

**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**

**Wednesday, 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
5. Expedited Review policies for turnaround of projects

**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/Lowe)  
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

3. Project No. 07-02-03 (Reviewer – Harris)  
Project Title: “Studying Youth in Northern California (SYNC):  
Qualitative Research Project”  
Principal Investigator: James Quesada, Phd  
SFSU  
San Francisco, CA
4. Project No. 07-02-09 (Reviewer – Lowe)  
Project Title: “Statewide Evaluation of First 5 California”  
Principal Investigator: Tina Fitzgerald, PhD  
First 5 California Children and Families Commission  
Sacramento, 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.**

5. 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
6. 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
7. Project No. 05-02-58 (Reviewer - Mihordin)  
Project Title: “The Effects of Traffic Exposure on Coronary Events”  
Principal Investigator: Michael Anderson  
UC Berkeley, School of Public Health  
Berkeley, CA
8. Project No. 08-02-01 (Reviewer - Harris)  
Project Title: “Improving Psychosocial Functioning and Reducing Burden:  
Cervical Cancer Survivorship Among African American, European  
American, and Latina American Survivors”  
Principal Investigator: Kimlin Ashing-Giwa, PhD  
City of Hope  
Duarte, CA
9. Project No. 04-12-52 (Reviewer - Kirkish)  
Project Title: “Health and Cost Consequences of Discontinuous Medi-Cal  
Enrollment”

Principal Investigator: Andrew Bindman, MD  
UC San Francisco  
San Francisco, CA

10. Project No. 07-02-01 (Reviewer - Murphy)

Project Title: "The Influence of Pharmacy-Based Syringe Disposal on Unsafe Syringe Discard Among Injection Drug Users in California"

Principal Investigator: Ricky Bluthenthal, PhD  
CSU Dominguez Hills, Sociology Dept.  
Carson, CA

11. Project No. 06-02-62 (Reviewer - Harris)

Project Title: "Linking Employment and Social Services in Los Angeles County"

Principal Investigator: Michael Bono, PhD  
Department of Public Social Services  
County of Los Angeles  
City of Industry, CA

12. Project No. 98-02-04 (Reviewer - Harris)

Project Title: "Maternal and Infant Health Assessment (MIHA)"

Principal Investigator: Paula Braveman, MD, MPH  
UC San Francisco  
San Francisco, CA

13. Project No. 08-02-51 (Reviewer - Kirkish)

Project Title: "Health Effects of Proton Pump Inhibitors"

Principal Investigator: Douglas Corley, MD, PhD  
Kaiser Permanente  
Oakland, CA

14. Project No. 04-02-01 (Reviewer - Lowe)

Project Title: "Assessing Screening Needs and Strategies for childhood Lead Poisoning Prevention"

Principal Investigator: Joseph Courtney, PhD, MPH  
CDPH, Childhood Lead Poisoning Prevention Branch  
Richmond, CA

15. Project No. 07-02-52 (Reviewer - Dinis)

Project Title: "Augmentation of CA CADDRE Studies"

Principal Investigator: Lisa Croen, PhD  
Kaiser Permanente Division of Research  
Oakland, CA

16. Project No. 02-02-09 (Reviewer - Ruiz)

Project Title: "CHAMACOS Project: Lead Sub-Study"

Principal Investigator: Brenda Eskenazi, PhD  
UC Berkeley, School of Public Health  
Berkeley, CA

17. Project No. 05-02-53 (Reviewer - Kirkish)

Project Title: "Postpartum Hospital Stay and the Outcomes of Mothers and their Newborns"

Principal Investigator: William Evans, PhD  
University of Maryland, Department of Economics  
College Park, MD

18. Project No. 06-02-01 (Reviewer - Kirkish)

Project Title: "The Evaluation of the Refugee Social Services (RSS) and Targeted Assistance Formula Grant (TAG) Programs"

Principal Investigator: Mary Farrell, M.P.P.M  
The Lewin Group  
Falls Church, VA

