

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 369
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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 7, 2011
8:30 am – 5:00 pm**

A. General Items

1. Bagley-Keene Open Meeting Act presentation (Jacob Knapp, OSHPD Senior Staff Counsel)
2. CPHS staff transitions (Roxana Killian)
 - a. Recruitment for AGPA position
3. CPHS Membership Subcommittee report (Dr. Lowe and Dr. Molitor)
4. Web-Based Application System update (Terry Nolan and Akash Dahliwal)
5. DRAFT of CPHS Data Security Subcommittee recommended requirements (Roberta Ward and Millard Murphy)
6. Status of Comments on Office of Human Subject Protections' Advanced Notice of Proposed Rulemaking (ANPRM) for Revisions to the Common Rule (Roxana Killian)

B. Approval of Minutes

August 5, 2011 Meeting Minutes

C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval**Projects with major revisions and requiring periodic review**

1. Project No. 98-10-15 (Reviewer-Ruiz/Dickey)
Project Title: "Visual Development in Infants"
Principal Investigator: Karen R. Dobkins, PhD
University of California, San Diego
La Jolla, 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. 05-10-58 (Reviewer-Mihordin)

Project Title: "Medicaid Claims and Self-Reported Health Status in a
Public Mental Health System"

Principal Investigator: Jim Banta, PhD, MPH
Loma Linda University
Loma Linda, CA

3. Project No. 07-10-60 (Reviewer-Dinis)

Project Title: "Pregnancy-Associated Mortality in California"

Principal Investigator: Patrick Fox, PhD, MSW
Institute for Health and Aging
San Francisco, CA

4. Project No. 07-10-56 (Reviewer-Lowe)

Project Title: "Bay Area Data Collaborative: A Regional Approach to
Disparities in Perinatal Outcome"

Principal Investigator: Johnson Yeva, MD, MPH
Department of Public Health
San Francisco, CA

5. Project No. 05-10-52 (Reviewer-Mihordin)

Project Title: "Use of County Mental Health Services by Older
Californians"

Principal Investigator: Brian Kaskie, PhD
University of Iowa
Iowa City, IA

6. Project No. 10-08-74 (Reviewer-Murphy)

Project Title: "Community-Based Research to Reduce Health Disparities
in Access to Pediatric Care"

Principal Investigator: Katrina Kubicek
Childrens Hospital Los Angeles
Los Angeles, CA

7. Project No. 08-06-07 (Reviewer-Mihordin)

Project Title: "Evaluation of Patient and Provider Perspectives on Routine
HIV Screening in Bay Area Emergency Departments"

Principal Investigator: Tim Lane, PhD, MPH
University of San Francisco
San Francisco, CA

8. Project No. 08-06-62 (Reviewer-Mihordin)

Project Title: "A Comparison of Clinical Outcomes from Methicillin-
Resistant Staphylococcus aureus infections due to Pulsed-
Field Type USA 100 versus Pulsed-Field Type USA300"

Principal Investigator: Arthur Reingold, MD
University of California, Berkeley
Berkeley, CA

9. Project No. 08-10-62 (Reviewer-Dickey)
Project Title: "Monitoring the Effects of Citizenship Documentation Requirements"
Principal Investigator: Gerry Fairbrother, PhD
Cincinnati Children's Hospital Medical Center
Cincinnati, OH

10. Project No. 10-08-67 (Reviewer-Molitor)
Project Title: "Air Pollution and Birth Outcomes in the US"
Principal Investigator: Naresh Kumar,
University of Iowa
Iowa City, IA

11. Project No. 06-10-57 (Reviewer-Dinis)
Project Title: "An Epidemiologic Investigation of Tuberculosis Reactivation-San Francisco, 1985-2006"
Principal Investigator: Travis Porco, PhD, MPH
University of California, San Francisco
San Francisco, CA

12. Project No. 97-10-04 (Reviewer-Lowe)
Project Title: "Perchlorate Exposure and Neonatal Thyroid Hormone Levels"
Principal Investigator: Marilyn Underwood, PhD
CDPH, Environmental Health Investigations Branch
Richmond, 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.

