

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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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

Friday, March 26, 2010
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. Expedited review of minor revisions for moderate risk projects
 - b. Web-based application system update
 - c. CPHS review of grant applications requirement
2. CPHS data review policy
3. New member appointments and re-appointments update
 - a. Duties of Chair and Vice Chair
 - i. Review all expedited review projects
 - ii. Approve HIPAA waivers of authorization
 - iii. Consult with Administrator on research and exemption determinations
 - iv. Meet to assign projects and policy issues
 - v. SB 13 Work Group
4. Implementation of new guidance on engagement in research policy
 - a. Revision of departmental letter
 - b. Instructions for Researchers
 - c. Forms
 - d. Bulletin and Update
5. SBX5 2 implementation .

B. Approval of Minutes

September 25, 2009 and January 29, 2010 Meeting Minutes

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

1. Project No. 02-12-01 (Reviewer - Lowe)
Project Title: "Social and Moral Development in Twins"
Principal Investigator: Laura Baker, PhD

USC, Department of Psychology
Los Angeles, CA

2. Project No. 08-04-01 (Reviewer - Harris)
Project Title: "Evaluation of a Mindfulness-Based Stress Reduction Program for Parents and Caregivers"
Principal Investigator: Alicia Bazzano, MD, MPH
Westside Regional Center
Culver City, CA
3. Project No. 05-04-51 (Reviewer - Harris)
Project Title: "California Public Assistance Programs: An Examination of Temporary Assistance for Needy Families (TANF) and Food Stamp Populations"
Principal Investigator: Henry Brady, PhD
UC Berkeley
Berkeley, CA
4. Project No. 08-12-63 (Reviewer - Mihordin)
Project Title: "The Impact of E-Prescribing in Northern Sierra Rural Health Network"
Principal Investigator: Kevin Boesen, PharmD
University of Arizona
Tucson, AZ
5. 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
6. Project No. 02-04-07 (Reviewer - Mihordin)
Project Title: "Venous Thromboembolism in Cancer Patients: A Study of the Epidemiology, Risk Factors, and Outcomes Among Patients with Different Types of Cancer"
Principal Investigator: Helen Chew, MD
UC Davis, Cancer Center
Sacramento, CA
7. Project No. 04-02-54 (Reviewer - Mihordin)
Project Title: "Prenatal and Neonatal Biological Markers for Autism"
Principal Investigator: Lisa Croen, PhD
Kaiser Permanente Division of Research
Oakland, CA
8. Project No. 08-04-58 (Reviewer - Mihordin)
Project Title: "Diverticulitis in California, 1990-2007"

Principal Investigator: David Etzioni, MD, MSHS
University of Southern California
Los Angeles, CA

9. Project No. 08-12-58 (Reviewer - Mihordin)
Project Title: "Pilot Study of Trends and Risks in Gestational Diabetes"
Principal Investigator: Assiamira Ferrara, MD, PhD
University of Southern California
Los Angeles, CA
10. Project No. 06-04-52 (Reviewer - Ruiz)
Project Title: "Aerial Pesticide Spraying for West Nile Virus Mosquito Control and the Incidence of Respiratory Complaints in California, 2005"
Principal Investigator: Estella Geraghty, MD, MS
University of California Davis Medical Center
Sacramento, CA
11. Project No. 08-04-05 (Reviewer - Ruiz)
Project Title: "Forteo Post-Approval Surveillance Study: Case Series"
Principal Investigator: Alicia Gilsean, PhD
RTI-HS
Research Triangle Park, NC
12. Project No. 07-04-06 (Reviewer - Kirkish)
Project Title: "The Development of Object Representation in Infancy"
Principal Investigator: Lisa Oakes, PhD
UC Davis
Davis, CA
13. Project No. 09-04-59 (Reviewer - Harris)
Project Title: "Improving Understanding of Breast and Colorectal Cancer Health Disparities Using Linked Datasets"
Principal Investigator: Scarlett Gomez, PhD
Northern California Cancer Center
Fremont, CA
14. Project No. 08-04-06 (Reviewer - Harris)
Project Title: "Child Development Study: Individual Difference Factors"
Principal Investigator: Gail Goodman, PhD
University of California, Davis
Davis, CA
15. Project No. 03-06-54 (Reviewer - Harris)
Project Title: "Investigation of Maternal Antibodies in Association with Childhood Autism"
Principal Investigator: Judith Grether, PhD
CDPH

Richmond, CA

16. Project No. 90-04-02 (Reviewer - Lowe)
Project Title: "Natural History of Chromosome Abnormalities Diagnosed Prenatally"
Principal Investigator: Ernest Hook, MD
UC Berkeley, School of Public Health
Berkeley, CA
17. Project No. 08-04-08 (Reviewer - Kirkish)
Project Title: "DE-activating Command Hallucinations"
Principal Investigator: Joseph Malancharuvil, PhD, MS, ABPP
Patton State Hospital
Patton, CA
18. Project No. 04-06-61 (Reviewer - Harris)
Project Title: "Effects of Five-Year Time Limits in California"
Principal Investigator: Jane Mauldon, PhD
UC DATA
Berkeley, CA
19. Project No. 01-12-15 (Reviewer - Mihordin)
Project Title: "Assessment of Mental Illness, Violence Risk and Readiness for Release in a Forensic Facility"
Principal Investigator: Barbara McDermott, PhD
UC Davis, School of Medicine
Sacramento, CA
20. Project No. 07-04-06 (Reviewer - Kirkish)
Project Title: "The Development of Object Representation in Infancy"
Principal Investigator: Lisa Oakes, PhD
UC Davis
Davis, CA
21. Project No. 05-04-54 (Reviewer - Mihordin)
Project Title: "Evaluation of the Association Between Geographic Distribution and Clustering of Exemptions and Outbreak of Vaccine Preventable Diseases"
Principal Investigator: Saad Omer, MBBS, MPH, PhD
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD
22. Project No. 07-04-61 (Reviewer - Lowe)
Project Title: "Policies for Improving Non-English Speakers' Access & Care"
Principal Investigator: Lonnie Snowden, PhD
UC Berkeley, School of Social Welfare
Berkeley, CA

