

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, August 5, 2011
8:30 am – 5:00 pm**

A. General Items

1. Bageley-Keene Open Meeting Act presentation (Jacob Knapp, OSHPD Senior Staff Counsel)
2. CPHS staff transitions (Roxana Killian)
 - a. Status of freeze exemption requests
 - b. Student Assistants
3. CPHS Membership Subcommittee report (Dr. Lowe and Dr. Molitor)
4. Web-Based Application System (Roxana Killian and Akash Dahliwal)
 - a. CPHS member representative(s) to advise on customization
 - b. Contract revision
5. DRAFT of CPHS Data Security Subcommittee recommended requirements (Millard Murphy)
6. Update on California Department of Education's institutional review board coordination with CPHS (Roxana Killian)
7. Review of new grant applications for on-going projects (Dr. Lowe)
8. 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

February 4, 2011 Meeting Minutes
April 1, 2011 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. 06-08-65 (Reviewer-Lowe)
Project Title: "Children's Coverage Program Evaluation Phase II"

Principal Investigator: Michael Cousineau, DrPH
University of Southern California
Alhambra, CA

2. Project No. 06-08-59 (Reviewer-Lowe)
Project Title: "Rates of and Risk Factors for Hospitalization of Persons with Developmental Disabilities Compared to other California Populations"
Principal Investigator: Thomas E. MaCurdy
Acumen LLC
Burlingame, CA
3. Project No. 01-08-03 (Mihordin)
Project Title: "Prenatal Diagnosis of Smith Lemli-Optiz Syndrome"
Principal Investigator: Marie Robertson
California Department of Public Health
Richmond, CA
4. Project No. 00-08-07 (Reviewer-Mihordin)
Project Title: "Survey of HIV Seroprevalence, Markers for Hepatitis and Sexually Transmitted Diseases, and Assessment of Associated Risk Behaviors in Young men Residing in Low-Income Neighborhoods in Five Northern California Counties"
Principal Investigator: Mark Damesyn
Office of AIDS, CDPH
Sacramento, CA
5. Project No. 09-08-52 (Reviewer-Lowe)
Project Title: "Sub-Specialization and Performance-Based Matching in CABG Surgery"
Principal Investigator: Kyna Fong
UC Berkeley
Berkeley, CA
6. Project No. 03-08-51(Reviewer-Kirkish)
Project Title: "Surgical Management of Endometrial Cancer in California"
Principal Investigator: Gary Leiserowitz
UCD Medical Center
Sacramento, 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.

1. Project No. 11-06-52 (Reviewer-Molitor)
Project Title: "Improving the Reporting of Race, Ethnicity, and Language in California"

Principal Investigator: David Zingmond, MD, PhD
UCLA School of Medicine
Los Angeles, 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. 11-08-68 (Reviewer-Dickey)
Project Title: “Implementation and Outcomes of Establishing Antimicrobial Stewardship Programs in Three Stand-alone Long-term Care Facilities, Targeting Residents with Urinary Tract Infections”
Principal Investigator: Kavita K. Trivedi, MD
CDPH
Sacramento, CA
2. Project No. 11-08-74 (Reviewer-Dinis-English and Spanish)
Project Title: “Medicaid Incentives for Prevention of Chronic Diseases”
Principal Investigator: Shu-Hong Zhu, PhD
UCSD
La Jolla, CA
3. Project No. 11-08-73 (Reviewer-Bazzano)
Project Title: “The Adult Glioma Study (Member of the Glioma International Case-Control and GLIOGENE Consortia)”
Principal Investigator: Margaret Wrensch, PhD
University of California, San Francisco
San Francisco, CA
4. Project No. 11-08-71 (Reviewer-Mihordin)
Project Title: “California Encephalitis Project: Human Genetics of Viral Meningoencephalitis”
Principal Investigator: Carol Ann Glaser, DVM, MPVM, MD
CDPH
Richmond, CA
5. Project No. 11-08-72 (Reviewer-Lowe)
Project Title: “Brief Manualized Treatment for Romantic Partners of Problem Gamblers”
Principal Investigator: Timothy Fong, MD
University of California, Los Angeles
Los Angeles, CA
6. 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

7. Project No. 11-08-01 (Reviewer-Mihordin)

Project Title: "Health Benefits of Expressive Writing Among Chinese breast cancer survivors"

Principal Investigator: Qian Lu, MD, PhD
University of Houston
Houston, TX

8. Project No. 11-08-78 (Reviewer-Molitor)

Project Title: "Identification and Characterization of CFTR mutations among nonwhite patients with cystic fibrosis to improve the clinical sensitivity of neonatal screening and diagnostic testing"

Principal Investigator: Martin Kharrazi, PhD
Genetic Disease Screening Program
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)

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.

1a. Project No. 00-04-04 (Reviewer-Dickey)

Project Title: "California Health Interview Survey"

Principal Investigator: E. Richard Brown
CHIS
Los Angeles, CA

1b. Project No. 00-04-04 (Reviewer-Dickey)

Project Title: "CHIS Smoker Follow-up Study"

Principal Investigator: Wael Al-Delaimy
University of California, San Diego
San Diego, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for October 7, 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.

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

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