

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, September 25, 2009
8:30 am – 5:00 pm

A. General Items

1. Administrator's update
 - a. Web-Based Application System
 - b. Meeting schedule through June 2010
2. CPHS membership update
 - a. Reappointments of members – consideration of revisions in the policies and procedures to allow members to serve until replaced
 - b. Appointment of new members
3. SB 13 Work Group report
 - a. Revisions to the Information Practices Act
 - b. Changes to the SB 13 review
4. Data
 - a. Link of OSHPD/CCR databases
 - b. CDPH databases covered by HIPAA
5. Change in Reliance on other IRBs policy

B. Approval of Minutes

June 5, 2009 and August 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. 05-10-57 (Harris)
Project Title: "Resource Use in California Hospitals"
Principal Investigator: Laurence Baker, PhD
Stanford University School of Medicine
Stanford, CA
2. Project No. 05-10-58 (Mihordin)

Project Title: "Medicaid Claims and Self-Reported Health Status in a
Public Mental Health System"

Principal Investigator: Jim Banta, PhD, MPH
Loma Linda University
Loma Linda, CA

3. Project No. 99-10-14 (Murphy)

Project Title: "Improving Case Follow-Up in the California Cancer
Registry"

Principal Investigator: Janet Bates, MD, MPH
Public Health Institute/California Cancer Registry
Sacramento, CA

4. Project No. 03-10-04 (Harris)

Project Title: "California Medicaid Undercount Experiment (CMUE)"

Principal Investigator: E. Richard Brown, PhD
UCLA, Center for Health Policy Research
Los Angeles, CA

5. Project No. 08-08-08 (Kirkish)

Project Title: "The Early Autism Risk Longitudinal Investigation (EARLI)
Study - Phase 1"

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

6. Project No. 05-10-53 (Mihordin)

Project Title: "Evaluation of Adherence to the 2002 Revised Guideline For
the Prevention of Perinatal Group B Streptococcus Disease"

Principal Investigator: Pamala Daily Kirley, MT, MPH
CDPH California Emerging Infections Program
Oakland, CA

7. Project No. 01-10-13 (Harris)

Project Title: "HIV Prevalence, Incidence and Risks Among Young Latino
Men Who Have Sex with Men in Imperial County, California
and Mexicali, Baja California Mexico"

Principal Investigator: Mark Damesyn, DrPH
Office of AIDS, CDPH
Sacramento, CA

8. Project No. 98-10-15 (Ruiz)

Project Title: "Visual Development in Infants"

Principal Investigator: Karen Dobkins, PhD
UC San Diego
La Jolla, CA

9. Project No. 02-10-02 (Murphy)

Project Title: "Environmental Health Tracking Pilot Project"
Principal Investigator: Paul English, PhD, MPH
CDPH
Richmond, CA

10. Project No. 02-10-12 (Kirkish)

Project Title: "Ethnic Disparities in Perinatal Outcomes: Role of Maternal and Neonatal Conditions Present at Time of Delivery"
Principal Investigator: Gabriel Escobar, MD
Kaiser Permanente Division of Research
Oakland, CA

11. Project No. 99-10-16 (Murphy)

Project Title: "Pilot Evaluation of an Education Intervention to Reduce Risk for HIV/AIDS Among African-American Adolescents at High Risk in California"
Principal Investigator: Matthew Facer, PhD
CDPH, HIV/AIDS Epidemiologic Studies Section
Sacramento, CA

12. Project No. 08-10-62 (Dickey)

Project Title: "Monitoring the Effects of Citizenship Documentation Requirements"
Principal Investigator: Gerry Fairbrother, PhD
Cincinnati Childrens Hospital Medical Center
Cincinnati, OH

13. Project No. 07-10-60 (Harris)

Project Title: "Pregnancy-Related and Pregnancy-Associated Mortality in California"
Principal Investigator: Partick Fox, PhD
UCSF
San Francisco, CA

14. Project No. 07-12-52 (Mihordin)

Project Title: "Influence of Trends in Operative Mortality rate for Esophageal, Pancreas and Liver Resections to their Referral Pattern to Tertiary Care Centers in California"
Principal Investigator: Warren Gasper, MD
UCSF
San Francisco, CA

