

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, June 6, 2008
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. Continuing Review Forms changes
 - b. Tips for researchers
 - c. NorCal Consortium meeting on 6/10 at CPHS
 - d. Membership recruitment memo
2. SB 13
 - a. Management Memo and State Administrative Memo language status
 - b. Status of Northern California Cancer Center collaboration
3. Facilitated Review Process

B. Approval of Minutes

April 4, 2008 Meeting Minutes

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

1. Project No. 07-08-02 (Reviewer – Dinis-English and Spanish)
Project Title: "Improving the Opt-Out Option: Formative Evaluation On Client Perspectives and Characteristics of Repeat HIV Testers in California HIV Counseling and Testing Sites; and Implementing the Opt-Out Option"
Principal Investigator: Christopher Krawczyk, PhD
CDPH Office of AIDS
Sacramento, CA

Projects requiring periodic review only

Some projects listed may have been approved by expedited review prior to this meeting and will not be reviewed by the full committee.

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.

2. Project No. 07-02-02 (Reviewer – Ward)
Project Title: “Markers for Autism Risk in Babies-Learning Early Signs (MARBLES)”
Principal Investigator: Irva Hertz-Picciotto, PhD
UC Davis
Davis, CA
3. Project No. 07-06-06 (Reviewer - Dickey)
Project Title: “The Lotus Project”
Principal Investigator: Barbara Sultan, LMFT
Westside Regional Center
Sacramento, CA
4. Project No. 07-12-03 (Reviewer - Mihordin)
Project Title: “Exercise for Bone Health: Young Breast Cancer Survivors”
Principal Investigator: Ingrid Oakley-Girvan, PhD, MPH
Northern California Cancer Center
Fremont, CA
5. Project No. 07-10-01 (Reviewer – Ruiz-English and Spanish)
Project Title: “Impact of Institutional-and Individual-level Discrimination on Medical Care and Quality of Life among Breast Cancer Survivors”
Principal Investigator: Scarlett Lin Gomez, PhD
Northern California Cancer Center
Fremont, CA
6. Project No. 01-08-12 (Reviewer – Galbraith)
Project Title: “Adult Testicular Cancer Lifestyle and Blood Specimen Study”
Principal Investigator: Stephen Schwartz, PhD
Fred Hutchinson Cancer Research Center
Seattle, WA

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. 08-06-01 (Reviewers – Dickey)
Project Title: “Neural Tumor Registry”
Principal Investigator: Shahab Asgharzadeh, MD
USC/Childrens Hospital Los Angeles
Los Angeles, CA
2. Project No. 08-06-02 (Reviewer – Ruiz-English and Spanish)
Project Title: “Causes of Testicular Cancer and Cryptorchidism”

Principal Investigator: Victoria Cortessis, PhD
USC Keck School of Medicine
Los Angeles, CA

3. Project No. 08-06-03 (Reviewer – Lowe)
Project Title: “California Encephalitis Project: Population-Based Study”
Principal Investigator: Carol Glaser, DVM, MPVM, MD
CDPH
Richmond, CA
4. Project No. 08-06-04 (Reviewer – Murphy)
Project Title: “Immune Response Genes and Young Adult Hodgkin
Lymphoma: Greater Bay Area Extension”
Principal Investigator: Sally Glaser, PhD
Northern California Cancer Center
Fremont, CA
5. Project No. 08-06-05 (Reviewer – Dinis)
Project Title: “Genetic Susceptibility to Breast Cancer in African
Americans”
Principal Investigator: Christopher Haiman, ScD
USC Keck School of Medicine
Los Angeles, CA
6. Project No. 08-06-06 (Reviewer – Ward)
Project Title: “Disparity in the Quality of Breast Cancer Treatment and
Effect of Outcomes-Los Angeles Subcontract”
Principal Investigator: Ann Hamilton, PhD
USC Keck School of Medicine
Los Angeles, CA
7. Project No. 08-06-07 (Reviewer – Mihordin)
Project Title: “Evaluation of Patient and Provider Perspectives on Routine
HIV Screening in Bay Area Emergency Departments”
Principal Investigator: Tim Lane, PhD, MPH
UCSF
San Francisco, CA
8. Project No. 08-06-08 (Reviewer – Murphy)
Project Title: “Evaluation of Sexual Barrier Device Pilot Program in one
California State Prison Facility”
Principal Investigator: Kimberley Lucas, MPH
CDPH Office of AIDS
Sacramento, CA
9. Project No. 08-06-09 (Reviewer – Harris)
Project Title: “Categorization of Infant-Directed Speech”
Principal Investigator: David Moore, PhD

Pitzer College and Claremont Graduate University
Claremont, CA

10. Project No. 08-06-10 (Reviewer – Harris)

Project Title: “A Study of Primary and Secondary Prevention Behavior Practiced Among 5-Year Survivors of Colorectal Cancer”
Principal Investigator: Nikki Hawkins, PhD
Centers for Disease Control and Prevention
Atlanta, GA

11. Project No. 08-06-11 (Reviewer – Dickey)

Project Title: “Pilot Study to Test Laboratory Components of the California Environmental Contaminant Biomonitoring Program”
Principal Investigator: Myrto Petreas, PhD, MPH
CA Department of Toxic Substances Control
Berkeley, CA
Michael Lipsett, MD
Peter Flessel, PhD
CDPH
Richmond, 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. 08-06-54 (Reviewer – Snipes)

Project Title: “Central Valley Autism Project, Inc. Center Based Services Outcomes Study”
Principal Investigator: Mieke San Julian, MA
Central Valley Autism Project, Inc.
Modesto, CA

2. Project No. 08-06-55 (Reviewer - Snipes)

Project Title: “Central Valley Autism Project, Inc. Younger Children in EIBT Outcome Study”
Principal Investigator: Mieke San Julian, MA
Central Valley Autism Project, Inc.
Modesto, CA

3. Project No. 08-06-56 (Reviewer - Snipes)

Project Title: “Central Valley Autism Project, Inc. Older Children in EIBT Outcome Study”
Principal Investigator: Mieke San Julian, MA
Central Valley Autism Project, Inc.
Modesto, 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

Project Title: "Descriptive Epidemiology of Birth Defects in California"
Principal Investigator: Gary Shaw, DrPH
March of Dimes

I. Next Meeting

The next CPHS meeting is scheduled for August 1, 2008 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.

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