS – Purview over non-HHSA departments/agencies (Murphy)
4. California PROTocol Electronic Communication and Tracking System (CalPROTECTS) Subcommittee Report – (Molitor)
 - a. Two Reviewer or Continuing Review Requests (Lisa)
 - b. HIPPA – (Lowe)

B. Approval of Minutes**C. New Projects Calendar****New Projects - Full Committee Review Required**

1. Project #: **12-07-0574** (Dinis)
Title: At Home Group Video Calling to Support Rural Women
PI: Cheryl Koopman, PhD
Co-PI: Mary Kreshka, MA
Stanford University
Stanford, CA
2. Project #: **12-08-0606** (Molitor)
Title: Program Evaluation of the Pilot Implementation of the Positive Prevention PLUS Curriculum with Adolescent Family Life
PI: Jeannie Huh-Kim, PhD
Reach Out West End
Upland, CA
3. Project #: **12-08-0638** (Takahashi)
Title: EHS-Net Food Allergen Study
PI: Susan Strong
California Department of Public Health
Sacramento, CA

4. Project #: **12-08-0671** (Dickey)
Title: Tolerability and Immunogenicity of Investigational Recombinant Botulinum Vaccine in Volunteers Previously Immunized with Investigational Pentavalent Botulinum Toxoid
PI: Stephen Arnon, MD, MPH
Co-PI: Jessica Khouri, MD
California Department of Health
Richmond, CA
5. 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
6. Project #: **12-05-0259** (Lowe)
Title: Novo Nordisk Medullary Thyroid Carcinoma Surveillance Study: A Case-Series Registry
PI: Gretchen Dieck
United BioSource Corporation
Blue Bell, PA
7. Project No. **12-08-0644** (Bazzano)
Title: WIC ITFPS-2: Feeding My Baby – A National WIC Study
PI: Gail Harrison
University of California, Los Angeles
Los Angeles, CA
8. Project #: **12-08-0637** (Perel)
Title: Los Angeles Foster Care Youth
PI: Bianca Wilson, PhD
Co-PI: Khush Cooper, PhD
University of California, Los Angeles
Los Angeles, CA
9. Project #: **12-07-0500** (Lowe)
Title: Evaluation of the Permanency Innovation Initiative: California Partners for Permanency Los Angeles Foster Care Youth
PI: Andrea Sedlak, PhD
Westat
Rockville, MD

10. Project #: **12-08-0678** (Dickey)
Title: Permanency Innovations Initiative (PII), Recognize Intervene Support Empower (RISE) Pilot Program
PI: Curtis Shepard, PhD
Co-PI: Andrea Sedlak, PhD
LA Gay & Lesbian Center
Los Angeles, CA

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.

11. Project #: **12-08-0652**
Title: Merkel Cell Carcinoma: What makes a difference?
PI: John Vetto, MD
Co-PI: Jennifer Tseng, MD
12. Project #: **12-04-0106**
Title: Ongoing Surveillance and Research of Air Pollution Effects on Death
PI: Cynthia Garcia, BA
Co-PI: Poh-Sin Yap, PhD
13. Project #: **12-08-0658**
Title: Personal Responsibility and Education Program (PREP) Evaluation
PI: Claire Brindis, DrPH
14. Project #: **12-08-0688** (Bazzano/Molitor)
Title: Outcome Prediction in Children with Positive California Cystic Fibrosis Newborn Screening
PI: Daniel Salinas, MD
Co-PI: Martin Kharrazi, PhD
15. Project #: **12-08-0635** (Takahashi/Parker)
Title: Examining Racial Disparities in Breast Cancer Subtype within the Context of Neighborhood Social Environments
PI: Erin Linnenbringer, MS
16. Project #: **12-07-0519** (Bazzano/Dickey)
Title: Impact Of Genomic and Personalized Medicine in Women Under 65 with Breast Cancer
PI: Arnold Potosky, PhD

17. Project #: **12-07-0562** (Dinis/Schaeuble)
Title: Motivation to Succeed: Individual and community factors which predict success with individuals released from CONREP in California.
PI: Cathryn Adams
18. Project #: **12-08-0696** (Takahashi/Molitor)
Title: Understanding the Workplace Interactions of Young Adult Cancer Survivors with Occupational and Environmental Health Professionals
PI: Dawn Stone
19. Project #: **12-06-0459** (Ruiz/Bazzano)
Title: The Role of Physician Peer Learning in Autism Screening and Diagnosis
PI: Ezra Zuckerman, PhD
20. Project #: **12-05-0226** (Ruiz/Murphy)
Title: Outcomes of Recreation Therapy Interventions of Yoga and Meditation on Prison Inmates' Spiritual Well-Being
PI: Kim Pham
21. Project #: **12-08-0585** (Murphy/Bazzano)
Title: Sister Survivor: Improving the Survivorship Care of African-American Women with Breast Cancer
PI: Kimlin Ashing-Giwa, PhD
22. Project #: **12-08-0621** (Lowe/Ruiz)
Title: Restoration and Renewal: Potential for Arts in Corrections in California
PI: Larry Brewster, PhD
23. Project #: **12-08-0677** (Bazzano/Takahashi)
Title: Gestational Diabetes in Asian Americans: Predictors, Problems and Progression
PI: Latha Palaniappan, MD, MS
24. Project #: **12-08-0594** (Ruiz/Bazzano)
Title: Sentinel Headache: Incidence of an ED visit for headache preceding presentation with subarachnoid hemorrhage
PI: Molly Burnett, MD

25. Project #: **12-08-0681** (Takahashi/Parker)
Title: A Binational Population-based Study of Birth Outcomes of Mexican-origin women living in California and Mexico
PI: Sylvia Guendelman, PhD
Co-PI: Julia Walsh, MD

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

Projects with major revisions and requiring periodic review

1. Project #: **12-08-0213** (Murphy)
Title: The Adult Glioma Study (Member of the Glioma International Case-Control Consortium)
PI: Margaret Wrensch, PhD
Co-PI: John Wiencke, PhD
2. Project #: **12-08-0632** (Parker)
Title: Abstract Concepts and Language Development
PI: David Barner, PhD
University of California, San Diego
La Jolla, CA

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.

