

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 359
Sacramento, California 95811
(916) 326-3660 FAX (916) 322-2512

**AGENDA****COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS (CPHS)
CALIFORNIA HEALTH AND HUMAN SERVICES AGENCY**

400 R Street,
Sacramento River Room
Sacramento, CA 95811

***US Toll-Free Number: 888-636-3807**

Access Code: 963949

Friday, October 3, 2014

8:30 a.m. – 5:00 p.m.

A. General- Administrator Report

1. Reappointment of Members-Secretary Action Request (SAR) Package-Update (Rivera)
2. Cal Protects – Update (West)
3. Updates
4. Legislation (Rivera)
 - a. AB 1683 Ken Maddy California Cancer Registry, Introduced by Assembly Member Jones
 - b. AB 2059 Medical Records: Electronic Delivery, Introduced by Assembly Member Muratuschi
 - c. AB 2147 State Government Internet Website: Information Practices, Introduced by Assembly Member Melendez
5. CalProtects – Minors Checklist (Lowe)

B. Projects with Reported Adverse Events/Deviations (CPHS will decide if any action on these projects is necessary)

1. Project #: 14-02-1515 (Dickey)
Title: Consumer Engagement to Increase Advance Care Planning
PI: Amber Barnato, MD, MPH, MS
University of Pittsburgh
Pittsburgh, PA
Co-PI: Rebecca Sudore, MD
University of California, San Francisco
San Francisco, CA

2. Project #: 13-03-1140 (Murphy)
Title: Surveillance of HIV Risk & Prevention Behaviors of Men who Have Sex with Men, Injection Drug Users, and Heterosexuals
PI: Juliana Grant, MD, MPH
California Department of Public Health
San Diego, CA
3. Project #: 12-04-0119 (Ruiz)
Title: Evaluation of the Effectiveness of Tdap Vaccination Strategies at Preventing Infant Pertussis
PI: Pamala Kirley, MPH
California Emerging Infections Program
Oakland, CA
4. Project #: 12-08-0678 (Dickey)
Title: Permanency Innovations Initiative(PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
Co-PI: Andrea Sedlak, PhD
Westat
Rockville, MD
5. Project #: 12-08-0678 (Dickey) – 2nd report
Title: Permanency Innovations Initiative(PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
Co-PI: Andrea Sedlak, PhD
Westat
Rockville, MD

C. New Projects Calendar

New Projects - Full Committee Review Required

1. Project #: 13-12-1461 (Bauer)
Title: A Study in Twins to Identify a Possible Link between Blood Group Antigens and Susceptibility to Infant Botulism
PI: Stephen Arnon, MD, MPH
Co-PI: Mayuri Panditrao, PhD, MPH
California Department of Public Health
Richmond, CA

2. Project #: 14-08-1673 (Lowe)
Title: Early Socio-moral Development through Interactions with Others
PI: Audun Dahl, PhD
University of California, Santa Cruz
Santa Cruz, CA
3. Project #: 14-08-1681 (Grabau)
Title: Benefits and Limitations of the Collaborative Ceramic Art Therapy Studio
PI: Serena Duckrow, MA
Patton State Hospital
Patton, CA
4. Project #: 14-08-1671 (Trent)
Title: Commuter Exposure to Air Pollutants
PI: Walter Ham, PhD
Co-PI: Kathleen Kozawa, D. Env
California Air Resources Board
Sacramento, CA
5. Project #: 14-04-1566 (Molitor)
Title: Restaurant Program Lower Income Area Panel Survey
PI: Arie Kapteyn, PhD
University of Southern California
Playa Vista, CA
6. Project #: 14-06-1610 (Murphy)
Title: Exosomal miRNA, metabolites, and candidate factors in saliva of Schizophrenic patients
PI: Wolff Kirsch, MD
Co-PI: William Britt, PhD, ABN
Loma Linda University
Loma Linda, CA
7. Project #: 14-06-1627 (Dinis)
Title: Decision Making on Aromatase Inhibitors in Breast Cancer Survivors 65 Years and Older
PI: Huibrie Pieters
University of California, Los Angeles
Los Angeles, CA

