

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

Wednesday, December 2, 2009
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - a. Fellowship student, Sanaa Shabir attending meeting
 - b. Web-based application system update
 - c. PRIM&R conference report
 - d. Reliance policy suspension (for CPHS to rely on other IRBs) during furloughs
2. Membership update for new members and re-appointments
3. Encryption discussion (Steve Moore, DHCS)
4. CPHS policies to develop and implement
 - a. Determination of risk level
 - b. External verification determinations
 - c. Engagement in research form and process
5. Office of Human Research Protection Guidance
6. Senate Bill 2 (pupil data)
 - a. CPHS required to rely on Department of Education IRB
 - b. Allows nonprofit organizations to receive personal information

B. Approval of Minutes

August 5, 2009 and September 25, 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. 08-12-02 (Reviewer -Kirkish)
Project Title: "Early Autism Risk Longitudinal Investigation (EARLI)"
Principal Investigator: Irva Hertz-Picciotto, PhD
UCD
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. 05-12-52 (Reviewer - Murphy)
Project Title: "Impact of Violence During Pregnancy on Birth Outcomes"
Principal Investigator: Anna Aizer, PhD, MS
Brown University
Providence, RI

3. 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

4. Project No. 05-12-53 (Reviewer - Ruiz)
Project Title: "The Effect of Hospitals on racial Disparity in Coronary Artery Bypass Graft Surgery Outcomes"
Principal Investigator: Andrew Bindman, MD
UCSF
San Francisco, CA

5. Project No. 08-12-63 (Reviewer - Mihordin)
Project Title: "The Impact of E-Prescribing in Northern Sierra Rural Health Network"
Principal Investigator: Kevin Boesen, PharmD
University of Arizona
Tucson, AZ

6. Project No. 08-12-57 (Reviewer - Harris)
Project Title: "Chronic Disease Morbidity and Mortality among Medi-Cal Beneficiaries with Serious Mental Illness and Co-occurring Substance Use Disorders"
Principal Investigator: Tim-Allen Bruckner
California Institute of Mental Health
Sacramento, CA

7. Project No. 04-12-07 (Reviewer - Lowe)
Project Title: "California Drug Courts and the Substance Abuse and Crime Prevention Act"
Principal Investigator: Shannon Carey, PhD
NPC Research
Portland, OR

8. Project No. 02-12-15 (Reviewer - Harris)
Project Title: "Epidemiology of Lead Poisoning Due to In-Utero Exposure Among Neonates"
Principal Investigator: Joseph Courtney, PhD
CDPH
Richmond, CA

9. Project No. 03-12-01 (Reviewer - Murphy)
Project Title: "Father Involvement Initiative"
Principal Investigator: Philip Cowan, PhD
UC Berkeley
Kensington, CA
10. Project No. 01-12-04 (Reviewer - Murphy)
Project Title: "Use of Linked Data Bases to Assess Selected Quality Indicators
for Maternal and Infant Health"
Principal Investigator: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA
11. Project No. 03-12-54 (Reviewer - Murphy)
Project Title: "Delayed Health Care Among the Near-Elderly"
Principal Investigator: Carlos Dobkin, PhD
UC Santa Cruz
Santa Cruz, CA
12. Project No. 07-12-54 (Reviewer - Harris)
Project Title: "The Impact of Medicare on Emergency Department and Hospital
Treatment"
Principal Investigator: Carlos Dobkin, PhD
UC Santa Cruz
Santa Cruz, CA
13. Project No. 03-12-51 (Reviewer - Kirkish)
Project Title: "The Productivity of Medi-Cal Prescription Drug Spending"
Principal Investigator: Mark Duggan, PhD, MS
University of Maryland
College Park, MD
14. Project No. 07-12-05 (Reviewer - Ward)
Project Title: "A Multi-site Evaluation of a State-funded Peer-based
HIV Prevention Program for Injection Drug Users and
Satellite Syringe Exchanges in California"
Principal Investigator: Valorie Eckert, MPH
California Department of Public Health
Sacramento, CA
15. Project No. 98-04-04 (Reviewer - Lowe)
Project Title: "California Women's Health Survey"
Principal Investigator: Joan Epstein, MS
CDPH
Sacramento, CA
16. Project No. 08-12-58 (Reviewer - Mihordin)
Project Title: "Pilot Study of Trends and Risks in Gestational Diabetes"