9. Project No. 00-04-04 (Reviewer-Dickey)
Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: E. Richard Brown, PhD
UCLA Center for Health Policy Research
Los Angeles, CA

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

1. Project No. 11-08-70 (Reviewer-Murphy)
Project Title: "How Children Talk about Transgressions: Balancing Costs and Benefits of a Novel Interviewing Technique"
Principal Investigator: Elizabeth Rush, MA
Jodi Quas, PhD
University of California, Irvine
Irvine, CA

2. Project No. 11-08-73 (Reviewer-Bazzano)
Project Title: "The Adult Glioma Study (Member of the Glioma International Case-Control Consortium)"
Principal Investigator: Margaret Wrensch, PhD
University of California, San Francisco
San Francisco, CA
3. Project No. 11-02-22 (Reviewer-Bazzano/Murphy)
Project Title: "Autism Spectrum Disorders and Prematurity"
Principal Investigator: Michael Kuzniewicz, MD, MPH
Kaiser Permanente Division of Research
Oakland, CA

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project No. 11-10-01 (Reviewer-Parker/Lowe)
Project Title: "EEG Neurofeedback for Symptom Reduction in Schizophrenics"
Principal Investigator: Dennis W. Wallstrom, PhD
Patton State Hospital
Patton, CA
2. Project No. 11-10-02 (Reviewer-Takahashi)
Project Title: "Pilot Study of Pesticide Exposure and Breast Cancer Risk"
Principal Investigator: Myles Cockburn, PhD
University of Southern California
Los Angeles, CA
3. Project No. 11-10-03 (Reviewer-Murphy)
Project Title: "Understanding the Relation between Child Sleep Habits and Functional Outcomes"
Principal Investigator: Angela Lukowski, PhD
University of California, Irvine
Irvine, CA
4. Project No. 11-10-04 (Reviewer-Molitor)
Project Title: "Study of California's Health-e-App Public Access System"
Principal Investigator: Leslie Foster
Mathematica Policy Research, Inc
Oakland, CA
5. Project No. 11-10-05 (Reviewer-Ward/Ruiz)
Project Title: "Adding Hispanics to Ongoing GWAS in Colorectal Cancer"
Principal Investigator: Jane Figuerido, PhD and Robert Haile, DrPH
Keck School of Medicine
University of Southern California

Los Angeles, CA

6. Project No. 11-10-06 (Reviewer-Ward)
Project Title: "Culture, Social Support & Quality of Life: Asian American Breast Cancer Survivors"
Principal Investigator: Marjorie Kagawa-Singer, PhD, MA, MN, RN, FAAN
University of California, Los Angeles
Los Angeles, CA
7. Project No. 11-10-26 (Reviewer-Takahashi)
Project Title: "An Empirical Analysis of Medical Release in California Prisons"
Principal Investigator: Ashley Demyan, MA, ABD
University of California, Irvine
Irvine, CA
8. Project No. 11-10-07 (Reviewer-Ruiz)
Project Title: "Health Related Quality of Life: Exploring Pediatric Populations Diagnosed With Unilateral Hearing Loss"
Principal Investigator: Brooke Altamirano
California State University, Stanislaus
Patterson, 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.

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)

The adverse event to be discussed affects both projects listed below.

1. Project No. 11-02-10 (Reviewer-Molitor)
Project Title: "Reducing Breast Cancer Recurrence with Weight Loss: Vanguard Trial"
Principal Investigator: Cheryl L. Rock, PhD
University of California, San Diego
La Jolla, CA
2. Project No. 09-10-02 (Reviewer-Molitor)
Project Title: "Sun Protection Practices Among Young Children in California with a Family History of Melanoma"
Principal Investigator: Beth Glenn, PhD

University of California, Los Angeles
Los Angeles, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for December 2, 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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Committee for the Protection of Human Subjects

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