

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

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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, October 3, 2008
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. New CPHS member recruitment
2. Reliance on another IRB
 - a. Reliance policy report from Subcommittee
 - b. Authorization Agreement with Northern California Cancer Center
3. SB 13
 - a. Management Memo and questions
 - b. Reconvene SB 13 Work Group

B. Approval of Minutes

August 1, 2008

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

1. Project No. 07-10-06 (Reviewer – Lowe-English, Ruiz-Spanish)
Project Title: "Stress, Immunity, and Cervical Cancer: Biobehavioral Outcomes of a Randomized Trial"
Principal Investigator: Lari Wenzel, PhD
UC Irvine
Irvine, 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.

2. Project No. 02-08-03 (Reviewer – Mihordin/Dickey)
Project Title: "Genetic Susceptibility to Hypospadias"
Principal Investigator: Suzan Carmichael, PhD
March of Dimes
Oakland, CA
3. Project No. 99-10-14 (Reviewer – Murphy)
Project Title: "Improving Case Follow-up in the California Cancer Registry"

Principal Investigator: Janet Bates, MD
CDPH Public Health Institute
Sacramento, CA

4. Project No. 06-10-02 (Reviewer – Ruiz)
Project Title: “Early Detection of Hypothyroidism in Children with Optic Nerve Hypoplasia”
Principal Investigator: Mark Borchert, MD
Childrens Hopital Los Angeles/USC
Los Angeles, CA
5. Project No. 99-10-16 (Reviewer – 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
Sacramento, CA
6. Project No. 06-10-04 (Reviewer – Ward)
Project Title: “Brief Interventions for Problem Gamblers: Evaluating a Telephone Helpline Program”
Principal Investigator: Timothy Fong, MD
UCLA
Los Angeles, CA
7. Project No. 07-10-01 (Reviewer – Ruiz)
Project Title: “Impact of Institutional- and Individual-level Discrimination On Medical Care and Quality of Life among Breast Cancer Survivors (Equality in Breast Cancer Care)”
Principal Investigator: Scarlett Lin Gomez, PhD
Northern California Cancer Center
Fremont, CA
8. Project No. 07-10-59 (Reviewer – Ruiz)
Project Title: “Epidemiology of Peripartum Cardiomyopathy Study”
Principal Investigator: Erica Gunderson, PhD
Kaiser Permanente
Oakland, CA
9. Project No. 04-10-57 (Reviewer – Kirkish)
Project Title: “Inpatient Service Utilization by Adults with Congenital Heart Disease”
Principal Investigator: Michelle Gurvitz, MD
Children’s Hospital and Regional Medical Center
University of Washington
Seattle, WA

10. Project No. 07-10-02 (Reviewer – 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
Gardena, CA
11. Project No. 07-10-03 (Reviewer – 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
Gardena, CA
12. Project No. 05-10-56 (Reviewer – Ruiz)
Project Title: “Epidemiologic Survey of Long-Term Health Effects of West Nile Fever”
Principal Investigator: Anne Kjemtrup, DVM, MPVM, PhD
CDPH
Sacramento, CA
13. Project No. 07-08-03 (Reviewer – Murphy)
Project Title: “Prostate Cancer Outcomes by Race & Treatment Site”
Principal Investigator: Seira Kurian, MD, MS, MPH
City of Hope National Medical Center
Duare, CA
14. Project No. 02-10-01 (Reviewer – Murphy)
Project Title: “African American Women and Breast Cancer: What Works?”
Principal Investigator: Carol Somkin, PhD
Kaiser Permanente
Oakland, CA
15. Project No. 05-10-04 (Reviewer – Murphy)
Project Title: “Changes in HIV-related Risk Behaviors among Recently Released Prisoners: Comparing Two Interventions”
Principal Investigator: Barry Zack, MPH
Centerforce
San Rafael, CA
16. Project No. 02-10-02 (Reviewer –Murphy)
Project Title: “Environmental Health Tracking Pilot Project”
Principal Investigator: Paul English, PhD, MPH
CDPH

Richmond, CA

17. Project No. 05-10-54 (Reviewer – Ruiz)
Project Title: “Autism, Autoimmunity and the Environment”
Principal Investigator: Craig Newschaffer, PhD
Johns Hopkins Bloomberg School of Public Health
Philadelphia, PA

