

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**

***US Toll-Free Number: 877-581-9247
Access Code: 963949**

**Friday, February 3, 2012
8:30 am – 5:00 pm**

A. General Items

1. Open Meeting Act presentation (Jacob Knapp, OSHPD Counsel)
2. Update on California PROTocol Electronic Communication and Tracking System (CalPROTECTS)
 - a. Implementation time line
 - i. Registration of researchers for April cycle
 - ii. Required revisions of protocol due from vendor on 1/29/12
 - iii. All researchers will be required to submit all of their latest documents for this initial cycle
 - iv. Some components, such as continuing review questions, consent forms and vulnerable population checklists, are not on-line yet so paper forms will be attached at this time.
 - v. Projects that are Completed or Withdrawn will continue to submit hard copies for this first year only
 - vi. Committee meetings related to use of CalPROTECTS
 - b. Questions and comments from members regarding training on 1/20/12 and any additional training needs
 - c. Possible logos for CalPROTECTS
3. Suggestions for streamlining review process per CPHS retreat
 - a. IPA projects all have annual reviews (now only projects approved after the annual review requirement was approved are required to submit for annual review)
 - b. Revision of minor nature, change in RO, change in years of data, etc., be approved by one member or CPHS staff instead of two members
 - c. Sending non-approval letters to researchers who have been notified certain number of times that projects due for renewal
 - d. Expedited review options
 - i. Members assigned on weekly, monthly or cycle basis to approve ER project
 - e. Not include list of revisions in approval letter but refer to date of Request for Revision Form
 - f. A list of project status available for members to review
4. Member approval of expedited projects

5. Presentation by Lupe Alonzo-Diaz, Acting Chief Deputy Director of OSHPD
6. Additional member training for CalPROTECTS

B. Approval of Minutes

August 2011 Meeting Minutes

C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval

Projects with major revisions and requiring periodic review

1. Project No. 11-02-07 (Reviewers-Takahashi/Dickey)
Project Title: "Life Course Energy Balance and Breast Cancer Risk in Black/White Women) Under 50"
Principal Investigator: Katherine Henderson, PhD
City of Hope Comprehensive Cancer Center
Duarte, CA

Projects requiring periodic review only – (including greater than minimal risk projects)

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. 07-02-07 (Reviewer-Parker)
Project Title: "Seeking Thought of Parents about Cancer Study (STOP Cancer)"
Principal Investigator: Greta Bunin, PhD
Children's Hospital of Philadelphia
Philadelphia, PA
3. Project No. 10-02-54 (Reviewer- Lowe)
Project Title: "Effects of the Economic Downturn on Medi-Cal Enrollment, Retention and Cost"
Principal Investigator: Gerry Fairbrother, PhD
Academy Health
Washington, DC
4. Project No. 07-02-05 (Reviewer- Molitor)
Project Title: "The Nature of Dementia in an Aging Down Syndrome Population"
Principal Investigator: Markley Sutton, PhD
Sonoma Developmental Center
Eldridge, CA
5. Project No. 07-02-52 (Reviewer-Dinis)
Project Title: "Augmentation of CA CADDRE Studies"
Principal Investigator: Lisa Croen, PhD
Kaiser Permanente

Oakland, CA

6. Project No. 06-02-57 (Reviewer-Dickey)
Project Title: "Gestational Diabetes: Diagnostic Criteria and Outcomes"
Principal Investigator: Assiamira Ferrara, MD, PhD
Kaiser Permanente
Oakland, CA

7. Project No. 03-02-03 (Reviewer- Murphy)
Project Title: "Gestational Diabetes: Diagnostic Criteria and Outcomes"
Principal Investigator: Marion Gillen
UCSF
San Francisco, CA

8. Project No. 11-02-05 (Reviewer-Bazzano/Murphy)
Project Title: "Collection of CFTR Mutations for Laboratory Quality Assurance"
Principal Investigator: Martin Kharrazi, PhD, MPH
CDPH
Richmond, CA

9. Project No. 10-02-03 (Reviewer- Murphy)
Project Title: "Understanding the Relation between Sleep and Memory in Infants"
Principal Investigator: Angela Lukowski, PhD
UCI
Irvine, CA

