

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 369
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 300
Sacramento, CA 95811**

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

**Friday, February 4, 2011
8:30 am – 5:00 pm**

A. General Items

1. Open Meeting Act/conflict of interest/oath of office for members by Beth Wied, OSHPD Chief Counsel (20 minutes)
2. Suggested training of members topics
 - a. Timeline of review of projects
 - i. Prioritize Continuing Periodic Review and new full committee
 - ii. New ER and minor revisions not as time-sensitive
 - b. Review reviewer approvals on various forms
 - i. New Full Committee
 - ii. Information Practices Act
 - iii. Continuing
 - iv. Revisions
 - c. Working with investigators
 - i. Always copy CPHS staff on e-mails
 - ii. If review electronic versions for PI, still need to submit signed approval form and PI must send tracked changes and clean hard copies of revised documents and signatures if protocol changed to CPHS before approval letter is sent to PI
 - d. Organization of files
 - i. Maintain projects for which you are Primary Reviewer as CPHS staff may need to discuss determination letters
 - ii. Organizational tips
 - e. Making motions
 - i. Indicate which document(s) need revisions, section of document and specific revisions
 - f. Conflict of Interest definitions and procedures, recusals
 - g. Discussion regarding article about CPHS
3. Will new policy on engagement in research/Information Practices Act regarding annual renewals apply to only new projects or also to continuing review projects
4. Web-based application update
5. CPHS Data Security Subcommittee report
6. New member mentor assignments

B. Approval of Minutes

December 3, 2010 Meeting Minutes

C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval

Projects with major revisions and requiring periodic review

1. Project No. 07-02-02 (Reviewer-Ward)

Project Title: "Markers of Autism Risk in Babies: Learning Early Signs (MARBLES)"

Principal Investigator: Irva Hertz-Picciotto, PhD
Dept. of Public Health Sciences
University of California, Davis
Davis, CA

Projects requiring periodic review only – (including moderate risk)

Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.

2. Project No. 01-12-13 (Reviewer-Ruiz, English and Spanish)

Project Title: "Childhood Autism Risks from Genetics and the Environment"

Principal Investigator: Irva Hertz-Picciotto, PhD
Dept. of Public Health Sciences
University of California, Davis
Davis, CA

3. Project No. 07-02-06 (Reviewer-Ruiz)

Project Title: "A Pilot Study of DUI Court, Naltrexone, and Motivational Interviewing"

Principal Investigator: Dave DeYoung
Department of Motor Vehicles
Sacramento, CA

4. Project No. 09-10-06 (Reviewer-Ward)

Project Title: "Beta-Amyloid Probes of Alzheimer's Disease in Down Syndrome"

Principal Investigator: Linda Nelson, PhD
UCLA
Los Angeles, CA

5. Project No. 10-02-57 (Reviewer-Lowe)

Project Title: "Identifying Breast Cancer Recurrence and Treatment Details in California's Population-Bases Cancer, Patient Discharge and Ambulatory Care Registries"

Principal Investigator: Monica Brown, PhD
CDPH

Sacramento, CA

6. Project No. 09-12-56 (Reviewer-Murphy)
Project Title: "Alcohol Attributable Emergency Department Visits in California for 2006-2007"
Principal Investigator: Michael Burns, MD
UC, Irvine
Orange, CA
7. Project No. 04-02-01 (Reviewer-Lowe)
Project Title: "Assessing Screening Needs and Strategies for childhood Lead Poisoning Prevention"
Principal Investigator: Joseph Courtney, PhD, MPH
CDPH
Richmond, CA
8. Project No. 02-02-03 (Reviewer-Lowe)
Project Title: "Prenatal Factors and Breast Cancer Risk Study"
Principal Investigator: Jonathan Liff, PhD
Emory University
Atlanta, GA
9. Project No. 10-02-05 (Reviewer-Mihordin)
Project Title: "Correctional patients exposed to trauma: Describing psychological and offense characteristics"
Principal Investigator: Caroline Mok
DMH-VPP
Vacaville, CA
10. Project No. 07-04-51(Reviewer-Dickey)
Project Title: "Evaluating the Impact of FDA Warnings and Consensus Recommendations on Metabolic Screening and Monitoring for Patients Initiating Atypical Antipsychotic Medication: A Multi-State Medicaid Claims Study"
Principal Investigator: Elaine Morrato, DrPH, MPH
University of Colorado
Aurora, CO
11. Project No. 07-02-09(Reviewer-Lowe)
Project Title: "Statewide Evaluation of First 5 California"
Principal Investigator: Gayle Pitt, MA
First 5 California Children and Families Commission
Sacramento, CA
12. Project No. 06-02-60(Reviewer-Kirkish)
Project Title: "Hospitalizations for Benign Gynecological Conditions in California"
Principal Investigator: Elaine Waetjen, MD
UC Davis Health System

Sacramento, CA

13. Project No. 08-02-05 (Reviewer-Lowe)

Project Title: "Autism in an American Indian and Alaska Native sample: The contribution of demographic characteristics, level of acculturation, and cultural values and beliefs on service utilization"