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

17. Project No. 06-12-52 (Reviewer - Harris)

Project Title: "Utilization of Antidepressants in Children and Adolescents < 18 Years of Age"

Principal Investigator: Patrick Finley, Pharm.D
UCSF
San Francisco, CA

18. Project No. 03-12-55 (Reviewer - Harris)

Project Title: "Antecedent Pregnancy Outcomes of Children with Cerebral Palsy and other Neurologic Diseases"

Principal Investigator: William Gilbert, MD
UC Davis
Sacramento, CA

19. Project No. 03-12-53 (Reviewer - Kirkish)

Project Title: "Linking Hospital Organizational and Clinical Factors to Obstetrical Outcomes"

Principal Investigator: Kimberly Gregory, MD, MPH
UCLA
Los Angeles, CA

20. Project No. 03-12-52 (Reviewer - Murphy)

Project Title: "Occurrence and Distribution of Autism in California"

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

21. Project No. 04-12-03 (Reviewer - Dinis)

Project Title: "Making Consumer-Directed Homecare a Better Job"

Principal Investigator: Candace Howes, PhD
Connecticut College
New London, CT

22. Project No. 06-12-53 (Reviewer - Kirkish)

Project Title: "Maternal and Infant Health Outcomes among Women with Preexisting Morbidity in California"

Principal Investigator: Maria Jocson, MD, MPH
DHCS
Sacramento, CA

23. Project No. 08-12-56 (Reviewer - Ward)

Project Title: "Replication of Draper Study of Leukemia, Brain Tumors and Distance to Power Lines in California"

Principal Investigator: Leeka Kheifets, PhD, MA

UCLA
Los Angeles, CA

24. Project No. 08-12-54 (Reviewer - Kirkish)
Project Title: "Management of Dizziness in the Emergency Department"
Principal Investigator: Anthony Kim, MD
UCSF
San Francisco, CA
25. Project No. 07-12-60 (Reviewer - Kirkish)_
Project Title: "Breast Cancer After the Women's Health Initiative Study:
Declining Incidence?"
Principal Investigator: Nancy Krieger, PhD
Harvard School of Public Health
Boston, MA
26. Project No. 06-12-58 (Reviewer - Dinis)
Project Title: "Study of the Role of Cytokines in the Pathogenesis of Influenza
and other Respiratory Viruses"
Principal Investigator: Janice Louie, MD, MPH
CDPH
Richmond, CA
27. Project No. 02-12-09 (Reviewer - Kirkish)_
Project Title: "UCLA Study of Breast Cancer Care"
Principal Investigator: Rose Maly, MD, MSPH
UCLA
Los Angeles, CA
28. Project No. 07-12-02 (Reviewer – Kirkish)
Project Title: "Mental Rotation in Human Infants"
Principal Investigator: David Moore, PhD
Pitzer College and Claremont Graduate University
Claremont, CA
29. Project No. 08-12-62 (Reviewer - Harris)
Project Title: "The Effects of Choice Context on Decision-Making: An Application
to Voter Fatigue"
Principal Investigator: Scott Nicholson
Stanford University
Stanford, CA
30. Project No. 01-12-10 (Reviewer - Harris)_
Project Title: "Pediatric Low Vision"
Principal Investigator: Anthony Norcia, PhD
Smith-Kettlewell Eye Research Institute
San Francisco, CA

31. Project No. 98-12-01 (Reviewer - Harris)
Project Title: "Normal and Abnormal Spatial Vision in Infants and Form and Motion Integration"
Principal Investigator: Anthony Norcia, PhD
Smith-Kettlewell Eye Research Institute
San Francisco, CA
32. Project No. 01-12-09 (Reviewer - Harris)
Project Title: "Development of Form, Binocularity, and Rivalry"
Principal Investigator: Anthony Norcia, PhD
Smith-Kettlewell Eye Research Institute
San Francisco, CA
33. Project No. 98-12-09 (Reviewer - Mihordin)
Project Title: "Regional Variations in Breast Cancer Rates in California"
Principal Investigator: Peggy Reynolds, PhD
Northern California Cancer Center
Berkeley, CA
34. Project No. 08-12-55 (Reviewer - Dinis)
Project Title: "Cancers among Children with Birth Defects in California"
Principal Investigator: Peggy Reynolds, PhD
Northern California Cancer Center
Berkeley, CA
35. Project No. 07-12-61 (Reviewer – Harris)
Project Title: "High Medicaid Hospitals and Postoperative Cancer Outcomes in California"
Principal Investigator: Kim Rhoads, MD, MS, MPH
UCSF Institute for Health Policy Studies
San Francisco, CA
36. Project No. 01-12-11 (Reviewer - Murphy)
Project Title: "Survey of Proportion of Voluntary HIV Testing and Assessment of HIV Testing Method Preferences Among Incoming Prisoners at the California Medical Facility (CMF)"
Principal Investigator: Juan Ruiz, MD, DrPH, MPH
CDPH
Sacramento, CA
37. Project No. 07-12-09 (Reviewer - Harris)
Project Title: "Research in Language and Cognitive Development"
Principal Investigator: Catherine Sandhofer, PhD
UCLA
Los Angeles, CA
38. Project No. 07-12-04 (Reviewer - Murphy)
Project Title: "NIH-AARP Diet and Health Study"

