

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, December 2, 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. Administrative Assistant position
3. CPHS new members update (Roxana Killian)
4. Web-Based Application System update and training (Roxana Killian and Akash Dahliwal)
5. CPHS Data Security Requirements implementation (Millard Murphy)
6. Review criteria for research projects (Dr. Lowe and Dr. Dinis)

B. Approval of Minutes

August 5, 2011 and October 7, 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. 07-12-04 (Reviewer-Murphy/Lowe)
Project Title: "NIH-AARP Diet and Health Study"
Principal Investigator: Yikyung Park, ScD
National Cancer Institute
Bethesda, Maryland

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.
(See attached list of projects)

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.

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

1. Project No. 11-10-01 (Reviewers-Parker/Molitor)
Project Title: “EEG Neurofeedback for Symptom Reduction in Schizophrenics”
Principal Investigator: Dennis W. Wallstrom, PhD
Patton State Hospital
Patton, CA

2. Project No. 11-10-06 (Reviewer- Molitor)
Project Title: “Cultural, Social Support and 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

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

1. Project No. 11-12-01 (Reviewers-Ruiz/Dickey)
Project Title: “Tracking Development in Infant at Risk for Developing Autism Spectrum Disorders (ASDs)”
Principal Investigator: Karen R. Dobkins, PhD
University of California, San Diego
La Jolla, CA

2. Project No. 11-12-02 (Reviewer-Mihordin)
Project Title: “Assessment of Neurodegenerative Changes in Typical and Atypical Aging in Adults with Down Syndrome”
Principal Investigators: Linda Nelson, PhD
Jorge Barrio, PhD
University of California
Los Angeles, CA

3. Project No. 11-12-03 (Reviewer-Murphy)
Project Title: “Understanding Memory and Generalization Abilities in Children”
Principal Investigator: Angela Lukowski, PhD
Helen Milojevich
University of California, Irvine
Irvine, CA

4. Project No. 11-12-04 (Reviewer-Takahashi)

Project Title: "A cohort of Youth in Families form the Breast Cancer Family Registry"

Principal Investigator: Esther John, PhD, MSPH
Cancer Prevention Institute of California
Fremont, CA

5. Project No. 11-12-05 (Reviewer-Dinis)

Project Title: "Hot Spot and Cooling Communities: A Study of California Communities with Elevated Teen Birth Rates"

Principal Investigator: Claire Brindis, DrPH
University of California, San Francisco
San Francisco, CA

6. Project No. 11-12-06 (Reviewer-Bazzano)

Project Title: "Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis"

Principal Investigator: Kathleen Harriman, PhD, MPH, RN
California Department of Public Health
Richmond, CA

7. Project No. 11-12-07 (Reviewer-Mihordin)

Project Title: "Use of clofazimine for the treatment of multi-drug resistant (MDR) tuberculosis in patients with limited treatment options"

Principal Investigator: Pennan Barry, MD, MPH
California Department of Public Health
Richmond, 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)

1. Project No. 11-12-08 (Reviewer--Bazzano)

Project Title: "The Study to Explore Early Development (SEED): SEED Phase II"

Principal Investigator: Lisa Croen, PhD
Kaiser Permanente, Division of Research
Oakland, CA

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

1. Project No. 10-06-03 (Reviewer – Lowe)

Project Title: "Measuring Your Health (MY-Health): Validation Study of Health Outcome Measures"

Principal Investigator: Theresa Keegan, PhD, MS

Stanford University
Northern California Cancer Center
Fremont, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for February 3, 2012 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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Access Code: 963949

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