10. Project No. 06-02-04 (Reviewer-Bazzano)
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"
Principal Investigator: Arthur Reingold, MD
UCB
Berkeley, CA

11. Project No. 03-02-07 (Reviewer- Mihordin)
Project Title: "Candidate Genes and Congenital Malformations of Neural Crest Origin"
Principal Investigator: Gary Shaw, DrPH
Stanford University Medical Center
Stanford, CA

12. 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

13. 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
Oakland, CA
14. Project No. 06-12-06 (Reviewer- Murphy)
Project Title: "Positive Transitions"
Principal Investigator: Barry Zack, MPH
Centerforce, Inc.
San Rafael, CA
15. Project No. 11-02-55 (Reviewer- Bazzano)
Project Title: "Expanding the Role of Medicaid in Cancer Care for the Uninsured"
Principal Investigator: David Zingmond, MD, PhD
UCLA
Los Angeles, CA
16. Project No. 06-02-06 (Reviewer- Dickey)
Project Title: "Measured Parameters in Midpregnancy Blood Specimens and Newborn Bloodspots and Risks of Preterm Delivery"
Principal Investigator: Gary Shaw, DrPH
Stanford University Medical Center
Stanford, CA
17. Project No. 87-06-01 (Reviewer- Lowe/Molitor)
Project Title: "Epidemiologic Study of the Natural History of HIV"
Principal Investigator: Susan Buchbinder, MD
San Francisco Department of Public Health
San Francisco, CA
18. Project No. 11-02-03 (Reviewer- Ruiz/Murphy)
Project Title: "Genome Wide Admixture for Multiple Myeloma in African Americans"
Principal Investigator: Wendy Cozen, MPH, DO
USC
Los Angeles, CA
19. Project No. 07-02-02 (Reviewer- Murphy/Lowe)
Project Title: "Markers of Autism Risk in Babies: Learning Early Signs (MARBLES)"
Principal Investigator: Irva Hertz-Picciotto, PhD
UCD

Davis, CA

20. Project No. 05-02-01 (Reviewer- Mihordin/Dickey)

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
Richmond, CA

21. Project No. 00-02-08 (Reviewer- Mihordin/Lowe)

Project Title: "Foodborne Diseases Active Surveillance Network's Population Survey"

Principal Investigator: Lauren Lee, MD, MPH
CDPH
Oakland, CA

22. Project No11-02-06 (Reviewer- Parker/Ruiz)

Project Title: "Risk Factors for Invasive Methicillin-Resistant Staphylococcus aureus (MRSA) Infections among Recently Discharged Patients"

Principal Investigator: Joelle Nadle, MPH
CDPH and CEIP
Oakland, CA

23. Project No. 08-02-53 (Reviewer- Mihordin/Lowe)

Project Title: "Surveillance of Air Pollution and Related Cardiopulmonary Morbidity in California, 2000-2006"

Principal Investigator: Poh-Sin Yap, PhD
California Air Resources Board
Sacramento, CA

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

Project Title: "A Pilot Study of DUI Court, Naltrexone and Motivational Interviewing"

Principal Investigator: Dave DeYoung, MA
DMV
Sacramento, CA

25. Project No. 09-12-04 (Reviewer-Lowe/Murphy)

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

Principal Investigator: Paul Hastings, PhD
UCD
Davis, CA

26. Project No. 95-02-01 (Reviewer-Molitor)

Project Title: "Behavioral Correlates of Event-Related Potentials (ERPs)
and Background Electroencephalography (EEG)"

Principal Investigator: Stanley Lunde, PhD
Lanterman Developmental Center
Pomona, CA

27. Project No. 01-12-13 (Reviewer-)

Project Title: "Childhood Autism Risks from Genetics and the Environment
(the CHARGE Study)"

Principal Investigator: Irva Hertz-Picciotto, PhD
UCD
Davis, CA

28. Project No. 07-12-09 (Reviewer-Takahashi)

Project Title: "Research in Language and Cognitive Development"