Principal Investigator: Jennifer Wendt, MA
Alliant International University
San Diego, CA

14. Project No. 08-02-54 (Reviewer-Ruiz)

Project Title: "Obtaining a population based cohort of lung and colorectal cancer patients with registry-Medicare linked data"

Principal Investigator: David Herrington, PhD
Dana Ferber Cancer Institute
Boston, MA

15. Project No. 07-12-66 (Reviewer-Lowe)

Project Title: "Transmission Dynamics of Multi-drug Resistant Tuberculosis in California"

Principal Investigator: Philip Hopewell, MD
UCSF
San Francisco, CA

16. Project No. 07-02-03 (Reviewer-Lowe)

Project Title: "Studying Youth in Northern California (SYNC): Qualitative Research-Training Team Project"

Principal Investigator: James Quesada, PhD
San Francisco State University
San Francisco, CA

17. Project No. 06-02-06 (Reviewer-Ruiz)

Project Title: "Measured Parameters in MidPregnancy blood Specimens and Newborn Bloodspots and Risks of Preterm Delivery"

Principal Investigator: Gary Shaw, DrPH
Stanford University School of Medicine
Stanford, CA

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.

18. Project No. 00-04-04 (Reviewer-Dickey)

Project Title: "California Health Interview Survey (CHIS)"

Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA

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

1. Project No. 10-12-05 (Reviewer-Lowe)
Project Title: “Siblings of Children with Autism”
Principal Investigator: Scott Johnson, PhD
UCLA
Los Angeles, CA

E. New Projects Calendar
New Projects - Full Committee Review Required

1. Project No. 11-02-01 (Reviewer-Dinis)
Project Title: “Patient Involvement in Choice of Physician and Hospital for Breast Cancer Surgery”
Principal Investigator: Nancy L. Keating, MD, MPH
Department of Health Care Policy
Harvard Medical School
Boston, MA
2. Project No. 11-02-02 (Reviewer-Takahashi/ Dickey)
Project Title: “The Parkinson's Registry Investigation of Diagnosis and Etiology (PRIDE) study”
Principal Investigator: Caroline Tanner, MD, PhD
The Parkinson's Institute
Sunnyvale, CA
3. Project No. 11-02-03 (Reviewer-Murphy)
Project Title: “Genome Wide Admixture for Multiple Myeloma in African Americans”
Principal Investigator: Wendy Cozen, MPH, D.O.
Department of Preventive Medicine Keck School of Medicine, University of Southern California
Los Angeles, CA
4. Project No. 11-02-04 (Reviewer-Molitor/Ruiz-Spanish)
Project Title: “Kaiser RPGEH and Biomonitoring California Adult Cohort Project”
Principal Investigator: Rupali Das, MD, MPH, CDPH
CDPH, Environmental Health Investigations Branch
Richmond, CA
5. Project No. 11-02-05 (Reviewer-Bazzano/ Murphy)
Project Title: “Collection of CFTR Mutations for Laboratory Quality Assurance”
Principal Investigator: Martin Kharrazi, PhD, MPH
Genetic Disease Screening Program
Richmond, CA

6. Project No. 11-02-06 (Reviewer-Parker/ Ruiz)
Project Title: "Risk Factors for Invasive Methicillin-Resistant Staphylococcus aureus (MRSA) Infections among Recently Discharged Patients"
Principal Investigator: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA
7. Project No. 11-02-07 (Reviewer-Takahashi/ Dickey)
Project Title: "Life Course Energy Balance and Breast Cancer Risk in Black/White Women Under 50"
Principal Investigator: Katherine Henderson, PhD
Beckman Research Institute of the City of Hope
Duarte, CA
8. Project No. 11-02-08 (Reviewer-Ward)
Project Title: "Molecular Epidemiology of Pancreatic Cancer"
Principal Investigator: Paige M. Bracci, PhD, MS, MPH
UCSF
San Francisco, CA
9. Project No. 11-02-09 (Reviewer-Kirkish)
Project Title: "Improving Informed Choice about Medication Treatment for Persons with Severe and Chronic Mental Illness: Development of a Consumer Decision Support Tool"
Principal Investigator: Elizabeth Bromley, MD, PhD
UCLA Department of Psychiatry and Biobehavioral Sciences
Los Angeles, CA
10. Project No. 11-02-10 (Reviewer-Molitor/ Ruiz)
Project Title: "Reducing Breast Cancer Recurrence with Weight Loss: A Vanguard Trial"
Principal Investigator: Cheryl L. Rock, PhD, RD
UCSD
Moores UCSD Cancer Center
San Diego, CA

EE. New Projects - Expedited Review Requested, but which 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 No. 10-12-62 (Reviewer-Takahashi/Dickey)
Project Title: "Social Services and Employment Outcomes in Riverside County"
Principal Investigator: Sheri Studebaker
County of Riverside DPSS
Riverside, CA

F. 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)

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

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for April 1, 2011 in Sacramento.

J. 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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