18. Project No. 07-10-57 (Reviewer – Kirkish)
Project Title: “Establishment of a Population-Based Resource for the Study of Childhood Brain Tumors in California”
Principal Investigator: Peggy Reynolds, PhD
Northern California Cancer Center
Berkeley, CA

19. Project No. 05-10-55 (Reviewer – 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

20. Project No. 07-12-57 (Reviewer – Ruiz)
Project Title: “Investigating Disparities in Surgical Cancer Care and Outcomes – Secondary Data Analyses”
Principal Investigator: Joan Ryoo, MD
UCLA
Los Angeles, CA

21. Project No. 93-10-01 (Reviewer –Mihordin)
Project Title: “An Epidemiologic Study of Multiple Congenital Anomalies in California”
Principal Investigator: Gary Shaw, DrPH
March of Dimes
Oakland, CA

22. Project No. 03-10-01 (Reviewer – Galbraith)
Project Title: “Measured Parameters in MidPregnancy Blood Specimens and Risk of Birth Defects”
Principal Investigator: Gary Shaw, DrPH
March of Dimes
Oakland, CA

23. Project No. 01-10-11 (Reviewer – Ruiz)
Project Title: “Investigation of Patients Infected with Enteric Bacteria Showing Unusual Antimicrobial Resistance Patterns”
Principal Investigator: Duc Vugia, MD, MPH
CDPH

Richmond, CA

24. Project No. 06-12-05 (Reviewer – Ruiz)
Project Title: “Genetic Predictors of Developing Hemolytic-Uremic Syndrome Following Infection with *Escherichia coli* 0157”
Principal Investigator: Katie Wymore
CDPH California Emerging Infections Program
Oakland, CA

25. Project No. 06-10-51 (Reviewer – Galbraith)
Project Title: “Evaluation of the Potential Risk for Acetaminophen Toxicity in the Medi-Cal Population”
Principal Investigator: Timothy Albertson, MD, MPH, PhD
UCD Medical Center
Sacramento, CA

26. Project No. 01-10-13 (Reviewer – 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: Jennifer Baham, MPH
CDPH
Sacramento, CA

27. Project No. 06-10-57 (Reviewer – Snipes)
Project Title: “An Epidemiological Investigation of Tuberculosis Reactivation San Francisco, 1985-2006”
Principal Investigator: Travis Porco, PhD, MPH
UCSF
San Francisco, CA

28. Project No. 03-10-02 (Reviewer – Snipes)
Project Title: “HIV and Related Risk Behaviors and Perceptions among Latino Urban Day Laborers and Rural Migrant and Seasonal Workers in the Agricultural Sector”
Principal Investigator: Alan Schultz, MPH
CDPH
Sacramento, CA

29. Project No. 05-10-52 (Reviewer – Kirkish)
Project Title: “The Use of County Mental Health Services by Older Californians”
Principal Investigator: Brian Kaskie, PhD
University of Iowa
Iowa City, IA

30. Project No. 05-10-59 (Reviewer – Murphy)
Project Title: “Effects of Outlet/Ad Density on Teen Smoking and Brand

Choice”

Principal Investigator: Lisa Henriksen, PhD
Stanford School of Medicine
Palo Alto, CA

31. Project No. 00-10-07 (Reviewer – Ruiz)

Project Title: “Pesticide Exposure in Women of Reproductive Age:
A U.S.-Mexico Border Study”

Principal Investigator: Raquel Sabogal, MSPH
CDC
Chamblee, GA

32. Project No. 07-12-52 (Reviewer – 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

33. Project No. 04-08-03 (Reviewer – Mihordin)

Project Title: “A California Population-Based Twin Study of Autism”

Principal Investigator: Judith Grether, PhD
CDPH
Richmond, CA

34. Project No. 02-10-05 (Reviewer – Kirkish)

Project Title: “Epidemiology of Autism in Multiple Births”

Principal Investigator: Judith Grether, PhD
CDPH
Richmond, CA

35. Project No. 02-10-10 (Reviewer – Ruiz)

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

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

36. Project No. 06-10-60 (Reviewer – Ruiz)

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

Principal Investigator: David Zingmond, MD, PhD
UCLA
Los Angeles, 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.