15. Project No. 07-10-51 (Harris)

Project Title: "Epstein-Barr Virus and Breast Cancer: Extending Promising Work"
Principal Investigator: Sally Glaser, PhD
Northern California Cancer Center
Fremont, CA

16. Project No. 04-08-03 (Mihordin)
Project Title: "A California Population-Based Twin Study of Autism"
Principal Investigator: Judith Grether, PhD
CDPH
Richmond, CA
17. Project No. 02-10-05 (Kirkish)
Project Title: "Epidemiology of Autism in Multiple Births"
Principal Investigator: Judith Grether, PhD
CDPH
Richmond, CA
18. Project No. 02-10-18 (Lowe)
Project Title: "Assessing the Stress/Preterm-Low Birthweight Relationship"
Principal Investigator: Sylvia Guendelman, PhD
UC Berkeley
Berkeley, CA
19. Project No. 07-10-59 (Ruiz)
Project Title: "Epidemiology of Peripartum Cardiomyopathy Study"
Principal Investigator: Erica P. Gunderson, PhD
Kaiser Permanente
Oakland, CA
20. Project No. 04-10-57 (Kirkish)
Project Title: "Inpatient Service Utilization by Adults with Congenital Heart Disease"
Principal Investigator: Michelle Gurvitz, MD
Children Hospital and Regional Medical Center
Seattle, WA
21. Project No. 05-10-59 (Murphy)
Project Title: "Effects of Outlet/Ad Density on Teen Smoking and Brand Choice"
Principal Investigator: Lisa Henriksen, PhD
Stanford University
Stanford, CA
22. Project No. 07-10-55 (Harris)
Project Title: "Regionalizing Cancer Surgery"
Principal Investigator: Vivian Ho, PhD
Rice University
Houston, TX
23. Project No. 07-10-54 (Mihordin)
Project Title: "California Hospital - Insurer Contracting"

Principal Investigator: Katherine Ho, PhD, MA
Columbia University
New York, NY

24. Project No. 08-10-02 (Ruiz)

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

Principal Investigator: Michael Hoyt, PhD
UCLA, Department of Psychology
Los Angeles, CA

25. Project No. 99-02-10 (Lowe)

Project Title: "Evaluating the California Treatment Outcome Project (CalTOP)"

Principal Investigator: Yih-ing Hser, PhD
UCLA, Department of Psychology
Los Angeles, CA

26. Project No. 08-10-59 (Harris)

Project Title: "Scale Economics, Learning and Forgetting in CABG services"

Principal Investigator: Marco Huesch, MBBS, PhD
Fuqua School of Business
Durham, NC

27. Project No. 08-10-60 (Kirkish)

Project Title: "Vaccine Safety datalink (VSD)"

Principal Investigator: Steven Jacobsen, MD, PhD
Kaiser Permanente
Pasadena, CA

28. Project No. 98-10-12 (Dinis)

Project Title: "Contra Costa County Fetal Infant Mortality Review (FIMR) Program"

Principal Investigator: Suzzette C. Johnson, MSW,
Department of Public Health
Martinez, CA

29. Project No. 05-10-52 (Kirkish)

Project Title: "Use of County Mental Health Services by Older Californians"

Principal Investigator: Brian Kaskie, PhD
University of Iowa
Iowa City, IA

30. Project No. 02-10-07 (Mihordin)

Project Title: "An Assessment of the Seroprevalence of HCV Infection in Childbearing Women in San Diego, Orange and Imperial

Counties”

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

31. Project No. 07-10-03 (Kirkish)

Project Title: “Use of unpasteurized queso fresco and other high-risk foods during pregnancy: Prevalence, knowledge, attitudes, and practices among Latina women of childbearing age in Imperial County”

Principal Investigator: Akiko Kimura, MD
CDPH, Infectious Diseases Branch
Gardena, CA

32. Project No. 07-10-02 (Ruiz)

Project Title: “Understanding knowledge, attitudes, and behaviors regarding access to care and health issues including influenza and the influenza vaccine in border communities”