19. Project No. 04-02-05 (Reviewer - Harris)

Project Title: "Enhanced Surveillance to Identify Missed Opportunities for Prevention of Tuberculosis in the Foreign-born"

Principal Investigator: Jennifer Flood, MD, MPH  
CDPH, Tuberculosis Control Branch  
Richmond, CA

20. Project No. 08-02-53 (Reviewer - Mihordin)

Project Title: "Surveillance of Air Pollution and Related Cardiopulmonary Morbidity in California, 2000-2006"

Principal Investigator: Susan Gilbreath, PhD,  
California Air Resources Board  
Sacramento, CA

21. Project No. 03-02-03 (Reviewer - Murphy)

Project Title: "Sharps Injury Control: Product and Program Evaluation"

Principal Investigator: Marion Gillen, RN, MPH, PhD  
UCSF, School of Nursing  
San Francisco, CA

22. Project No. 05-02-59 (Reviewer - Kirkish)

Project Title: "Psychometric Evaluation of Assessment Measures Used in the SAMI Program at Patton State Hospital"

Principal Investigator: David Glassmire, PhD, ABPP  
DMH Patton State Hospital  
Patton, CA

23. Project No. 04-02-51 (Reviewer - Mihordin)

Project Title: "Candidate Genes for Childhood Autism"

Principal Investigator: Judith Grether, PhD  
CDPH  
Richmond, CA

24. Project No. 08-02-54 (Reviewer - Ruiz)

Project Title: "Obtaining a population based cohort of lung and colorectal cancer patients with registry-Medicare linked data"

Principal Investigator: David Harrington, PhD,  
Dana Ferber Cancer Institute  
Boston, MA

25. Project No. 08-02-03 (Reviewer - Mihordin)

Project Title: "Representational Correlates of Attachment in Infancy"

Principal Investigator: Susan Johnson, PhD,  
Stanford University  
Stanford, CA

26. Project No. 99-02-02 (Reviewer - Mihordin)

Project Title: "Improving HIV Treatment for the Seriously Mentally III"

Principal Investigator: David Kanouse, PhD  
RAND  
Santa Monica, CA

27. Project No. 05-02-01 (Reviewer - Mihordin)

Project Title: "Molecular Markers of Preterm Birth-Maternal and Infant Genetic Contributions to Preterm Birth: The Inflammatory Response"

Principal Investigator: Martin Kharrazi, PhD, MPH  
CDPH, Genetic Disease Screening Program  
Richmond, CA

28. Project No. 06-02-53 (Reviewer - Kirkish)

Project Title: "Atypical Antipsychotic Use Among Children in California's Medicaid Program: Trends and Patterns, 2000-2005"

Principal Investigator: Brason Lee, MSW, MS  
CDPH, Epidemiology and Evaluation Section  
Sacramento, CA

29. Project No. 02-02-03 (Reviewer - Lowe)

Project Title: "Prenatal Factors and Breast Cancer Risk Study"

Principal Investigator: Jonathan Liff, PhD  
The Rollins School of Public Health, Emory University  
Atlanta, GA

30. Project No. 02-12-08 (Reviewer - Murphy)

Project Title: "Adult Males' Perceptions of Children's Likeability"

Principal Investigator: Leah Livesey, MA  
Alliant International Universtiy  
San Diego, CA

31. Project No. 08-02-56 (Reviewer - Snipes)

Project Title: "Autism and Television Watching"