23. Project No. 04-06-03 (Reviewer - Kirkish)

Project Title: "Estimating and Assessing Unmet Need for People Living with AIDS and HIV"

Principal Investigator: Christopher Pauler
CDPH, Office of AIDS
Sacramento, CA

24. Project No. 09-04-04 (Reviewer - Mihordin)

Project Title: "Ethnicity and Breast Cancer Care"

Principal Investigator: Judy Huei-yu Wang, PhD
Georgetown University Medical Center
Washington, DC

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.

25. Project No. 06-12-51 (Reviewer -Harris)

Project Title: "Validation of Selected Items in the 2005 Patient Discharge Data Set"

Principal Investigator: Andrew Bindman, MD
UCSF
San Francisco, CA

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

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project No. 10-04-01 (Reviewer - Murphy)

Project Title: "In-TOUCH: innovative Technology-based Outreach and Utilization of Client Home-testing to Improve Chlamydia/ Gonorrhea Re-testing"

Principal Investigator: Heidi Bauer, MD, MPH, MS
CDPH/STD Control Branch
Richmond, CA

2. Project No. 10-04-02 (Reviewer - Murphy)

Project Title: "Autism in the second half of the lifespan: Behavior, daily living, service needs"

Principal Investigator: Ruth Carper, PhD
University of California, San Diego
La Jolla, CA

3. Project No. 10-04-03 (Reviewer - Mihordin)

Project Title: "Deprivation' and 'Enrichment' in Infant Spatial Cognitive Development"

Principal Investigator: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

4. Project No. 10-04-04 (Reviewer - Mihordin)

Project Title: "The Ontogeny infant Direction of Inauthentic Emotion"

Principal Investigator: Joseph Campos, PhD
University of California, Berkeley
Berkeley, CA

5. Project No. 10-04-05 (Reviewer – Ruiz English and Spanish)

Project Title: "Maternal and Infant Environmental Exposure Project"

Principal Investigator: Rupali Das, MD, MPH
CDPH, Environmental Health Investigations
Richmond, CA

6. Project No. 10-04-06 (Reviewer - Lowe)

Project Title: "Assessing the Quality and Effectiveness of the California Problem Gambling Treatment System"

Principal Investigator: Timothy Fong, MD
UCLA Gambling Studies Program
Los Angeles, CA

7. Project No. 10-04-07 (Reviewer - Harris)

Project Title: "Medication Therapy Management Services (MTMS) To Ensure Safe and Appropriate Use of Psychotropic Medications for Mental Health Patients in San Diego County-a Pilot"

Principal Investigator: Kelly Lee, PharmD, BCPP
UCSD
La Jolla, CA

8. Project No. 10-04-08 (Reviewer -)

Project Title: "Multiple sexual partners a cause of asthma in children; a case/ control study"

Principal Investigator: Patrick S. Topor, MD, MPH
Snossio Research
Carmichael, CA

9. Project No. 10-04-09 (Reviewer -)

Project Title: "Using Incentives to Improve Parolee Enrollment and Attendance in Community Treatment"

Principal Investigator: Michael Prendergast, PhD
UCLA
Los Angeles, CA

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. 10-04-55 (Reviewer - Mihordin)
Project Title: "An Analysis of Neuropsychological Functioning and Psychopathic Traits in Correctional Patients with Histories of Suicidal Behaviour"
Principal Investigator: Megan Jimenez, BA
Department of Mental Health-Vacaville
Vacaville, CA
2. Project No. 10-04-57 (Reviewer - Dinis)
Project Title: "A Multi-State Study of Cancer Treatment and Outcomes Among American Indians"
Principal Investigator: Carol Korenbrot, PhD
California Rural Indian Health Board
Sacramento, CA
3. Project No. 10-04-58 (Reviewer - Harris)
Project Title: "Postpartum Depression in Asian Americans: Diagnosis Rates and Risk Factors"
Principal Investigator: Latha Palaniappan, MD, MS
Palo Alto Medical Foundation Research Institute
Palo Alto, CA
4. Project No. 10-04-56 (Reviewer - Murphy)
Project Title: "Genetic Epidemiology of Early Onset Disordered - the Kaiser Permanente Northern California Family Linkage Project"
Principal Investigator: Neil Risch, PhD
Kaiser Permanente Division of Research
Oakland, CA
5. Project No. 10-04-54 (Reviewer - Mihordin)
Project Title: "Neonatal Healthcare Utilization in California"
Principal Investigator: Stephen Shew, MD
Mattel Children's Hospital
Los Angeles, CA
6. Project No. 10-04-52 (Reviewer - Mihordin)
Project Title: "Mortality and renal disease in a cohort study of lead-exposed workers in a surveillance system"
Principal Investigator: Kyle Steenland, PhD
Emory University
Atlanta, GA

7. Project No. 10-04-53 (Reviewer - Kirkish)

Project Title: "Trends in Hospital and Emergency Department Utilization
for Patients Diagnosed with HIV/ AIDS, 1988 to 2008"

Principal Investigator: Mary Tran, PhD, MPH
OSHPD
Sacramento, 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 May 28, 2010 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.

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 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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