

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, August 5, 2009
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. Status of CPHS Web-Based Application System
 - b. New meeting schedule due to furloughs
2. CPHS Membership
 - a. Re-appointment of members status
 - b. Appointment of new members status
 - c. Change in Policies and Procedures for length of time as member prior to becoming Chair
3. SB 13
 - a. SB 13 Work Group meeting status and agenda
 - b. Engagement in research policy implementation
4. Lawsuits related to collection of newborn blood samples (Roberta Ward)

B. Approval of Minutes

June 5, 2009 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; BabyBIG®)"
Principal Investigator: Stephen Arnon, MD
CDPH
Richmond, CA
2. Project No. 08-06-10 (Reviewer – Lowe)
Project Title: "A Study of Primary and Secondary Behavior Practiced Among 5-Year Survivors of Colorectal Cancer"
Principal Investigator: Nikki Hawkins, PhD

Centers for Disease Control and Prevention
Atlanta, GA

3. Project No. 07-08-51 (Harris)
Project Title: "Linkage with the California Cancer Registry"
Principal Investigator: Smita Bhatia, MD, MPH
City of Hope National Medical Center
Duarte, CA
4. Project No. 06-08-64 (Harris)
Project Title: "Preventable Hospitalizations by Health Plan in California 2004-2005"
Principal Investigator: Andrew Bindman, MD
UCSF
San Francisco, CA
5. Project No. 08-08-60 (Harris)
Project Title: "A prospective examination of the impact of alcohol - and drug-use disorders on subsequent psychosis, affective disorders, stroke, cardiac conditions, Parkinson's disease, injury, and death"
Principal Investigator: Russ Callaghan, PhD
Centre for Addiction and Mental Health
Toronto, ON
6. Project No. 08-08-54 (Harris)
Project Title: "Environmental Health Evaluation of Rule 4901: Domestic Wood Burning"
Principal Investigator: John Capitman, PhD
CSU Fresno
Fresno, CA
7. Project No. 08-08-56 (Harris)
Project Title: "Early Detection and Prevention of Psychosis"
Principal Investigator: Cameron Carter, MD
UC Davis
Sacramento, CA
8. Project No. 08-08-57 (Mihordin)
Project Title: "California Stroke Registry"
Principal Investigator: Lily Chaput, MD, MPH
DPH
Sacramento, CA
9. Project No. 05-08-55 (Ruiz)
Project Title: "Deregionalization of Perinatal Services in California: Better Care of Adverse Consequences"
Principal Investigator: Judith H. Chung, MD

UC Irvine
Irvine, CA

10. Project No. 01-08-02 (Lowe)

Project Title: "Association of Medicaid Status with Late-Stage Cancer and Validation of Medicaid Status from the Medical Record"

Principal Investigator: Christina Clarke, PhD
Northern California Cancer Center
Fremont, CA

11. Project No. 06-08-65 (Ruiz)

Project Title: "Children's Coverage Program Evaluation Phase II"

Principal Investigator: Michael Cousineau, DrPH
University of Southern California
Los Angeles, CA

12. Project No. 05-08-52 (Kirkish)

Project Title: "Longitudinal Study of Head Circumference in Autism"

Principal Investigator: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA

13. Project No. 99-08-01 (Harris)

Project Title: "Laboratory Reporting for Pesticide Illness Surveillance"

Principal Investigator: Rupali Das, MD
CDPH
Oakland, CA

14. Project No. 01-08-08 (Kirkish)

Project Title: "Linking Birth Certificate Data to the Southern California Children's Health Study Cohort Data"

Principal Investigator: Frank Gilliland, MD, PhD
USC Keck School of Medicine
Los Angeles, CA

15. Project No. 06-08-55 (Harris)

Project Title: "Establishment of a Statewide System of Linked Perinatal Databases for Use in Maternal/Child Health, Rapid-Cycle Quality Improvement Projects"

Principal Investigator: Jeffrey B. Gould, MD, MPH
Stanford University
Palo Alto, CA

16. Project No. 03-08-56 (Harris)

Project Title: "HLA in Hispanic and African American Autistic Subjects"

Principal Investigator: Judith Grether, PhD
CDPH

Richmond, CA

17. Project No. 04-08-56 (Harris)

Project Title: "A Study of Developmental Disability Service Utilization and Expenditures in California"

