

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
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, June 1, 2012
8:30 am – 5:00 pm**

A. General Items

1. Update on California PROTocol Electronic Communication and Tracking System (CalPROTECTS)
 - a. Member feedback on CalPROTECTS
 - b. Reviewer User Guide
 - c. System features
 - d. Instructions for Researchers
 - e. Bulletin and Update on CalPROTECTS
 - f. Definition of Terms
 - g. New Project Application form
2. CPHS staff transitions (Karen Miskanis)
3. CPHS new member update
 - i. SAR for recommendations
 - ii. New member training, mentors and project assignments
4. HIPAA limited sets with data use agreements as another option for HIPAA waiver (Dr. Dickey)
5. CPHS Data Security Requirements feedback
 - a. Template for letter or statement from data security staff
 - b. Request for data security agreements
 - c. Specifics of requirements (FIP 240 -2)
6. CPHS website re-design
7. Possible changes to CPHS meeting schedule if 38 hour work weeks are instituted.
8. Additional member training on 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. 12-03-0031 (Reviewer-Parker)
Project Title: "Language Development in the Human Brain: Neural Correlates of Infant Word Learning"
Principal Investigator: Jeffrey Ellman, PhD
UC San Diego Cognitive Science Dept.
La Jolla, 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. 12-04-0074 (Reviewers-Lowe/Dickey)
Project Title: "Unclaimed Children Revisited: California Case Study"
Principal Investigator: Yumiko Aratani, PhD
Columbia University National Center for Children in Poverty
New York, NY
3. Project No. 12-03-0039 (Reviewer- Lowe/Dickey)
Project Title: "Prenatal Biomarkers and Cancer Before, During and After Pregnancy"
Principal Investigator: Rebecca Baer, MPH
California Department of Public Health
Genetics Disease Screening Program
Richmond, CA
4. Project No. 12-04-0086 (Reviewer-Lowe/Ruiz)
Project Title: "Impact of processes on cost, quality and efficiency of hospital care"
Principal Investigator: Jillian Berry
Harvard Business School
Soldier Field, MA
5. Project No. 12-04-0079 (Reviewer- Murphy/Ruiz)

- Project Title: "Methods Development for Exposure-Related Behaviors"
Principal Investigator: William Carpenter, PhD, MHA
The University of North Carolina at Chapel Hill
Chapel Hill, NC
6. Project No. 12-03-0042 (Reviewer- Takahashi/Dickey)
Project Title: "Retrospective Evaluation of Outcomes of PET Scanning using the National Oncologic PET Registry (NORP)"
Principal Investigator: James Cone, MD, MPH
New York City Dept. of Health and Mental Hygiene,
World Trade Center Health Registry
New York, NY
7. Project No. 12-05-0170
Project Title: "Original Proposal Title: Causes of Testicular Cancer and Cryptorchidism; Updated Protocol Title: Cause of Germ Cell Tumors and Related Conditions"
Principal Investigator: Victoria Cortessis, PhD
University Southern California
8. Project No. 12-04-0050 (Reviewer- Ruiz/Dickey)
Project Title: "A Study of Cancer among United States Firefighters"
Principal Investigator: Robert Daniels, PhD
National Institute of Occupational Safety and Health
Cincinnati, OH
9. Project No. 12-04-0147
Project Title: "Joint Contributions of the Supplemental Nutrition Assistance Program, Unemployment Insurance, and Cash Assistance to California's Social Safety Net"
Principal Investigator: Caroline Danielson, PhD
Public Policy Institute of California
San Francisco, CA
10. Project No. 12-04-0080 (Lowe/Molitor)
Project Title: "Naming Practices Among California Parents"
Principal Investigator: Hannah Emery
University of California, Berkeley
Berkeley, CA
11. Project No. 12-04-0073 (Reviewer- Molitor/Ruiz)
Project Title: "Project MAPP: Mapping and Analyzing Patient Pathways"
Principal Investigator: Renee Hsia, MD, MSc
University of California, San Francisco
San Francisco, CA

12. Project No. 12-05-0209

Project Title: "Measuring Your Health (MY-Heath): Validation Study of Health Outcomes Measures"
Principal Investigator: Theresa Keegan, PhD
Cancer Prevention Institute of California
Freemont, CA

13. Project No. 12-04-0132 (Reviewer- Murphy/Lowe)

Project Title: "San Francisco Mammography Registry: A research resource"
Principal Investigator: Karla Kerlikowske, MD
University of California, San Francisco
Department of Epidemiology & Biostatistics and
Medicine
San Francisco, CA