Principal Investigator: Catherine Sandhofer, PhD
UCLA
Los Angeles, CA

29. 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

30. Project No. 10-02-56 (Reviewer-Mihordin)

Project Title: "Monthly Variation in Emergency Room Visits and
Hospitalization for Congestive Heart Failure and
Hypoglycemia"

Principal Investigator: Hilary Seligman, MD, MAS
UCSF
San Francisco, CA

31. Project No. 01-12-12 (Reviewer-Murphy)

Project Title: "Reproductive Outcomes among Female Flight Attendants"

Principal Investigator: Christina Lawson, PhD
NIH
Cincinnati, OH

32. Project No. 10-02-56 (Reviewer-Lowe/Dinis)

Project Title: "The Development of Object Representation in Infancy"

Principal Investigator: Lisa Oakes, PhD
UDC
Davis, CA

33. Project No. 07-02-09 (Reviewers-Lowe/Dinis)

Project Title: "Statewide Evaluation of First 5 California"

Principal Investigator: Millicent Barajas

First 5 California Children and Families Commission
Sacramento, CA

34. Project No. 02-02-12 (Reviewer-Bazzano/Murphy)

Project Title: "Development of the Brain Basis of Cognitive and Social Behavior in Human Infants"
Principal Investigator: Leslie Carver, PhD
UCSD
La Jolla, CA

35. Project No. 10-02-57

Project Title: "Identifying Breast Cancer Recurrence and Treatment Details in California's Population-Bases Cancer, Patient Discharge and Ambulatory Care Registries"
Principal Investigator: Monica Brown, PhD, MPH
California Department of Public Health
Sacramento, CA

36. Project No. 10-12-02

Project Title: "Los Angeles Mommy and Baby (LAMB) Project"
Principal Investigator: Sin Margaret Chao, PhD, MPH
Los Angeles County Department of Public Health,
Maternal, Child, and Adolescent Health Programs
Los Angeles, CA

37. Project No. 10-02-53

Project Title: "Young Adult Outcomes of Youth Existing Dependent or Delinquent Care in Los Angeles: Earnings, Homelessness, Criminal Justice System Involvement, Public Assistance, Receipt, Public Health Services Use, and Post-Secondary Education"
Principal Investigator: Dennis Culhane, PhD
University of Pennsylvania, School of Social Policy and Practice
Philadelphia, PA

38. Project No. 06-02-02

Project Title: "Understanding Barriers to Health Care Access For HIV + Persons in California Who Have Never Had HIV Medical Care"
Principal Investigator: Mark A. Damesyn, DrPH
California Department of Public Health
Sacramento, CA

39. Project No. 11-02-51

Project Title: "Differential Black-White Birth Outcomes due to Percieved Racism: Exploration of an acute, positive racial event within the context of a lifetime of experienced racism"

Principal Investigator: Desiree Dieste, MPH,
University of California, Berkeley - Graduate Schools
of Public Health and Social Welfare
Berkeley, CA

40. Project No. 10-12-05

Project Title: "Siblings of Children with Autism"
Principal Investigator: Scott Johnson, PhD
Psychology Department,
University of California, Los Angeles
Los Angeles, CA

41. Project No. 10-02-55

Project Title: "Predicting Autism Secondary to Mitochondrial Disease"
Principal Investigator: Martin Kharrazi, PhD, MPH,
California Department of Public Health
Richmond, CA

42. Project No. 04-02-06

Project Title: "Border Asthma and Allergies Study"
Principal Investigator: Michael Lipsett, MD., Chief
CPDH/ Chief, Exposure Assessment Section
Richmond, CA

43. Project No. 10-02-51

Project Title: "Cost of Alzheimer's Disease and Associated Dementias to
the California Medicaid [Medi-Cal] Program"
Principal Investigator: Jeff McCombs, PhD
Department of Clinical Pharmacy and Pharmaceutical
Economics and Policy
USC
Los Angeles, CA

44. Project No. 04-02-57

Project Title: "The Relationship between Air Pollution and Childhood Brain
Tumors in Southern California"
Principal Investigator: Roberta McKean-Cowdin, PhD
University of Southern California
Norris Comprehensive Cancer Center
Los Angeles, CA

