

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, January 29, 2010
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. PRIM&R Conference Report
 1. Review of grant applications by one reviewer
 2. Annual approval of consent forms
 - b. Web-based application system update
 - c. New Acting Chief Deputy, Stephanie Clendenin
2. Change in Vital Statistic birth records policies related to publically available data (Jane McKendry, Section Chief, Office of Health Information and Research, CDPH)
3. Implementation of new guidance on engagement in research
4. Motions format include
 - a. Document in which revision is required
 - b. Location (page or section) of revision within document
 - c. The required revision
5. If expedited reviews projects not approved before the next full committee meeting then project will be placed on Full Committee agenda for approval
6. New member appointments and reappointments status
7. SBX5 2 signed by Governor (pupil data legislation that allows the UCs and other non-profit entities to apply for personal information for research purposes)

B. Approval of Minutes

August 5, 2009 and September 25, 2009, December 2, 2009 Meeting Minutes

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

1. Project No. 07-02-02 (Reviewer -Kirkish)
Project Title: "Markers of Autism Risk in Babies – Learning Early Signs (MARBLES)"
Principal Investigator: Irva Hertz-Picciotto, PhD
UC Davis
Davis, 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. 08-10-08 (Reviewer -Mihordin)
Project Title: “Use of Clofazimine for the Treatment of Extensive Drug-Resistant (XDR) Tuberculosis in a Patient with Limited Treatment Options”
Principal Investigator: Thomas Bertsch, MD
DHHS County of Sacramento
Sacramento, CA
3. 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
4. Project No. 09-02-51 (Reviewer - Harris)
Project Title: “Bouncebacks in the Emergency Department”
Principal Investigator: Shamena Anwar
Carnegie Mellon University
Pittsburgh, PA
5. 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
6. 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
7. 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
8. 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

9. 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

10. 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

11. 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

12. Project No. 06-02-57 (Reviewer - Murphy)

Project Title: "Gestational Diabetes: Diagnostic Criteria and Outcomes"

Principal Investigator: Assiamira Ferrara, MD, PhD
Kaiser Permanente
Oakland, CA

13. 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

14. 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

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

Project Title: "Candidate Genes for Childhood Autism"

Principal Investigator: Judith Grether, PhD

CDPH
Richmond, CA

16. Project No. 05-02-57 (Reviewer - Ruiz)
Project Title: "Women's Mental Health in Pregnancy and the Postpartum"
Principal Investigator: Sylvia Guendelman, PhD
UC Berkeley
Berkeley, CA
17. 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
18. Project No. 04-02-55 (Reviewer - Harris)
Project Title: "Evaluating the California Bloodborne Pathogen Standard"
Principal Investigator: Robert Harrison, MD, MPH
CDPH, California Occupational Health Branch
Richmond, CA
19. Project No. 08-02-55 (Reviewer - Harris)
Project Title: "Northern California Consortium for the National Children's Study"
Principal Investigator: Irva Hertz-Picciotto, PhD
University of California, Davis
Davis, CA
20. Project No. 07-12-66 (Reviewer - Harris)
Project Title: "Transmission Dynamics of Multi-drug Resistant Tuberculosis in California"
Principal Investigator: Philip Hopewell, MD
UCSF
San Francisco, CA
21. Project No. 99-02-02 (Reviewer - Mihordin)
Project Title: "Improving HIV Treatment for the Seriously Mentally Ill"
Principal Investigator: David Kanouse, PhD
RAND
Santa Monica, CA
22. 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

23. 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
24. Project No. 04-02-06 (Reviewer - Ruiz)
Project Title: "Border Asthma and Allergies Study"
Principal Investigator: Michael Lipsett, MD
CDPH
Richmond, CA
25. 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
CPDH/ Chief, Exposure Assessment Section
Richmond, CA
26. Project No. 95-02-01 (Reviewer - Kirkish)
Project Title: "Behavioral Correlates of Event-Related Potentials (ERPs) and
Background Electroencephalography (EEG)"
Principal Investigator: Stanley Lunde, PhD
DDS, Lanterman Developmental Center
Pomona, CA
27. Project No. 04-02-57 (Reviewer - Harris)
Project Title: "The Relationship between Air Pollution and Childhood Brain
Tumors in Southern California"
Principal Investigator: Roberta Mckean-Cowdin, PhD
University of Southern California
Los Angeles, CA
28. Project No. 04-02-52 (Reviewer - Kirkish)
Project Title: "Inpatient Care Trends Among Medicare Managed Care
Beneficiaries in California"
Principal Investigator: Glenn Melnick, PhD
USC, School of Planning, Policy, and Development
Los Angeles, CA
29. Project No. 08-02-56 (Reviewer - Kirkish)
Project Title: "Autism and Television Watching"
Principal Investigator: Jeff Miron
Harvard University
Cambridge, MA
30. Project No. 09-02-02 (Reviewer - Ruiz)