Principal Investigator: Charlene Harrington, PhD
UCSF
San Francisco, CA

18. Project No. 03-08-56 (Harris)

Project Title: "HLA in Hispanic and African American Autistic Subjects"

Principal Investigator: Judith Grether, PhD
CDPH
Richmond, CA

19. Project No. 04-08-56 (Harris)

Project Title: "A Study of Developmental Disability Service Utilization and Expenditures in California"

Principal Investigator: Charlene Harrington, PhD
UCSF
San Francisco, CA

20. Project No. 99-08-11 (Mihordin)

Project Title: "Newborn Screening for Cystic Fibrosis in California"

Principal Investigator: Martin Kharrazi, PhD
CDPH
Richmond, CA

21. Project No. 00-08-10 (Harris)

Project Title: "East Bay Children's Respiratory Health Study: Traffic-Related Air Pollution Near Busy Roads"

Principal Investigator: Janice J. Kim, MD, MPH
Office of Environmental Health Hazard Assessment
Oakland, CA

22. Project No. 06-06-02 (Harris)

Project Title: "Mercury Exposure Among Patients in a Private OB/GYN Practice"

Principal Investigator: Michael Lipsett, MD
CDPH
Richmond, CA

23. Project No. 06-08-52 (Harris)

Project Title: "Enhanced Surveillance in California for Emerging Viral and Rickettsial Diseases Using Hospitalization Data"

Principal Investigator: Janice Louie, MD, MPH
CDPH
Richmond, CA

24. Project No. 05-08-02 (Murphy)

Project Title: "Interpersonal/Social HIV Risk Among African American Inmates"

Principal Investigator: Kimberley Lucas, MPH
CDPH Office of AIDS
Sacramento, CA

25. Project No. 90-08-14 (Harris)

Project Title: "A Registry of California-born Twins"

Principal Investigator: Thomas Mack, MD, MPH
USC Keck School of Medicine
Los Angeles, CA

26. Project No. 06-08-59 (Kirkish)

Project Title: "Rates of and Risk Factors for Hospitalization of Persons with Developmental Disabilities Compared to Other California Populations"

Principal Investigator: Thomas MaCurdy, PhD
Acumen LLC
Burlingame, CA

27. Project No. 97-08-05 (Harris)

Project Title: "Linked Maternal-Infant Medical Record Surveillance RFA 96-27028"

Principal Investigator: Yvonne Maldonado, MD
Stanford University School of Medicine
Stanford, CA

28. Project No. 03-08-02 (Murphy)

Project Title: "In-School Evaluation of Tobacco Use Prevention Education Programs (2005-2006)"

Principal Investigator: William J. McCarthy, PhD
WestEd
Los Alamitos, CA

29. Project No. 07-08-55 (Dinis)

Project Title: "Chinese Herbal Medicine in the Treatment of Lung and Colon Cancers: A Retrospective Survival Analysis"

Principal Investigator: Michael McCulloch, Lac, MPH
UC Berkeley
Berkeley, CA

30. Project No. 07-08-53 (Harris)

Project Title: "Late HIV/AIDS Diagnoses Among Women in California"

Principal Investigator: Ann Nakamura
CDPH
Sacramento, CA

31. Project No. 06-08-57 (Harris)

Project Title: "The Association between Childhood Exposure to Indoor and Outdoor Toxins and Autism Spectrum Disorders in California Cities"

Principal Investigator: Sean Nicholson, PhD
Cornell University
Ithaca, NY

32. Project No. 94-10-03 (Harris)

Project Title: "California Emerging Infections Program"

Principal Investigator: Arthur Reingold, MD
UC Berkeley
Berkeley, CA

33. Project No. 96-08-08 (Lowe)

Project Title: "The Influence of Air Pollution in the Los Angeles Metropolitan Area on the Occurrence of Birth Defects"

Principal Investigator: Beate Ritz, MD, PhD
UCLA
Los Angeles, CA

34. Project No. 01-08-03 (Mihordin)

Project Title: "Prenatal Diagnosis of Smith Lemli-Opitz Syndrome"

Principal Investigator: Marie Roberson, PhD
Dept. of Public Health
Berkeley, CA

35. Project No. 99-08-13 (Harris)

Project Title: "HIV Prevalence, Incidence, and Risk Behaviors Among Young Latino Men Who Have Sex with Men in San Diego, California, and Tijuana, Mexico"

