

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

Friday, February 4, 2009
8:30 am – 5:00 pm

A. General Items

1. Administrators Report
 - a. Reliance on Northern California Cancer Center Institutional Review Board status
 - b. New member recruitment/applications
 - c. Request that Primary Reviewers retain project documents from meetings
 - d. CPHS web-based application budget change proposal approved
 - e. State staff furloughs/rescheduling CPHS meetings
 - f. Member laptops assignments and updating schedule
2. Engagement in research Secretary Action Request status
3. Proposed changes to SB 13 review (e.g., small cell size)
4. Bill of rights

B. Approval of Minutes

August 1, 2008 and December 5, 2008

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

1. Project No. 07-12-09 (Reviewer – Galbraith)
Project Title: "Research in Language and Cognitive Development"
Principal Investigator: Catherine Sandhofer, PhD
UCLA
Los Angeles, CA
2. Project No. 07-02-02 (Reviewer – Dickey)
Project Title: "Markers for Autism Risk in Babies-Learning Early Signs (M.A.R.B.L.E.S)"
Principal Investigator: Irva Hertz-Picciotto, PhD
UCD
Davis, 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.

1. Project No. 08-10-08 (Reviewer - Mihordin)
Project Title: “Use of Clofazimine for the Treatment of Extensive Drug-resistant (XDR) Tuberculosis in a Patient with Limited Therapeutic Options”
Principal Investigator: Thomas Bertsch, MD
County of Sacramento Chest Clinic
Sacramento, CA
2. Project No. 07-02-06 (Reviewer - Ruiz)
Project Title: “A Pilot Study of DUI Court, Naltrexone, and Motivational Interviewing”
Principal Investigator: Dave DeYoung
Department of Motor Vehicles
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.

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. 09-02-01 (Reviewer - Kirkish)
Project Title: “Teen Live Well & Get Fit Program”
Principal Investigator: Alicia Bazzano, MD
Westside Regional Center
Culver City, CA
2. Project No. 09-02-02 (Reviewer - Ruiz)
Project Title: “Pesticide and Gene Interactions in Breast Cancer in Hispanic Farm Workers”
Principal Investigator: Paul Mills, PhD
UCSF
Fresno, CA
3. Project No. 09-02-03 (Reviewer - Mihordin)
Project Title: “The Neurobehavioral Development of Social Behavior”
Principal Investigator: Nim Tottenham, 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.

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 April 3, 2009 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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