45. Project No. 04-02-52

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

46. Project No. 09-10-06

Project Title: "Beta-Amyloid Probes of Alzheimer's Disease in Down Syndrome"

Principal Investigator: Linda Nelson, PhD, ABPN
UCLA
Los Angeles, CA

47. Project No. 10-12-06

Project Title: "Screening for Dementia in People with Down Syndrome"

Principal Investigator: Linda Nelson, PhD, ABPN
University of California, Los Angeles
Los Angeles, CA

48. Project No. 00-02-06

Project Title: "Early Childhood Longitudinal Study, Birth Cohort (ECLS-B)"

Principal Investigator: Jennifer Park, PhD
National Center for Education Statistics
Department of Education
Washington, DC

49. Project No. 07-02-03

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

50. Project No. 11-02-10

Project Title: "Reducing Breast Cancer Recurrence with Weight Loss: Vanguard Trial"

Principal Investigator: Cheryl Rock, PhD, RD
University of California, San Diego
La Jolla, CA

51. Project No. 01-02-09

Project Title: "Malignant Disease in Women Giving Birth in California 1992-1997: Study of Clinical Outcomes"

Principal Investigator: Anne Rodriguez, MD
UCD
Department of Obstetrics and Gynecology
Sacramento, CA

52. Project No. 10-12-54

Project Title: "IBM-Endicott Retrospective Cohort Study"

Principal Investigator: Sharon Silver, MS
National Institute for Occupational Safety and Health (NIOSH)
Cincinnati, OH

53. Project No. 05-02-60

Project Title: "An Analysis of Molecular Epidemiology of MultiDrug-Resistant M. Tuberculosis in the United States"
Principal Investigator: Sumi Sun, MPH
CDPH, Epidemiologist, Tuberculosis Control Branch
Berkeley, CA

54. Project No. 08-02-04

Project Title: "Study of Air Pollution, Genetics and Early-Life Events (SAGE)"
Principal Investigator: Ira Tager, MD, MPH
University of California Berkeley,
School of Public Health
Berkeley, CA

55. Project No. 06-02-60

Project Title: "Hospitalizations for Benign Gynecological Conditions in California"
Principal Investigator: Elaine Waetjen, MD
UC Davis Health System
Department of Obstetrics and Gynecology
Sacramento, CA

56. Project No. 08-12-61

Project Title: "Medi-Cal Spending on Psychotropic Drugs and Its Effect on Health Outcomes and Expenditures"
Principal Investigator: Jangho Yoon, PhD
Department of Health Care Services
Sacramento, 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.

1. Project No. 00-04-04 (Reviewer-Dickey/ Ruiz)

Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: E. Richard Brown, PhD
UCLA
Los Angeles, 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. 12-02-03 (Reviewer-Murphy)
Project Title: "Methamphetamine Abuse: Long-Term Trajectories"
Principal Investigator: Mary-Lynn Brecht, Ph.D.
UCLA Integrated Substance Abuse Programs
Santa Monica, CA

2. Project No. 12-02-02 (Reviewer-Bazzano)
Project Title: "Improving cancer screening among breast and colorectal cancer survivors and their relatives through the Los Angeles County Cancer Surveillance Program"
Principal Investigator: Beth Glenn, PhD
UCLA
Los Angeles, CA

3. Project No. 12-02-04 (Reviewer-Molitor/Mihordin=PR)
Project Title: "Attitudes and Knowledge of Clozapine Use among State Hospital Psychiatrists"
Principal Investigator: Rebecca Kornbluh, MD
Patton State Hospital
Patton, CA

4. Project No. 12-02-05 (Reviewer-Parker/Ruiz for Spanish)
Project Title: "FACIAL: Planning grant for genome-wide association study of Craniofacial Microsomia"
Principal Investigator: Carrie Heike, MD, MS
Jacqueline Starr, PhD, MPH
Seattle Children's Hospital
Seattle, WA

EE. 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 April 6, 2012 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.

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Access Code: 963949

If you have any questions or comments, please contact CPHS at 916-326-3660 or cphs-mail@oshpd.ca.gov.

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