Principal Investigator: Juan Ruiz, MD, DrPH, MPH
CDPH
Sacramento, CA

36. Project No. 00-08-07 (Mihordin)

Project Title: "Survey of HIV Seroprevalence, Markers for Hepatitis and Sexually Transmitted Diseases, and Assessment of Associated Risk Behaviors in Young Men Residing in Low-Income Neighborhoods in Five Northern California Counties"

Principal Investigator: Juan Ruiz, MD, DrPH, MPH
CDPH
Sacramento, CA

37. Project No. 96-08-02 (Murphy)

Project Title: "Kawasaki Disease – archive for Etiological Testing"

Principal Investigator: Robert Schechter, MD
CDPH

Berkeley, CA

38. Project No. 05-08-61 (Harris)

Project Title: "Competition, Volume, and Outcomes in Cancer Surgeries"

Principal Investigator: Min-Woong Sohn, PhD
Northwestern University
Chicago, IL

39. Project No. 01-08-07 (Harris)

Project Title: "Community Geographic Information System Project"

Principal Investigator: Stacie Sormano, MA
First 5 California
Sacramento, CA

40. Project No. 05-08-05 (Harris)

Project Title: "Low Birth Weight and Other Risk Factors for
Hepatoblastoma"

Principal Investigator: Logan G. Spector, PhD
University of Minnesota
Minneapolis, MN

41. Project No. 98-08-03 (Murphy)

Project Title: "Maternal Age-Specific Prevalence Rates of Chromosome
Abnormalities by Race/Ethnicity in the Kaiser Health Plan
in Northern and Southern California and Portland"

Principal Investigator: Joseph Terdiman, MD, PhD
Kaiser Permanente Division of Research
Oakland, CA

42. Project No. 91-08-07 (Lowe)

Project Title: "Smoking as a Risk Factor in the Etiology of
Down Syndrome"

Principal Investigator: Claudine Torfs, PhD
Public Health Institute
Emeryville, CA

43. Project No. 00-06-08 (Mihordin)

Project Title: "Trisomy 21: Risk Factors for Chromosome
Nondisjunction"

Principal Investigator: Claudine P. Torfs, PhD
Public Health Institute
Emeryville, CA

44. Project No. 03-08-53 (Murphy)

Project Title: "California Injury Surveillance"

Principal Investigator: Roger B. Trent, PhD
CDPH
Sacramento, CA

45. Project No. 05-08-06 (Harris)

Project Title: "2005 Prevalence Study of Problem Gambling in California"
Principal Investigator: Rachel A. Volberg, PhD
University of Chicago
Northampton, MA

46. Project No. 99-08-06 (Harris)

Project Title: "Enhancement of Mandated Surveillance of Communicable Diseases Using California Hospital Discharge Data"
Principal Investigator: Duc Vugia, MD, MPH
CDPH
Berkeley, CA

47. Project No. 06-08-03 (Mihordin)

Project Title: "Assessment of Screening for Dyslipidemia and Type II Diabetes in Medi-Cal Patients Newly Started on Antipsychotics"
Principal Investigator: Victor M. Walker
CDPH
Sacramento, CA

48. Project No. 05-08-60 (Kirkish)

Project Title: "Venous Thromboembolism in California, Who is at Highest Risk?"
Principal Investigator: Richard H. White, MD
UC Davis
Davis, CA

49. Project No. 06-08-60 (Murphy)

Project Title: "Autism and Peri-Natal Hormone Markers"
Principal Investigator: Gayle C. Windham, PhD
CDPH
Richmond, CA

50. Project No. 05-08-07 (Dickey)

Project Title: "Mechanical Intervention in Children with Cerebral Palsy"
Principal Investigator: Tishya Wren, PhD
Childrens Hospital Los Angeles
Los Angeles, CA

51. Project No. 89-08-08 (Harris)

Project Title: "California Pediatric HIV Infection Active Surveillance"
Principal Investigator: Qiang Xia, MD, MPH
CDPH Office of AIDS
Sacramento, CA

52. Project No. 06-08-54 (Kirkish)

Project Title: "The Increasing Prevalence of Autism in California:
Perinatal, Parental, Social and Environmental Risk Factors"
Principal Investigator: Peter S. Bearman, PhD
Columbia University
New York, NY