37. Project No. 03-12-02 (Reviewer – Lowe)

Project Title: “California Toddler Twin Study (CATTS)”
Principal Investigator: Theodore Jacob, PhD
VA Palo Alto Health Care System
Menlo Park, CA

38. Project No. 08-04-03 (Reviewer – Ward)

Project Title: “Adolescent and Young Adult Health Outcomes and Patient Experience Study (AYA HOPE)”
Principal Investigator: Rosemary Cress, DrPH
CCR Public Health Institute
Sacramento, CA

39. Project No. 08-08-08 (Reviewer – Kirkish)

Project Title: “The Early Autism Risk Longitudinal Investigation (EARLI) – Phase I”
Principal Investigator: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA

40. Project No. 08-08-10 (Reviewer – Murphy)

Project Title: “Survey of HIV and STD associated Risk Behaviors in Substance Using and At-Risk Youth (14-25 years) in Five Northern California Counties”
Principal Investigator: Juan Ruiz, MD, MPH, DrPH
CDPH
Sacramento, CA

D. Second Review Calendar – Projects not previously approved that require full committee review

1. Project No. 08-08-05 (Reviewer – Murphy)

Project Title: “Medi-Cal Disease Management Pilot Program Evaluation”
Principal Investigator: Gerald Kominski, PhD
UCLA
Los Angeles, CA

E. New Projects Calendar

New Projects - Full Committee Review Required

1. Project No. 08-10-01 (Reviewers – Ward)

Project Title: “Epidemiologic Investigation of Body Lice on Homeless Persons”
Principal Investigator: Denise Bonilla, MS
CDPH

Richmond, CA

2. Project No. 08-10-02 (Reviewer – Ruiz)
Project Title: “Health-Related Quality of Life in Young Men with Testicular Cancer”
Principal Investigator: Michael Hoyt, PhD
UCLA
Los Angeles, CA
3. Project No. 08-10-03 (Reviewer – Galbraith)
Project Title: “Psychometric Evaluation of Malingering Potential in Intellectually Deficient Individuals in a Governmental Institutional Setting (Porterville Pictures and Shapes Study)”
Principal Investigator: Christopher Love, PsyD
DMH Patton State Hospital
Patton, CA
4. Project No. 08-10-04 (Reviewer – Harris)
Project Title: “Quantification and Language Development”
Principal Investigator: David Barner, PhD
UC San Diego
La Jolla, CA
5. Project No. 08-10-05 (Reviewer – Kirkish)
Project Title: “Genetics of Breast Cancer in Latinas”
Principal Investigator: Elad Ziv, MD
UCSF
San Francisco, CA
6. Project No. 08-10-06 (Reviewer –Galbraith)
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
Berkeley, CA
7. Project No. 08-06-07 (Reviewer –Kirkish)
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

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. 08-10-53 (Reviewer –Snipes)
Project Title: “Prenatal Medication Use and the Risk of Congenital Heart Defects”
Principal Investigator: De-Kun Li, MD, PhD
Kaiser Permanente
Oakland, CA
2. Project No. 08-10-54 (Reviewer –Ward)
Project Title: “Evaluation of 12-Month Continuous Eligibility in Medicaid”
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA
3. Project No. 08-10-57 (Reviewer –Snipes)
Project Title: “Costs of Preterm Birth in California and the United States”
Principal Investigator: Cheryl Walker, MD
UCD
Sacramento, CA
4. Project No. 08-10-58 (Reviewer –Harris)
Project Title: “A Study on CABG Surgery Outcomes in Asians, Using CCORP Data from 2003-2005”
Principal Investigator: Diana Lau, RN, MS, CNS
UCSF
San Francisco, CA
5. Project No. 08-10-59 (Reviewer –Galbraith)
Project Title: “Scale Economies, Learning and Forgetting in CABG Services”
Principal Investigator: Marco Huesch, MBBS, PhD
Duke University
Durham, NC
6. Project No. 08-10-60 (Reviewer –Kirkish)
Project Title: “Vaccine Safety Datalink (VSD) Study Usage of Birth Statistical Master File”
Principal Investigator: Steven Jacobsen, MD, PhD
Kaiser Permanente
Pasadena, CA
7. 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

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 5, 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. CPHS will ensure that it makes every effort to fulfill the request.

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