Project Title: "Pesticide and Gene interactions in Latina Farm Workers"
Principal Investigator: Paul Mills
UCSF
Fresno, Ca

31. Project No. 08-02-04 (Reviewer - Ruiz)

Project Title: "Study of Air Pollution, Genetics and Early-Life Events (SAGE)"
Principal Investigator: Kathleen Mortimer, MPH
University of California, Berkeley
Berkeley, CA

32. Project No. 06-12-56 (Reviewer - Ruiz)

Project Title: "Enhancement of Surveillance of Vaccine Preventable Diseases
Using California Hospital Discharge Data"
Principal Investigator: Robert Schechter, MD
CDPH
Richmond, CA

33. Project No. 03-02-07 (Reviewer - Mihordin)

Project Title: "Candidate Genes and Congenital Malformations of Neural Crest
Origin"
Principal Investigator: Gary Shaw, DrPH
Stanford School of Medicine
Stanford, CA

34. 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

35. 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

36. 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

37. 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

38. 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

39. Project No. 07-02-05 (Reviewer - Kirkish)

Project Title: "The Nature of Dementia in an Aging Down Syndrome Population"
Principal Investigator: Markley Sutton, PhD
Sonoma Developmental Center
Eldridge, CA

40. Project No. 07-02-03 (Reviewer - Harris)

Project Title: "Studying Youth in Northern California (SYNC): Qualitative Research-Training Team Project"
Principal Investigator: James Quesada, PhD
San Francisco State University
San Francisco, CA

41. Project No. 06-02-04 (Reviewer - Harris)

Project Title: "California Case-Control Study of the Effectiveness of Trivalent Inactivated Influenza Vaccine among Children Aged 6-59 months in Preventing Hospitalization with Influenza during the 2007-08 Influenza Season"
Principal Investigator: Arthur Reingold, MD
UC Berkeley, School of Public Health
Berkeley, CA

42. Project No. 06-02-06 (Reviewer - Harris)

Project Title: "Measured Parameters in Midpregnancy Blood Specimens and Newborn Bloodspots and Risks of Preterm Delivery"
Principal Investigator: Gary Shaw, DrPH
Stanford School of Medicine
Stanford, CA

43. Project No. 07-02-05 (Reviewer - Kirkish) Project Title: "The Nature of Dementia in an Aging Down Syndrome Population"

Principal Investigator: Markley Sutton, PhD
Sonoma Developmental Center

Eldridge, CA

44. 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
45. Project No. 06-02-60 (Reviewer - Kirkish)
Project Title: "Hospitalizations for Benign Gynecological Conditions in California"
Principal Investigator: Elaine Waetjen, MD
UC Davis Health System
Sacramento, CA
46. Project No. 08-02-05 (Reviewer - Harris)
Project Title: "Autism in an American Indian and Alaska Native sample: The contribution of demographic characteristics, level of acculturation, and cultural values and beliefs on service utilization"
Principal Investigator: Jennifer Wendt, MA
Alliant International University
San Diego, CA
47. Project No. 06-02-07 (Reviewer - Mihordin)
Project Title: "FoodNet Study of Escherichia coli O157:H7 Infection: Antibiotic Exposure and the Risk of Hemolytic Uremic Syndrome"
Principal Investigator: Katie Wymore, MPH
CDPH, California Emerging Infections Program
Oakland, CA
48. Project No. 07-02-53 (Reviewer - Ward)
Project Title: "Exploratory Spatial Data Analysis of Community Environmental Risk Factors for Teen Pregnancy and Related Birth Outcomes"
Principal Investigator: Ikuho Yamada, PhD
University of Utah, Dept. of Geography
Salt Lake City, UT
49. Project No. 00-12-13 (Reviewer - Harris)
Project Title: "Caring for California Initiative"
Principal Investigator: Bonnie Zima, MD, MPH
UCLA, Child and Adolescent Psychiatry
Los Angeles, CA
50. Project No. 09-02-54 (Reviewer - Kirkish)
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

51. Project No. 06-02-02 (Reviewer - Kirkish)

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

52. Project No. 06-12-06 (Reviewer - Murphy)

Project Title: “Positive Transitions”

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

53. Project No. 06-02-56 (Reviewer - Ruiz)

Project Title: “Outcome After treatment of Cerebrovascular Disease Outcome of
Patients with Parkinson's Disease Following General Surgery”