53. Project No. 07-08-56 (Kirkish)

Project Title: "Determinants of Excess Hospitalization and Emergency
Department Utilization Among Medi-Cal Beneficiaries with
Serious Mental Illness"
Principal Investigator: Cheryl Cashin, PhD
California Institute of Mental Health
Sacramento, CA

54. Project No. 05-08-53 (Harris)

Project Title: "Meeting the Need for Publicly Funded Family Planning
Services Among Low-Income Women in California"
Principal Investigator: Philip Darney, MD
UCSF
San Francisco, CA

55. Project No. 99-08-08 (Lowe)

Project Title: "Environmental Approaches to Prevention Project"
Principal Investigator: Paul Gruenewald, PhD
Prevention Research Center
Berkeley, CA

56. Project No. 06-08-56 (Ward)

Project Title: "An Examination of Unexplained Causes of Early Child
Mortality and the Value of Newborn Screening"
Principal Investigator: Martin Kharrazi, PhD
CDPH
Richmond, CA

57. Project No. 01-08-18 (Harris)

Project Title: "Indicators of Maternal Quality of Care for the State of
California"
Principal Investigator: Michael C. Lu, MD, MPH
UCLA
Los Angeles, CA

58. Project No. 04-08-57 (Ruiz)

Project Title: "Infectious Diseases Related to Hospitalization of
Children in California"
Principal Investigator: Yvonne Maldonado, MD
Stanford University
Stanford, CA

59. Project No. 07-08-08 (Dinis-English and Spanish)

Project Title: "The AHPPAL Survey Field Test"

Principal Investigator: Susan E. Palsbo, PhD
George Mason University
Fairfax, Virginia

60. Project No. 01-08-12 (Lowe)

Project Title: "Adult Testicular Cancer Lifestyle and Blood Specimen
(ATLAS) Study"

Principal Investigator: Stephen M. Schwartz, PhD
Fred Hutchinson Cancer Research Center
Seattle, WA

61. Project No. 02-06-08 (Dinis)

Project Title: "Evaluation of the Substance Abuse and Crime Prevention
Act of 2000"

Principal Investigator: Darren Urada, PhD
UCLA
Los Angeles, CA

62. Project No. 08-08-51 (Murphy)

Project Title: "Project MAPP: Mapping and Analyzing Patient Pathways"

Principal Investigator: Susan Huang, MD, MPH
UC Irvine
Irvine, CA

63. Project No. 08-08-52 (Ruiz)

Project Title: "Does Reduced Rifampin Susceptibility Increase Possibility
for Tuberculosis Relapse?"

Principal Investigator: Grace Lin
CDPH
Richmond, CA

64. Project No. 08-08-55 (Mihordin)

Project Title: "Impacts of Climate Change and Meteorological Conditions
on Deaths, Hospitalizations and Emergency Room Visits in
California"

Principal Investigator: Helene Margolis, PhD, MA
CDPH
Sacramento, CA

65. Project No. 08-08-53 (Ward)

Project Title: "Ambulance Diversion and Adverse Outcomes in California,
2005-2007"

Principal Investigator: Benjamin Sun, MD, MPP
UCLA
Los Angeles, CA

66. Project No. 08-08-58 (Harris)

Project Title: "California Autism Family Linkage Project"
Principal Investigator: Judith Grether, PhD
CDPH
Richmond, 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.

67. Project No. 99-02-10 (Reviewer – Lowe)

Project Title: "Evaluating the California Treatment Outcome Project (CalTOP)"
Principal Investigator: Yih-ing Hser, PhD
UCLA
Los Angeles, CA

68. Project No. 00-04-04 (Reviewer – Dickey/Lowe)

Project Title: "California Health Interview Survey"
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA

69. 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
NCCC
Fremont, CA

70. Project No. 09-06-02 (Reviewer – Ward)

Project Title: "Genome-wide Association Study of Radiation Exposure and
Bilateral Breast Cancer"
Principal Investigator: Ester John, PhD, MSPH
NCCC
Fremont, CA

71. Project No. 09-06-03 (Reviewer – Murphy)

Project Title: "Impact of Online Support System on Health Related Quality of
Life among Men Diagnosed with Prostate Cancer"
Principal Investigator: Jerry Lee, PhD
Loma Linda University
Loma Linda, CA