Principal Investigator: Akiko Kimura, MD
CDPH, Infectious Diseases Branch
Gardena, CA

33. Project No. 05-10-56 (Ruiz)

Project Title: “Epidemiologic Survey of Long-Term Health Effects of West Nile Fever”

Principal Investigator: Anne Kjemtrup, DVM, MPVM, PhD
DPH, Vector-Borne Disease Section
Sacramento, CA

34. Project No. 08-06-07 (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-CAPS
San Francisco, CA

35. Project No. 08-10-58 (Harris)

Project Title: “A Study on CAGB Surgery Outcomes in Asians Using CCORP Data from 2003-2005”

Principal Investigator: Diana Lau, RN, MS, CNS
UCSF Mount Zion Campus
San Francisco, CA

36. Project No. 08-10-53 (Dinis)

Project Title: “Prenatal Medication Use and the Risk of Congenital Heart Defects”

Principal Investigator: De-Kun Li, MD, PhD

Kaiser Permanente Medical Group
Oakland, CA

37. Project No. 00-10-01 (Lowe)
Project Title: "The Effects of Hospital Market Competition and Cost-Containment on Patient Outcomes"
Principal Investigator: David Meltzer, MD, PhD
Pritzker School of Medicine
Chicago, IL
38. Project No. 05-12-51 (Harris)
Project Title: "Factors Affecting Stem Cell Transplantation for Leukemia and Lymphoma"
Principal Investigator: Jean Mitchell, PhD
Georgetown Public Policy Institute
Washington, DC
39. Project No. 99-10-01 (Harris)
Project Title: "Market Change and Access to Inpatient Psychiatric Care"
Principal Investigator: Jack Needleman, PhD
UCLA, School of Public Health
Los Angeles, CA
40. Project No. 05-10-54 (Ruiz)
Project Title: "Autism, Autoimmunity, and the Environment"
Principal Investigator: Craig Newschaffer, PhD
Johns Hopkins University
Philadelphia, PA
41. Project No. 05-10-60 (Kirkish)
Project Title: "Hospital Utilization in Adult Survivors of Chronic Childhood Illness: State Re-Admission Rate Study"
Principal Investigator: Megumi Okumura, MD
University of California, San Francisco
San Francisco, CA
42. Project No. 03-10-05 (Kirkish)
Project Title: "Does Tobacco Exposure Delay Conception?"
Principal Investigator: Michelle Pearl, PhD
CDPH, Genetic Disease Branch
Richmond, CA
43. Project No. 06-10-56 (Kirkish)
Project Title: "Phytoestrogens and Time Pregnancy"
Principal Investigator: Michelle Pearl, PhD
CDPH, Genetic Disease Branch
Richmond, CA

44. Project No. 07-10-57 (Kirkish)

Project Title: "Establishment of a Population-Based Resource for the Study of Childhood Brain Tumors in California"

Principal Investigator: Reynolds Peggy, PhD
Northern California Cancer Center
Berkeley, CA

45. Project No. 06-10-57 (Dinis)

Project Title: "An Epidemiologic Investigation of Tuberculosis Reactivation-San Francisco, 1985-2006"

Principal Investigator: Travis Porco, PhD, MPH
University of California, San Francisco
San Francisco, CA

46. Project No. 08-10-06 (Dinis)

Project Title: "Effectiveness of Trivalent Inactivated Influenza Vaccine in Preventing Laboratory-confirmed Influenza Hospitalizations among Adults aged 50 years and older"

Principal Investigator: Arthur Reingold, MD
UC Berkeley, School of Public Health
Berkeley, CA

47. Project No. 08-06-62 (Mihordin)

Project Title: "A Comparison of Clinical Outcomes from Methicillin-Resistant Staphylococcus aureus Infections due to Pulsed-Field Type USA100 versus Pulsed-Field Type USA300"

Principal Investigator: Arthur Reingold, MD
UC Berkeley, School of Public Health
Berkeley, CA

48. Project No. 05-10-55 (Ruiz)

Project Title: "Newborn Fetal Hemoglobin Levels and Cancer in Childhood"

Principal Investigator: David Richardson, PhD
University of North Carolina at Chapel Hill
Chapel Hill, NC