3. Project #: **12-08-0685** (Dinis/Lowe)
Title: Mental Health Tracking System for the State of California
PI: Sergio Aguilar-Gaxiola
Co-PI: Estella Geraghty, MD, MS, MPH
4. Project #: **12-07-0484** (Bazzano)
Title: The Study to Explore Early Development
PI: Lisa Croen, PhD
Co-PI: Gayle Windham, PhD
5. Project #: **12-08-0679** (Murphy)
Title: Economic Analysis of Air Quality Impacts of Forest Fires
PI: Stephen Davies, PhD
Co-PI: John Loomis, PhD

6. Project #: **12-08-0595** (Bazzano)
Title: Ethnic Disparities in Perinatal Outcomes: Role of Maternal and Neonatal Conditions Present at Time of Delivery
PI: Gabriel Escobar, MD
7. Project #: **12-08-0690** (Dickey)
Title: An Experimental Comparison of Telepsychiatry and Conventional Psychiatry for Mentally Ill Parolees
PI: David Farabee
8. Project #: **12-08-0657** (Lowe/Perel)
Title: Use of Patient Discharge Data for Legislatively Mandated Risk Adjusted Outcomes Studies
PI: Merry Holliday-Hanson
9. Project #: **12-07-0540** (Molitor/Parker)
Title: Impact of Remote Familial Colorectal Cancer Assessment & Counseling (Family CARE Project)
PI: Anita Kinney, PhD
10. Project #: **12-08-0622** (Parker/Lowe)
Title: Medicare Health Plan (Medicare Advantage, MA) vs. Fee-for-Service (FFS) Outcomes Analysis
PI: Harlan Krumholz
Co-PI: Elizabeth Drye
11. Project #: **12-07-0568** (Takahashi)
Title: Factors Affecting Stem Cell Transplantation for Leukemia and Lymphoma
PI: Jean Mitchell, PhD
12. Project #: **12-09-0699** (Takahashi)
Title: Fertility preservation in young female cancer survivors- A survey of patients in the California Cancer Registry
PI: Mitch Rosen, MD
13. Project #: **12-08-0616** (Dickey/Bazzano)
Title: The California Unexplained Pneumonia Project (CUPP): Diagnostic evaluation of acute pulmonary syndrome
PI: Gretchen Rothrock, MPH
14. Project #: **12-08-0683** (Dickey)
Title: "Competition, Volume, NICU level and Outcomes in California"
PI: Min-Woong Sohn, PhD

15. Project #: **12-08-0643** (Murphy)
Title: PROSTATE CANCER OUTCOMES BY RACE & TREATMENT SITE
PI: Can-Lan Sun, MD, PhD
16. Project #: **12-04-0161** (Murphy)
Title: Probabilistic Inference and Categorization Development in Infants
PI: Fei Xu, PhD
17. Project #: **12-08-0590** (Dickey)
Title: Development of a Mid-trimester Screening Algorithm for Early-onset Preeclampsia
PI: Juan Yang, PhD
Co-PI: Martin Kharrazi, PhD
18. Project #: **12-07-0506** (Takahashi)
Title: The impact of physician supply, SES, and insurance on preventable hospitalizations and ED visits
PI: David Zingmond, MD, PhD
19. Project #: **12-09-0718**
Title: The Nature of Psychopathy Among Forensic Patients and Prefrontal Functioning
PI: Annette Ermshar, PhD, ABPP
20. Project #: **12-08-0659**
Title: Contra Costa County Fetal Infant Mortality Review (FIMR) Program
PI: Suzzette Johnson, MSW, MPA
21. Project #: **12-08-0589**
Title: Phytoestrogens and Time to Pregnancy
PI: Michelle Pearl, PhD
22. Project #: **12-06-0449**
Title: Antecedent pregnancy outcomes of children with cerebral palsy and other neurologic diseases
PI: Yvonne Wu, MD, MPH

E. 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 #: **12-04-0125** (Parker)
Title: Political Engagement Before and After the Death of a Spouse
PI: James Fowler, PhD

2. Project #: **12-08-0607** (Parker/Lowe)
Title: Evaluation of the Impact of the CalPERS Reference Pricing Benefit Design on Use and Expenditures for Hip and Knee Replacement Surgery
PI: James Robinson, PhD
3. Project #: **12-08-0605** (Bazzano)
Title: Maternal and Infant Environmental Exposure Project (also known as Chemicals in Our Bodies Project)
PI: Michael Lipsett, MD
4. Project #: **12-02-0012** (Dickey/Schaueble)
Title: The Neurobehavioral Development of Social Behavior
PI: Nim Tottenham, PhD

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

G. 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)

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

No reports.

I. Exemption Request

1. Project #: **12-08-0682**
Title: Dampness and Mold, Fungi Identified by DNA-Based Assays, and Respiratory Health in CHAMACOS Children
PI: Mark Mendell, PhD
2. Project #: **12-07-0571** (Dickey)
Title: Linkage of Medi-Cal Administrative Data with Data from the California Birth Statistical Master File.
PI: Aldona Herrndorf, MPH

J. Next Meeting

The next CPHS meeting is scheduled for December 7, 2012 in Sacramento.

K. 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.**

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If you have any questions or comments, please contact CPHS at 916-326-3660 or cphs-mail@oshpd.ca.gov.

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