72. Project No. 97-06-09 (Reviewer – Ruiz)

Project Title: "National Birth Defects Prevention Study-California Component"
Principal Investigator: Gary Shaw, DrPH
Stanford School of Medicine
Stanford, CA

73. Project No. 08-04-09 (Reviewer – Dickey)
Project Title: “National Survey of Child and Adolescent Well-Being”
Principal Investigator: Kathryn Dowd, PhD
RTI International
Research Triangle Park, NC

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. 09-08-01 (Reviewer – Ward)
Project Title: “Memory Processes in Childhood”
Principal Investigator: Simona Ghetti, PhD
UCD and Center for Mind and Brain
Davis, CA
2. Project No. 09-08-02 (Reviewer – Ward-English, Dinis-Spanish)
Project Title: “Feasibility of Retrospectively Obtaining Guthrie Spots (FROGS) Study”
Principal Investigator: Amy Linabery, MS
Julie Ross, PhD
University of Minnesota
Minneapolis, MN
3. Project No. 09-08-03 (Reviewer - Harris)
Project Title: “Evaluation of California’s Residentially Based Services Reform Project”
Principal Investigator: Peter Pecora, PhD
Casey Family Programs
Seattle, WA
Fred Molitor, PhD
Walter R. McDonald & Associates, Inc.
Sacramento, CA
4. Project No. 09-08-04 (Reviewer - Mihordin)
Project Title: “Assessment and Management of Serial Murderers in a Correctional Mental Health Setting”
Principal Investigator: Juliana Rohrer, PhD
DMH Vacaville Psychiatric Program
Vacaville, CA
5. Project No. 09-08-05 (Reviewer - Mihordin)
Project Title: “Study to Assess Serum Levels of Polybrominated Diphenyl Ether (PBDE) Flame Retardants in Flight Attendants”
Principal Investigator: Robert Harrison, MD, MPH
CDPH

Richmond, CA

6. Project No. 09-08-06 (Reviewer - Harris)
Project Title: "Cigarette Smoking and Bladder Cancer: An Opportunity to Improve Quality of Care?"
Principal Investigator: Christopher Saigal, MD, MPH
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. 09-08-54 (Reviewer – Murphy/Lowe) **Referred to Full Committee**
Project Title: "Unionization, Concerted Activities and the Quality of Patient Care"
Principal Investigator: Samuel Kleiner, MA
Heinz College, Carnegie Mellon University
Pittsburg, PA
2. Project No. 09-08-53 (Reviewer - Ruiz)
Project Title: "Impact of Regionalization of Care for Acute Stroke"
Principal Investigator: Prasanthi Govindarajan, MD
UCSF
San Francisco, CA
3. Project No. 09-08-55 (Reviewer - Mihordin)
Project Title: "Access to Medical Resources and Infant Mortality"
Principal Investigator: Mindy Marks, PhD
UC Riverside
Riverside, CA
4. Project No. 09-08-56 (Reviewer - Ward)
Project Title: "Investigation of the Relation of Fine Particulate Air Pollution and Temperature to Hospital Admissions and Emergency Room Visits in California"
Principal Investigator: Bart Ostro, PhD
Cal/EPA
Oakland, CA
5. Project No. 09-08-57 (Reviewer - Ward)
Project Title: "Neighborhood Cultural Context and Infant Mortality in Los Angeles County"
Principal Investigator: Lisa Ross DeCamp, MD, MSPH
University of Michigan
Ann Arbor, MI

6. Project No. 09-08-58 (Reviewer - Mihordin)
Project Title: "The Impact of Palivizumab on Hospitalization Rates for Bronchiolitis in California"
Principal Investigator: Andrew Racine, MD, PhD
Albert Einstein College of Medicine
Bronx, NY

7. Project No. 09-08-63 (Reviewer - Kirkish)
Project Title: "Birth Outcomes and Infant Mortality among Blacks and Whites by Nativity"
Principal Investigator: Irma Elo
University of Pennsylvania
Philadelphia, PA

8. Project No. 09-08-64 (Reviewer - Dinis)
Project Title: "Administrative Measures Evaluation for Public Reporting of Hospital Performance in California"
Principal Investigator: R. Adams Dudley, MD, MBA
UCSF
San Francisco, 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 October 2, 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.

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