Principal Investigator: Arthur Schatzkin, MD, MPH, DrPH
National Cancer Institute
Bethesda, MD

39. Project No. 06-10-59 (Reviewer - Kirkish)

Project Title: "Quantitative Evaluation of the Mental Health Services Act (Prop 63)"

Principal Investigator: Richard Scheffler, PhD
UC Berkeley
Berkeley, CA

40. Project No. 07-12-64 (Reviewer - Harris)

Project Title: "Hospital Unions, Staffing, Wages, and Patient Safety"

Principal Investigator: Joanne Spetz, PhD
UCSF
San Francisco, CA

41. Project No. 08-12-51 (Reviewer - 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

42. Project No. 08-12-52 (Reviewer - 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

43. Project No. 08-12-59 (Reviewer - Harris)

Project Title: "Cord Morality Risk Adjustment with Present on Admission Diagnoses"

Principal Investigator: George J. Stukenborg, PhD, MA
University of Virginia
Charlottesville, VA

44. Project No. 07-12-07 (Reviewer – Harris)

Project Title: "Children's Developing Speech Perception and Production"

Principal Investigator: Megha Sundara, PhD
UCLA
Los Angeles, CA

45. Project No. 05-12-03 (Reviewer - Mihordin)

Project Title: "The Multiethnic Pediatric Eye Disease Study (MEPEDS)"

Principal Investigator: Rohit Varma, MD

Doheny Eye Institute
Los Angeles, CA

46. Project No. 08-12-61 (Reviewer - Ward)
Project Title: "Medi-Cal Spending on Psychotropic Drugs and Its Effect on Health Outcomes and Expenditures"
Principal Investigator: Jangho Yoon, PhD, MSPH
DHCS
Sacramento, CA
47. Project No. 03-02-06 (Reviewer - Lowe)
Project Title: "Survey of Body Burden in California Communities"
Principal Investigator: Kim Hooper, PhD
Department of Toxic Substances Control
Berkeley, CA
48. Project No. 06-10-59 (Reviewer - Harris)
Project Title: "Quantitative Evaluation of the Mental Health Services Act"
Principal Investigator: Richard Scheffler, PhD
UC Berkeley
Berkeley, CA
49. Project No. 05-10-02 (Reviewer - Harris)
Project Title: "Quantitative California Behavioral Risk Factor Survey"
Principal Investigator: Joan Epstein, MS
CDPH
Sacramento, CA
50. Project No. 08-12-06 (Reviewer - Harris)
Project Title: "Children's Development of Grammatical Rules"
Principal Investigator: Nina Hyams, PhD
UCLA
Los Angeles, CA
51. Project No. 05-12-05 (Reviewer - Murphy)
Project Title: "Healthy Relationships: Evaluating Program Effectiveness with HIV-Positive Prisoners"
Principal Investigator: Barry Zack, MPH
Centerforce, Inc.
San Rafael, CA
52. Project No. 08-12-08 (Reviewer - Murphy)
Project Title: "Validation of the Revised COJAC Screening Tool for Co-Occurring Disorders"
Principal Investigator: Martha Jessup, PhD, RN
UCSF
San Francisco, CA

53. Project No. 08-12-03 (Reviewer - Ruiz)
Project Title: "California Youth Risk Behavior Survey"
Principal Investigator: Arti Parikh-Patel, PhD, MPH,
California Cancer Registry's
Sacramento, CA
54. 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
55. Project No. 08-04-57 (Reviewer - Murphy)
Project Title: "Economic Analysis of Air Quality Impacts of Forest Fires"
Principal Investigator: Stephen Davies
Colorado State University
Fort Collins, CO
56. 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
CA Emerging Infections Program
Oakland, CA
57. 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