Principal Investigator: Jeff Miron  
Harvard University

Cambridge, MA

32. Project No. 06-02-59 (Reviewer - Harris)  
Project Title: "Health Effects of Air Pollution from Fires"  
Principal Investigator: Sarah Reber, PhD  
UCLA  
Los Angeles, CA
33. Project No. 06-02-05 (Reviewer - Kirkish)  
Project Title: "Survey of Birthing Hospital to Assess Readiness and Experiences with Counseling and Rapid HIV Testing for Women in Labor and Delivery"  
Principal Investigator: Juan Ruiz, MHS  
CDPH, Office of AIDS  
Sacramento, CA
34. Project No. 03-02-07 (Reviewer - Mihordin)  
Project Title: "Candidate Genes and Congenital Malformations of Neural Crest Origin"  
Principal Investigator: Gary Shaw, DrPH  
March of Dimes  
Oakland, CA
35. Project No. 97-12-04 (Reviewer - Harris)  
Project Title: "Development of Auditory-Visual Localization"  
Principal Investigator: Shinsuke Shimojo, PhD  
California Institute of Technology  
Pasadena, CA
36. Project No. 07-02-56 (Reviewer - Mihordin)  
Project Title: "Severe Psychiatric Comorbidity in Children with Diabetes"  
Principal Investigator: Arlene Smaldone, DNS, CPNP, CDE  
Columbia University School of Nursing  
New York, NY
37. Project No. 01-02-09 (Reviewer - Mihordin)  
Project Title: "Malignant Disease in Women Giving Birth in California 1992-1997: Study of Clinical Outcomes"  
Principal Investigator: Lloyd Smith, MD, PhD  
UC Davis Medical Center  
Sacramento, CA
38. Project No. 06-02-55 (Reviewer - Harris)  
Project Title: "Pregnancy Outcomes of Women with Spinal Cord Injuries: A Population Based Study"  
Principal Investigator: Lloyd Smith, MD, PhD  
UC Davis Medical Center  
Sacramento, CA

39. Project No. 02-02-02 (Reviewer - Harris)  
Project Title: "Ethnic Minority Children in Public Mental Health"  
Principal Investigator: Lonnie Snowden, PhD  
UC Berkeley, School of Social Welfare  
Berkeley, CA
40. Project No. 02-02-04 (Reviewer - Murphy)  
Project Title: "Competition, Volume, and Outcome in Cardiovascular Care in California, 1992-1999"  
Principal Investigator: Min-Woong Sohn, PhD  
Northwestern University  
Chicago, IL
41. Project No. 03-02-10 (Reviewer - Harris)  
Project Title: "The Effect of Hospital Competition and Financial Stress in Hospitals on Quality of Care"  
Principal Investigator: Kevin Volpp, MD, PhD  
Philadelphia VAMC  
Philadelphia, PA
42. Project No. 00-02-08 (Reviewer - Mihordin)  
Project Title: "Foodborne Diseases Active Surveillance Network's Population Survey"  
Principal Investigator: Duc Vugia, MD, MPH  
CDPH, Infectious Diseases Branch  
Richmond, CA
43. Project No. 06-02-60 (Reviewer - Snipes)  
Project Title: "Hospitalizations for Benign Gynecological Conditions in California"  
Principal Investigator: Elaine Waetjen, MD  
UC Davis Health System  
Sacramento, CA
44. Project No. 06-02-02 (Reviewer - Snipes)  
Project Title: "Understanding Barriers to Health Care Access For HIV + Persons in California Who Have Never Had HIV Medical Care"  
Principal Investigator: Qiang Xia, MD, MPH  
CDPH Office of AIDS  
Sacramento, CA
45. Project No. 06-12-06 (Reviewer - Murphy)  
Project Title: "Positive Transitions"  
Principal Investigator: Barry Zack, MPH  
Centerforce, Inc.  
San Rafael, CA
46. Project No. 05-12-56 (Reviewer - Mihordin)  
Project Title: "Use of Appropriate Medications in the Medi-Cal Fee-for-Service

Asthmatic Population”

Principal Investigator: Timothy Albertson, MD, PhD, MPH  
UC Davis Medical Center  
Sacramento, CA

47. Project No. 04-02-55 (Reviewer - Snipes)

Project Title: “Evaluating the California Bloodborne Pathogen Standard”

Principal Investigator: Robert Harrison, MD, MPH  
CDPH, California Occupational Health Branch  
Richmond, CA

