

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, August 6, 2010
8:30 am – 5:00 pm**

A. General Items

1. Administrator's Report
 - a) Meeting schedule
 - b) Web-based application system update, preview and need CPHS members to test system
2. Facilitated review – can project commence before CPHS provides Facilitated Review approval for new project
3. Data Security Subcommittee Report
4. CPHS membership
 - a) New member and member re-appointment update
 - b) Recommendation and recruitment of new members
 - c) Alternate Members and Consultants
 - d) Change in Policies and Procedures related to requirement that Chair must be staff from Health and Human Services Agency
5. Implementing new guidance on engagement in research and grant application policy
 - a) Are CHHSA departments required to submit Initial Review Letters for SB 13 projects?
 - b) Timeline
 - c) Notification of changes on website, Bulletin and Update and researcher letters

B. Approval of Minutes

March 26, 2010 and May 28, 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. 98-08-12 (Reviewer -Mihordin)
Project Title: "Production of the Public Service Orphan Drug Human Botulism Immune Globulin (BIG-IV; Baby BIG®)"
Principal Investigator: Stephen Arnon, MD
CDPH
Richmond, CA
2. Project No. 08-12-03 (Reviewer –Ruiz, English and Spanish)
Project Title: "California Youth Risk Behavior Survey"
Principal Investigator: Arti Parikh-Patel, PhD, MPH
CDPH
Sacramento, CA
3. Project No. 03-08-01 (Lowe)
Project Title: "11th Biennial California Student Survey, 2005-06"
Principal Investigator: Gregory Austin, PhD
WestEd
Los Alamitos, CA
4. Project No. 08-08-02 (Kirkish)
Project Title: "Ivengar Yoga for Breast Cancer Survivors with Persistent Fatigue"
Principal Investigator: Julienne Bower, PhD
UCLA
Los Angeles, CA
5. Project No. 00-08-11 (Lowe)
Project Title: "UCSF, Department of Obstetrics Gynecology and Reproductive Sciences"
Principal Investigator: Mary Croughan, PhD
UCSF
San Francisco, CA
6. Project No. 08-08-01 (Dinis)
Project Title: "Neuro-Developmental Disabilities Screening and Assessment in Uganda"
Principal Investigator: Judith Grether, PhD
Sequoia Foundation
Berkeley, CA
7. Project No. 01-08-12 (Lowe)
Project Title: "Adult Testicular Cancer Lifestyle and Blood Specimen (ATLAS) Study"
Principal Investigator: Pamala Daily Kirley, PhD
CDPH

Oakland, CA

8. Project No. 09-08-54 (Lowe)
Project Title: "Unionization, Concerted Activities and the Quality of Patient Care"
Principal Investigator: Samuel Kleiner
Carnegie Mellon University
Pittsburgh, PA
9. Project No. 01-08-18 (Kirkish)
Project Title: "Indicators of Maternal Quality of Care for the State of California"
Principal Investigator: Michael C. Lu, MD, MPH
UCLA
Los Angeles, CA
10. Project No. 09-08-06 (Kirkish)
Project Title: "Cigarette Smoking and Bladder Cancer: An Opportunity to Improve Quality of Care"
Principal Investigator: Christopher Saigal, MD, MPH
UCLA
Los Angeles, CA
11. Project No. 05-08-05 (Kirkish)
Project Title: "Low Birth Weight and Other Risk Factors for Hepatoblastoma"
Principal Investigator: Logan G. Spector, PhD
University of Minnesota
Minneapolis, MN

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.

12. Project No. 07-04-06 (Reviewer –Lowe/Kirkish)
Project Title: "The Development of Object Representation in Infancy"
Principal Investigator: Lisa Oakes, PhD
UCD
Davis, 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. 10-08-01 (Reviewer - Dickey)
Project Title: "PM-PREP: Disaster Preparedness for Adults with Developmental Disabilities (Phase 2)"
Principal Investigator: David Eisenman, MD, MSHS
UCLA
Los Angeles, CA

2. Project No. 10-08-02 (Reviewer - Ruiz)
Project Title: "The Effects of the Healthy Families Program Waiting List"
Principal Investigator: Gerry Fairbrother, PhD
Cincinnati Children's Hospital Medical Center
University of Cincinnati
Cincinnati, OH

3. Project No. 10-08-03 (Reviewer - Mihordin)
Project Title: "Cancer Care Outcomes Research and Surveillance Consortium (CanCORS) A Population-Based Study of Care and Outcomes in Lung and Colorectal Cancer Patients"
Principal Investigator: Dee West, PhD
Cancer Prevention Institute of California
Fremont, CA

Katherine Kahn, MD
RAND
David Geffen School of Medicine

4. Project No. 10-08-04 (Reviewer - Mihordin)
Project Title: "Evaluating the Effectiveness of Remote Patient Monitoring Technologies in Medi-Cal Waiver Programs"
Principal Investigator: Joseph Hafkenschiel
California Association for Health Services at Home
Sacramento, 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)

1. Project No. 08-08-02 (Reviewer – Dickey)
Project Title: "Ivengar Yoga for Breast Cancer Survivors with Persistent Fatigue"
Principal Investigator: Julienne Bower, PhD

UCLA
Los Angeles, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for October 1, 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.

California Health and Human Services Agency
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