14. Project No. 12-03-0027 (Reviewer- Molitor/Lowe)

Project Title: "Racial/Ethnic Segregation in Hospital Care"
Principal Investigator: Karl Kronebusch
Baruch College, The City University of New York
School of Public Affairs
New York, NY

15. Project No. 12-04-0095 (Reviewer- Ruiz/Molitor)

Project Title: "Study of Infant Sleeping Position and SIDS Risk"
Principal Investigator: De-Kun Li, MD, PhD
Kaiser Permanente Medical Group
Oakland, CA

16. Project No. 12-04-0102 (Reviewer- Lowe/Murphy)

Project Title: "Research Program in Medication Use and Outcomes in Pregnancy"
Principal Investigator: De-Kun Li, MD, PhD
Kaiser Permanente Medical Group
Oakland, CA

17. Project No. 12-05-0195 (Reviewer- Lowe/Dinis)

Project Title: "Evaluation of California's Residentially Based Services Reform Project."
Principal Investigator: Carolyn Lichtenstein, PhD
Walter R. McDonald & Associates
Rockville, MD

18. Project No. 12-04-0144 (Reviewer- Murphy/Ruiz)

Project Title: "In School Evaluation of Tobacco Use Prevention Education Programs, 2005-2006"
Principal Investigator: William McCarthy, PhD

WestEd
Los Alamitos, CA

19. Project No. 12-05-0205

Project Title: "The effectiveness of a risk screening instrument in identifying patients at risk of aggression: The use of the COVR in a psychiatric hospital."
Principal Investigator: Barbara McDermott, PhD
University of California, Davis
Davis, CA

20. Project No. 12-04-0146

Project Title: "Categorization of Infant-Directed Speech"
Principal Investigator: David Moore, PhD
Claremont Colleges
Claremont, CA

21. Project No. 12-04-0126 (Reviewer- Dickey/Parker)

Project Title: "The Utility of the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) in a State Hospital"
Principal Investigator: Stephen Nitch, PhD
California Department of Mental Health

22. Project No. 12-04-0062 (Reviewer- Dickey/Ruiz)

Project Title: "Pilot Study to Test Laboratory Components of the California Biomonitoring Program"
Principal Investigator: Myrto Petreas, PhD, MPH
California Department of Toxic Substances Control
Berkeley, CA

23. Project No. 12-05-0233

Project Title: "Assessment and Management of Serial Murderers in a Correctional Mental Health Setting"
Principal Investigator: Juliana Rohrer, PhD
California Department of Mental Health

24. Project No. 12-05-0198

Project Title: "Trends and Outcomes in the Treatment of Thoracic Aortic Dissection in California, 1992 – 2007"
Principal Investigator: Min-Woong Sohn, PhD
Northwestern University

25. Project No. 12-04-0084 (Reviewer- Ruiz/Murphy)

Project Title: "Open versus Endovascular Repair for Abdominal Aortic Aneurysm: An Exploration with Discharge and Post-Discharge-Mortality Data"
Principal Investigator: Claudia Steiner, MD, MPH

Agency for Healthcare Research and Quality (AHRQ)
Rockville, MD

26. Project No. 12-04-0141 (Reviewer- Dickey/Ruiz)
Project Title: "Perchlorate and Thyroid Hormones in Pregnancy and Infants in Southern California"
Principal Investigator: Craig Steinmaus, MD, MPH
University of California, Berkeley, School of Public Health
Berkeley, CA
27. Project No. 12-04-0140 (Reviewer- Ruiz/Dickey)
Project Title: "California Parkinson's Disease Registry Pilot Project Research: Use of Medicare Data to Assess Registry Data Collection Efficiency"
Principal Investigator: Caroline Tanner, MD, PhD
The Parkinson's Institute
Sunnyvale, CA
28. Project No. 12-04-0120 (Reviewer- Ruiz/Dickey)
Project Title: "Mortality and Morbidity predictors of neonates with surgical conditions: Health services research using linked PDD/Cohort file of OSHPD database"
Principal Investigator: Caroline Tanner, MD, PhD
The Parkinson's Institute
Sunnyvale, CA
29. Project No. 12-04-0164 (Reviewer- Ruiz/Molitor)
Project Title: "FoodNet Case-Control Study of Selected Salmonella Stereotypes"
Principal Investigator: Katie Wymore, MPH
California Emerging Infections Program
Oakland, CA
30. Project No. 12-04-0105 (Reviewer- Ruiz/Dickey)
Project Title: "The Impact of lower extremity orthopedic surgery on the lives of children with cerebral palsy"
Principal Investigator: Stephanie Yu, MSPT, PCS
County of Los Angeles California Children's Services
Long Beach, 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.