49. Project No. 03-10-58 (Mihordin)

Project Title: "Tracking Perinatal Exposures to Airborne Toxics, Blood Lead Levels, and Health Outcomes of Pregnancy and Early Childhood"

Principal Investigator: Eric Roberts, MD, PhD
CDPH, Environmental Health Investigations Branch
Richmond, CA

50. Project No. 01-10-12 (Mihordin)

Project Title: "The California Unexplained Pneumonia Project (CUPP):

Diagnostic Evaluation of Acute Pulmonary Syndrome”
Principal Investigator: Gretchen Rothrock, MPH
CDPH California Emerging Infections Program
Oakland, CA

51. Project No. 00-10-07 (Ruiz)

Project Title: “Pesticide Exposure in Women of Reproductive Age: A U.S.
- Mexico Border Study”
Principal Investigator: Raquel Sabogal, MSPH
National Center for Environmental Health
Chamblee, GA

52. Project No. 03-10-01 (Kirkish)

Project Title: “Measured Parameters in Midpregnancy Blood Specimens
and Risks for Birth Defects”
Principal Investigator: Gary Shaw, DrPH
March of Dimes
Oakland, CA

53. Project No. 02-10-14 (Harris)

Project Title: “Competition, Volume, NICU Level, and Outcomes in
California”
Principal Investigator: Min-Woong Sohn, PhD
Northwestern University
Chicago, IL

54. Project No. 02-10-01 (Murphy)

Project Title: “African American Women and Breast Cancer: What
Works?”
Principal Investigator: Carol Somkin, PhD
Kaiser Permanente Division of Research
Oakland, CA

55. Project No. 07-10-56 (Harris)

Project Title: “Bay Area Data Collaborative: A Regional Approach to
Disparities in Perinatal Outcome”
Principal Investigator: Ellen J. Stein, MD, MPH,
San Francisco Office of Public Health (SFDPH), Bay Area
San Francisco, CA

56. Project No. 08-12-51 (Harris)

Project Title: “Reevaluation of the Association between Short Birth Interval
and Poor perinatal outcomes”
Principal Investigator: Claudia Steiner, MD, MPH
Agency for Healthcare Research and Quality (AHRQ)
Rockville, MD

57. Project No. 08-12-52 (Harris)

Project Title: "The Ten Group Classification for Cesarean Delivery: A New Classification for Clinical Management and Epidemiologic Comparisons"

Principal Investigator: Claudia Steiner, MD, MPH
Agency for Healthcare Research and Quality (AHRQ)
Rockville, MD

58. Project No. 07-08-03 (Murphy)

Project Title: "Prostate Cancer Outcomes by Race & Treatment Site"

Principal Investigator: Canlan Sun, MD, PhD
City of Hope National Medical Center
Duarte, CA

59. Project No. 97-10-04 (Lowe)

Project Title: "Perchlorate Exposure and Neonatal Thyroid Hormone Levels"

Principal Investigator: Marilyn Underwood, PhD
CDPH, Environmental Health Investigations Branch
Richmond, CA

60. Project No. 01-10-11 (Ruiz)

Project Title: "Investigation of Patients Infected with Enteric Bacteria Showing Unusual Antimicrobial Resistance Patterns"

Principal Investigator: Duc Vugia, MD, MPH
CDPH, Infectious Diseases Branch
Richmond, CA

61. Project No. 08-10-57 (Dinis)

Project Title: "Costs of Prematurity in California and the United States"

Principal Investigator: Cheryl Walker, MD
Department of Ob/Gyn
Sacramento, CA

62. Project No. 06-12-05 (Ruiz)

Project Title: "Genetic Predictors of Developing Hemolytic-Uremic Syndrome following Infection with Escherichia coli O157"

Principal Investigator: Katie Wymore, MPH
DPH, California Emerging Infections Program
Oakland, CA

63. Project No. 05-10-04 (Murphy)

Project Title: "Changes in HIV-Related Risk Behaviors Among Recently Released Prisoners: Comparing Two Interventions"