48. Project No. 06-02-54 (Reviewer - Kirkish)

Project Title: “Prenatal Care Among Low-Income Women: A Profile of Medi-Cal Beneficiaries Receiving Comprehensive Perinatal Care”

Principal Investigator: Brason Lee, MSW, MS  
CDPH, Epidemiology and Evaluation Section  
Sacramento, CA

49. Project No. 06-02-03 (Reviewer - Murphy)

Project Title: “Evaluation of Paying Spouses and Parents of Minors for Personal Care, Advance Pay, and Restaurant Vouchers in California's IHSS Program”

Principal Investigator: Robert Newcomer, PhD  
UC San Francisco  
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.**

50. Project No. 04-04-04 (Reviewer-Dickey)

Project Title: “California Health Interview Survey”

Principal Investigator: E. Richard Brown, PhD  
UCLA  
Los Angeles, CA

51. Project No. 04-04-04 (Reviewer-Lowe)

Project Title: “Health-Related Quality of Life in Young Men with Testicular Cancer”

Principal Investigator: Michael Hoyt, PhD  
UCLA  
Los Angeles, CA

52. Project No. 08-12-02 (Reviewer-Kirkish)

Project Title: “Early Autism Risk Longitudinal Investigation (EARLI)”

Principal Investigator: Irva Hertz-Picciotto, PhD  
UC Davis  
Davis, CA

53. Project No. 08-10-61 (Reviewer-Ward)  
Project Title: "Kaiser Permanente Northern California Family Linkage Project"  
Principal Investigator: Neil Risch, PhD  
Kaiser Permanente  
Oakland, CA
54. Project No. 08-08-09 (Reviewer-Dickey)  
Project Title: "Central Valley Autism Project, Inc., Early Intensive Behavioral Treatment Outcome Study"  
Principal Investigator: Mieke San Julian, MA  
Central Valley Autism Projects, Inc.  
Modesto, CA
55. Project No. 87-06-01 (Reviewer-Lowe)  
Project Title: "Epidemiologic Study of the Natural History of HIV"  
Principal Investigator: Susan Buchbinder, MD  
SFDPH  
San Francisco, 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. 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.**

1. Project No. 09-02-51 (Reviewer - Snipes)  
Project Title: "Bouncebacks in the Emergency Department"  
Principal Investigator: Shamena Anwar  
Carnegie Mellon University  
Pittsburgh, PA
2. Project No. 09-02-52 (Reviewer - Snipes)  
Project Title: "Examining the Effects of Public Reporting and Pay-for-Performance on Health Care Quality"  
Principal Investigator: Andrew Bindman, MD  
UC San Francisco  
San Francisco, CA
3. Project No. 09-02-53 (Reviewer - Harris)  
Project Title: "Impact of Regionalization of Orthopedic and Cardiac Surgery"  
Principal Investigator: Stephen Lyman, PhD  
Weill Cornell Medical College  
New York, NY
4. Project No. 09-02-54 (Reviewer - Galbraith)  
Project Title: "Assessing Stroke Care Quality, Validating Stroke Outcomes Based Upon Discharge Data, and Conducting the Research and Creating the Reports Needed for OSHPD to Perform Public Reporting of Stroke Care"  
Principal Investigator: David Zingmond, MD, PhD  
UCLA  
Los Angeles, CA
5. Project No. 09-02-55 (Reviewer - Murphy)  
Project Title: "Severe Community-Onset Staphylococcus aureus Infection Surveillance Through Active Bacterial Core Surveillance/ Emerging Infections Program"  
Principal Investigator: Gretchen Rothrock, MPH  
DPH California Emerging Infections Program  
Oakland, 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**

**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](mailto: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](mailto: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  
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](mailto:rkillian@oshpd.ca.gov)  
Joan Mock  
Assistant Administrator  
[jmock@oshpd.ca.gov](mailto:jmock@oshpd.ca.gov)  
CPHS website  
[www.oshpd.ca.gov/boards/cphs](http://www.oshpd.ca.gov/boards/cphs)