31. Project No. 12-05-0176 (Reviewer-Dickey/Ruiz)
Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: David Grant, PhD

University of California, Los Angeles
Los Angeles, CA

32. Project No. 12-04-0101 (Reviewer- Ruiz)
Project Title: "Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis"
Principal Investigator: Kathleen Harriman, PhD, MPH, RN
CDPH, Immunization Branch
Richmond, CA
33. Project No. 12-04-0148 (Reviewer- Molitor/Ruiz)
Project Title: "Early Language and Social Cognition"
Principal Investigator: Rose Scott
University of California, Merced
Merced, CA
34. Project No. 12-05-0217
Project Title: "Outcomes in Adolescents and Young Adults (AYAs) with Cancer: Race, Ethnicity and Treatment Site"
Principal Investigator: Julie Wolfson, MD, MSHS
City of Hope

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. 12-04-0138 (Reviewer- Molitor/Dinis)
Project Title: "New Diagnosis of Bladder Cancer: Smokers Opportunity to Quit"
Principal Investigator: Jeffrey Basset, MD
University of California, Los Angeles
Los Angeles, CA
2. Project No. 12-04-0128 (Reviewer- Takahashi)
Project Title: "EHS-Net Listeria Retail Deli Study"
Principal Investigator: Susan Strong, REHS
California Department of Public Health
Sacramento, CA

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.

1. Project No. 12-04-0090 (Reviewer-Murphy/Lowe)

- Project Title: "Evaluation of Kairos Prison Ministry at California State Prison Sacramento: A Qualitative Case Study"
- Principal Investigator: W. Edward Bureau, PhD
Drexel University
Sacramento, CA
2. Project No. 12-04-0059 (Reviewer- Takahashi/Murphy)
Project Title: "GRIP Effects of Increased Self Control on Psychological and Physical Health"
- Principal Investigator: Floris Baron van Imhoff, PhD
University of Amsterdam
Amsterdam, Netherlands
3. Project No. 12-03-0025 (Reviewer- Dickey/Takahashi)
Project Title: "Treatment Center Effect on Early Death Rate in Acute Promyelocytic Leukemia (APL)"
- Principal Investigator: Jae Park, MD
Memorial Sloan-Kettering Cancer Center
New York, NY
4. Project No. 12-04-0053 (Reviewer- Lowe/Parker)
Project Title: "RealAge Collaboration – Prediction of Mortality Risk Using Online Health and Health Interest Data"
- Principal Investigator: James Fowler
University of California, San Diego
La Jolla, CA
5. Project No. 12-04-0125 (Reviewer- Parker/Dickey)
Project Title: "Political Engagement Before and After the Death of a Spouse"
- Principal Investigator: James Fowler
University of California, San Diego
La Jolla, CA
6. Project No. 12-04-0055 (Reviewer- Lowe/Dinis)
Project Title: "Life and Love: How California's Life-Term Prisoners Impact and are Impacted by Their Families and Romantic Partners"
- Principal Investigator: Nazgol Ghandnoosh, MA, C.Phil
University of California, Los Angeles
Las Angeles, CA
7. Project No. 12-04-0064 (Reviewer- Murphy/Ruiz)
Project Title: ""
- Principal Investigator: Phillip Hopewell, MD
San Francisco General Hospital
San Francisco, CA
8. Project No. 12-03-0036 (Reviewer- Ruiz/Dickey)

Project Title: "Trial Participation for Cancer Patients"
Principal Investigator: Anup Malani, JD, PhD
University of Chicago
Chicago, IL

9. Project No. 12-03-0043 (Reviewer- Takahashi/Molitor)

Project Title: "Health and Promotion Coaching/Vaccine for Homeless Parolees"
Principal Investigator: Adeline Nyamathi, ANP, PhD, FAAN
University of California, Los Angeles
Los Angeles, CA

10. Project No. 12-04-0083

Project Title: "Community Vulnerability and Resiliency to Heat Waves"
Principal Investigator: Martha Harnly, MPH
California Department of Public Health
Richmond, 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)

1. Project No. 11-10-03 (Reviewer-Murphy)

Project Title: "Understanding the Relation between Child Sleep Habits and Functional Outcomes"
Principal Investigator: Angela Lukowski
University of California, Irvine
Irvine, CA

H. Exemption Request

I. Next Meeting

The next CPHS meeting is scheduled for August 3, 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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If you have any questions or comments, please contact CPHS at 916-326-3660 or cphs-mail@oshpd.ca.gov.

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