Principal Investigator: Barry Zack, MPH
Centerforce, Inc.
San Rafael, CA

64. Project No. 02-10-10 (Ruiz)

Project Title: "Evaluating the Care of HIV/AIDS Patients on Medi-Cal through the Creation, Validation, and Analysis of Statewide Patient Level Clinical Data, Care Abstracts, and Payment Claims"

Principal Investigator: David Zingmond, MD, PhD
UCLA, School of Medicine
Los Angeles, CA

65. Project No. 06-10-60 (Ruiz)

Project Title: "Impact of Comorbid Illness on Persons Living with HIV/AIDS"

Principal Investigator: David Zingmond, MD, PhD
UCLA, School of Medicine
Los Angeles, CA

66. Project No. 08-10-05 (Kirkish)

Project Title: "Genetics of Breast Cancer in Latinas"

Principal Investigator: Elad Ziv, MD
UCSF
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.

67. Project No.06-12-02 (Reviewer – Dickey)

Project Title: "Theory of Mind Test Validation Study"

Principal Investigator: Mieke San Julian
Central Valley Autism Project, Inc.
Modesto, 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. 09-10-01 (Reviewer – Ruiz)

Project Title: "Screening for Jervell and Lange-Nielsen Syndrome"

Principal Investigator: Ruey-Kang Chang, MD, MPH
UCLA
Torrance, CA

2. Project No. 09-10-02 (Reviewer - Kirkish)

Project Title: "Sun Protection practices among young children in California with a family history of melanoma"

Principal Investigator: Beth Glenn, PhD
UCLA

- Los Angeles, CA
3. Project No. 09-10-03 (Reviewer - Harris)
Project Title: "Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment"
Principal Investigator: Celia P. Kaplan
University of California, San Francisco
San Francisco, CA
 4. Project No. 09-10-04 (Reviewer - Murphy)
Project Title: "Communication in Asian American Families with Breast Cancer Survivors"
Principal Investigator: Jung-Won Lim, PhD, MSW
Center of Community Alliance for Research and Education
Duarte, CA
 5. Project No. 09-10-05 (Reviewer - Dinis)
Project Title: "Pesticides and Prostate Cancer"
Principal Investigator: Paul K. Mills, PhD, MPH
Fresno Medical Education and Research Program
Fresno, CA
 6. Project No. 09-10-06 (Reviewer - Ward)
Project Title: "Amyloid Plaque and tangle imaging in Alzheimer's disease and Down syndrome"
Principal Investigator: Linda D. Nelson, PhD, ABPN
UCLA Semel Institute of Neuroscience and Human Behavior
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. 09-10-53 (Reviewer – Dinis)
Project Title: "Perinatal Characteristics and Adult Ovarian and Circadian Function: Validation Study"
Principal Investigator: Kathryn L. Adeney
University of Washington
Seattle, WA
2. Project No. 09-10-54 (Reviewer - Ruiz)
Project Title: "Surveillance for Guillain-Barre Syndrome in California"
Principal Investigator: Carol Glaser, DMV, MD, MPVM
California Department of Public Health
Richmond, CA
3. Project No. 09-10-55 (Reviewer - Kirkish)
Project Title: "Physician Induced Demand: Evidence from Patients with MD's"

Principal Investigator: Erin Johnson
University of California, Berkeley
Berkeley, CA

4. Project No. 09-10-56 (Reviewer - Murphy)

Project Title: "The Effectiveness of a screening process for reducing length of stay in Incompetent to Stand Trials (IST) patients in a forensic psychiatric hospital"

Principal Investigator: Barbara E. McDermott, PhD
UC Davis Department of Psychiatry
Sacramento, CA

5. Project No. 09-10-57 (Reviewer - Harris)

Project Title: "The Effect of Local Drug Enforcement on Drug-Related Hospitalizations"

Principal Investigator: Katie Winder, PhD
University of California, Merced
Merced, CA

6. Project No. 09-10-57 (Reviewer - Mihordin)

Project Title: "Evaluation Services to Enhance the Data Management System in California (EnCal-Secondary Data Analysis)"

Principal Investigator: Richard Rawson, PhD
UCLA Integrated Substance Abuse Services
Los Angeles, 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 December 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.

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