

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 369
Sacramento, California 95811
(916) 326-3660 FAX (916) 322-2512

**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, April 1, 2011
8:30 am – 5:00 pm**

A. General Items

1. Discussion on current CPHS policy to only require treatment for injury to be addressed in consent form if project more than minimal risk.
2. Revisions of Request for Determination of Whether Project is Research and Exempt from CPHS Review
3. Applicant for membership
4. California Department of Education institutional review board
5. Federalwide Assurance renewal – uncheck the box?
6. Training of members
 - i. Categories of projects
 - ii. Prioritizing project reviews
 1. New, full committee projects and continuing projects
 2. New expedited reviews and review of minor revisions
 3. Turn-around time for reviews
 - iii. Working with the researchers/CPHS staff on approvals
 - iv. Approving expedited projects – review of forms
 - v. Making motions at the meeting
 1. Waivers
 2. HIPAA waivers and alterations
 3. Vulnerable populations
 4. Grant applications consistent with protocol review
 5. English/Spanish
 6. Identify documents that require revisions

B. Approval of Minutes

February 4, 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. 97-06-09 (Reviewer-Ruiz)
Project Title: "National Birth Defects Prevention Study–California
Component"
Principal Investigator: Gary Shaw, Dr PH
Stanford University School of Medicine
Stanford, 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. 09-06-55 (Reviewer-Kirkish)
Project Title: "Hospital Characteristics and the Quality of Cancer Care and Outcomes in California"
Principal Investigator: Kim Rhoads, MD, MS, MPH
Stanford University
Stanford, CA
3. Project No. 08-04-58 (Reviewer-Mihordin)
Project Title: "Diverticulitis in California, 1990-2007"
Principal Investigator: David Etzioni, MD, MSHS
USC
Los Angeles, CA
4. Project No. 09-04-56 (Reviewer-Kirkish)
Project Title: "Readmissions that are the Sequeale of Hospital Acquired Conditions"
Principal Investigator: Peter McNair, MS
UCSF
San Francisco, CA
5. Project No. 01-06-05 (Reviewer-Dinis)
Project Title: "Linking California Infant Birth and Death Records to Evaluate the Relationship Between Air Pollution and Infant Mortality in California"
Principal Investigator: Tracey Woodruff, PhD, MPH
UCSF
San Francisco, 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.

6. Project No. 07-02-02 (Reviewer-Murphy)
Project Title: "Markers of Autism Risk in Babies: Learning Early Signs (MARBLES)"
Principal Investigator: Irva Hertz-Picciotto, PhD
University of California, Davis
Davis, CA

7. Project No. 09-10-03 (Reviewer-Kirkish)
Project Title: "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment"
Principal Investigator: Celia Kaplan, Dr PH, MA
UCSF
San Francisco, CA
8. Project No. 06-12-02 (Reviewer-Dickey)
Project Title: "Theory of Mind Test Validation Study"
Principal Investigator: Mieke San Julian, MA
Central Valley Autism Project, Inc.
Modesto, 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. 11-04-01 (Reviewer-Molitor/Mihordin)
Project Title: "Early Language and Social Cognition"
Principal Investigator: Rose Scott, PhD
University of California Merced
Merced, CA 95340
2. Project No. 11-04-02 (Reviewer-Dinis-English and Spanish)
Project Title: "California Children's Healthy Eating and Exercise Practices Survey"
Principal Investigator: Susan Foerster, MPH, RD
CDPH
Sacramento, CA
3. Project No. 11-04-03 (Reviewer-Takahashi/Dickey)
Project Title: "Assessment of California's Local Environmental Health Agencies' Capacity in 2011"
Principal Investigator: Susan Strong, REHS
CDPH
Sacramento, CA
4. Project No. 11-04-04 (Reviewer-Takahashi/Dickey)
Project Title: "Food and Water Safety Risk Factors Associated with Mobile Food Vehicles"
Principal Investigator: Susan Strong, REHS
CDPH
Sacramento, 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)

1. Project No. 08-08-05 (Reviewer-Murphy)
Project Title: "Medi-Cal Disease Management Pilot Program Evaluation"
Principal Investigator: Gerald Kominski, PhD
UCLA
Los Angeles, CA
2. Project No. 09-08-07 (Reviewer-Kirkish/Ruiz)
Project Title: "Fertility Preservation in Young Female Cancer Survivors:
A Survey of Patients in the California Cancer Registry"
Principal Investigator: Mitchell Rosen, MD
UCSF
San Francisco, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for June 3, 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.

*The Committee for the Protection of Human Subjects ("CPHS") encourages public attendance and participation at CPHS meetings. As a convenience to the public, CPHS has also established a toll-free phone number for members of the public who would like to monitor or participate in a CPHS meeting remotely. To dial in, please call the following phone number and enter the below access code when prompted. CPHS will endeavor to make telephonic access available at all times during CPHS public meetings.

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

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

California Health and Human Services Agency
Committee for the Protection of Human Subjects
400 R Street, Room 369
Sacramento, CA 95811
Phone: (916) 326-3660
Fax: (916) 322-2512
Roxana Killian, LCSW
Administrator
rkillian@oshpd.ca.gov
Joan Mock
Assistant Administrator
jmock@oshpd.ca.gov
CPHS website
www.oshpd.ca.gov/boards/cphs