Principal Investigator: Mitchell Berman, MD, MPH
Columbia University
New York, NY

54. Project No. 09-04-02 (Reviewer - Kirkish)

Project Title: “Registeries of Excellence: Improving Follow-Up and Research
Availability of Adolescent and Young Patients in the Population-
based Cancer Registry”

Principal Investigator: Dennis Deapen, DrPH
USC School of Medicine
Los Angeles, CA

55. Project No. 07-02-06 (Reviewer - Ruiz)

Project Title: “A pilot Study of DUI Court, Naltrexone and Motivational
Interviewing”

Principal Investigator: Dave DeYoung, MA
Research and Development Branch
Department of Motor Vehicles
Sacramento, CA

56. Project No. 05-02-02 (Reviewer - Ruiz)

Project Title: “Increasing Influenza Vaccination of Long Term Care Facility Staff”

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

57. Project No. 07-04-51 (Reviewer - Harris)

Project Title: "Evaluating the Impact of FDA Warnings and Consensus Recommendations on Metabolic Screening and Monitoring for Patients Initiating Atypical Antipsychotic Medication: A Multi-State Medicaid Claims Study"

Principal Investigator: Elaine Morrato, DrPH, MPH
University of Colorado
Aurora, CO

58. Project No. 08-02-04 (Reviewer - Ruiz)

Project Title: "Study of Air Pollution, Genetics and Early-Life Events (SAGE)"

Principal Investigator: Kathleen Mortimer, MPH
University of California, Berkeley
Berkeley, CA

59. 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

60. 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

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.

61. Project No. 08-08-01 (Reviewer -Harris)

Project Title: "Neuro-Developmental Disabilities Screening and Assessment in Uganda"

Principal Investigator: Judith Grether, PhD
Sequoia Foundation
LaJolla, CA

62. Project No. 00-04-04 (Reviewer -Dickey)

Project Title: "California Health Interview Survey CHIS"

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

63. Project No. 06-12-51 (Reviewer -Harris)

Project Title: "Validation of Selected Items in the 2005 Patient Discharge Data Set"

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

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

1. Project No. 09-12-07 (Reviewer – Kirkish)
Project Title: “Establishing Best Treatment Practices for Pathological Gamblers”
Principal Investigator: Timothy Fong
UCLA
Los Angeles, CA

E. New Projects Calendar
New Projects - Full Committee Review Required

1. Project No. 10-02-01 (Reviewer – Murphy)
Project Title: “National Youth in Transition Database Project”
Principal Investigator: Dr. Gail S. Goodman
UC Davis
Davis, CA
2. Project No. 10-02-02 (Reviewer - Ruiz)
Project Title: “Evaluating the Effectiveness of a 13-Valent Pneumococcal Conjugate Vaccine among Children”
Principal Investigator: Mirasol Apostol Largeteau, MPH
California Emerging Infections Program
Oakland, CA
3. Project No. 10-02-03 (Reviewer - Murphy)
Project Title: “Understanding the Relation between Sleep and Memory in Infants”
Principal Investigator: Angela Lukowski, PhD
UC Irvine
Irvine, CA
4. Project No. 10-02-04 (Reviewer - Ruiz)
Project Title: “Evaluating the Effectiveness of a 13-Valent Pneumococcal Conjugate Vaccine among Children”
Principal Investigator: Laurene Mascola
County of LA Dept of Public Health
LA, CA
5. Project No. 10-02-05 (Reviewer – Mihordin)
Project Title: “Correctional patients exposed to trauma: Describing psychological and offense characteristics:
Principal Investigator: Caroline Mok and Megan Jimenez

Dept of Mental Health-Vacaville Psychiatric Program
Vacaville, CA

6. Project No. 10-02-06 (Reviewer – Dinis)
Project Title: “Knowledge and practice patterns regarding vasectomy
Family PACT providers
Principal Investigator: Heile Thiel de Bocanegra and Christine Dehlendorf
California Dept of Public Health
Sacramento, CA
7. Project No. 10-02-07 (Reviewer – Murphy)
Project Title: “Forteo Patient Registry”
Principal Investigator: Alicia Gilsenan, PhD
RTI Health Solutions
Research Triangle Park, NC
8. Project No. 09-12-54 (Reviewer – Dinis)
Project Title: “Use of Treatments for Children with Autism Spectrum
Disorders (ASD): A Survey of Parents”
Principal Investigator: Alicia Bazzano
Westside Regional center
Culver City, 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.

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)

Project No. 00-04-04 (Reviewer - Dickey)
Project Title: “California Health Interview Survey CHIS”
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for March 26, 2010 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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