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.**

58. Project No. 00-04-04 (Reviewer -Dickey)
Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, CA
59. 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/PHI
Sacramento, CA

60. Project No. 04-02-54 (Reviewer -Mihordin)

Project Title: "Prenatal and Neonatal Biological Markers for Autism Study"
Principal Investigator: Lisa Croen, PhD
Kaiser Permanente
Oakland, CA

61. 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

62. Project No. 03-08-02 (Reviewer -Murphy)

Project Title: "In-school Evaluation of the Tobacco Use Prevention
Education (TUPE) Program, 2009-10"
Principal Investigator: Barbara Dietsch, PhD
WestEd
Los Alamitos, CA

63. Project No. 03-08-01 (Reviewer -Lowe)

Project Title: "13th Biennial California Student Survey (CSS),
2009-10"
Principal Investigator: Greg Austin, PhD
WestEd
Los Alamitos, CA

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

Project Title: "Sun Protection Practices among Young Children
with a Family History of Melanoma"
Principal Investigator: Beth Glenn, PhD
UCLA
Los Angeles, CA

65. Project No.08-10-06 (Reviewer -Dinis)

Project Title: "California Case-Control Study of the Effectiveness
of Trivalent Inactivated Influenza Vaccine in Preventing RT-
PCR-confirmed Seasonal Influenza
Hospitalizations among Adults Aged 50 Years and
Older"
Principal Investigator: Pamala Daily Kirley, MPH
California Emerging Infections Program
Oakland, CA

66. Project No. 09-06-02 (Reviewer -Ward)
Project Title: "Genome-wide Association Study of Radiation Exposure and Bilateral Breast Cancer"
Principal Investigator: Esther John, PhD, MSPH
NCCC
Fremont, CA
67. 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, CA
68. Project No. 06-10-02 (Reviewer -Dinis)
Project Title: "Predictors of Violence and Suicide Risk in Psychiatrically Hospitalized Inmate/Patients"
Principal Investigator: Robert Horon, PhD
DMH
Vacaville, CA

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

1. Project No. 09-10-03 (Reviewer – Ward)
Project Title: "Amyloid Plaque and Tangle Imaging in Alzheimer's Disease and Down Syndrome"
Principal Investigator: Linda Nelson, PhD, ABPN
UCLA
Los Angeles, CA

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

1. Project No. 09-12-01 (Reviewer – Kirkish)
Project Title: "Families-In-Motion Program"
Principal Investigator: Alicia Bazzano, MD, MPH
Westside Regional Center
Culver City, CA
2. Project No. 09-12-02 (Reviewer - Dickey)
Project Title: "Computer-based Video Game Therapy for Gait and balance in Cerebral Palsy"
Principal Investigator: Glenna A. Dowling, PhD, RN
UCSF
San Francisco, CA
3. Project No. 09-12-03 (Reviewer - Ruiz)

Project Title: "California Breast cancer Research Program Study:
Developing sociodemographic questions for breast cancer
disparities research"

Principal Investigator: Scarlett Lin Gomez, PhD
Northern California Cancer Center
Fremont, CA

4. Project No. 09-12-04 (Reviewer - Mihordin)

Project Title: "The Physiology of Positive Emotions and Behaviors in
Mothers and Children"

Principal Investigator: Paul D. Hastings, PhD
University of California, Davis
Davis, CA

5. Project No. 09-12-05 (Reviewer - Ruiz)

Project Title: "Project Forward"

Principal Investigator: Kathleen Meeske, PhD
Keck School of Medicine, USC
Los Angeles, CA

6. Project No. 09-12-06 (Reviewer – Ward)

Project Title: "Culture and Breast Cancer Survivorship"

Principal Investigator: Judy Huei-Yu Wang, PhD
Georgetown University Medical Center
Washington, DC

7. Project No. 09-12-07 (Reviewer – Kirkish)

Project Title: "Establishing Best Treatment Practices for Pathological
Gamblers"

Principal Investigator: Timothy Fong
UCLA
Los Angeles, CA

8. Project No. 09-12-08 (Reviewer – Lowe)

Project Title: "WIC Breastfeeding with Formula "Top Off" Survey"

Principal Investigator: Cynthia Ramierz, RN
WIC
Rancho Cordova, 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)

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for January 29, 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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