D. New Projects - Expedited Review Requested

These 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 #: 14-07-1642 (Lowe/Palacio)
Title: Characterizing the Epidemiology of Patients Presenting to California Emergency Departments with Traumatic Brain Injuries
PI: Bharath Chakravarthy
Co-PI: Ahmed Elrefaie
University of California, Irvine
Irvine, CA

2. Project #: 14-05-1584 (Molitor/Trent)
Title: SEER Pharmacy Data Linkage Pilot
PI: Sally Glaser, PhD
Cancer Prevention Institute of California
Fremont, CA
Co-PI: Dennis Deapen, DrPH
University of Southern California
Los Angeles, CA

3. Project #: 14-07-1655 (Ruiz/Molitor)
Title: Emerging Infections Program (EIP) Innovations Evaluation of Antibiotic Prescribing Quality in Hospitalized Patients
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA

4. Project #: 14-08-1588 (Grabau/Murphy)
Title: Testing the Relationship between Presence of Violence, Type of Crime, Psychological Diagnosis and Cognitive Functioning as Measured by the Repeatable Battery for the Assessment of Neuropsychological Status (RBANS) in a State Hospital
PI: Stephen Nitch, PhD
Department of State Hospitals
Patton, CA
Co-PI: Kayla Kinworthy, MA
Loma Linda University
Loma Linda, CA

**E. Projects requiring periodic review only – (including greater than minimal risk).
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 #: 13-07-1292 (Dickey)
Title: Tolerability and Immunogenicity of Investigational Recombinant Botulinum Vaccine Combined with BabyBIG® Source Plasma Donation in Volunteers Previously Immunized with Investigational Pentavalent Botulinum Toxoid
PI: Stephen Arnon, MD, MPH
Co-PI: Jessica Khouri, MD
California Department of Public Health
Richmond, CA
2. Project #: 12-08-0585 (Murphy)
Title: Improving the Survivorship Care of Women with Breast Cancer
PI: Kimlin Ashing-Giwa, PhD
City of Hope
Duarte, CA
3. Project #: 12-08-0621 (Lowe)
Title: Restoration and Renewal: Potential for Arts in Corrections in California
PI: Larry Brewster, PhD
University of San Francisco
San Francisco, CA
4. Project #: 12-08-0690 (Dickey)
Title: An Experimental Comparison of Telepsychiatry and Conventional Psychiatry for Mentally Ill Parolees
PI: David Farabee
University of California, Los Angeles
Los Angeles, CA
5. Project #: 12-08-0630 (Lowe)
Title: California Breast Cancer Survivorship Consortium
PI: Scarlett Gomez, PhD
Cancer Prevention Institute of California
Fremont, CA
6. Project #: 12-08-0629 (Lowe)
Title: The Oncoshare Project: Creating an Anonymized Data Set for Breast Cancer Research
PI: Scarlett Gomez, PhD
Cancer Prevention Institute of California
Fremont, CA

7. Project #: 13-02-1085 (Molitor)
Title: The Connie Wofsy Women's HIV Study (Northern CA WIHS)
PI: Ruth Greenblatt, MD
University of California, San Francisco
San Francisco, CA
8. Project #: 13-07-1274 (Grabau)
Title: The Development of Compassion in the Transition to School Age
PI: Paul Hastings, PhD
University of California, Davis
Davis, CA
9. Project #: 12-06-0304 (Lowe)
Title: Minorities and Clinical Trials: Patients, Physicians, Clinical Trial Characteristics and their Environment
PI: Celia Kaplan, DrPH, MA
University of California, San Francisco
San Francisco, CA
10. Project #: 12-07-0555 (Murphy)
Title: The Effectiveness of a Screening Process for Reducing Length of Stay in Incompetent to Stand Trial (IST) Patients in a Forensic Psychiatric Hospital
PI: Barbara McDermott, PhD
University of California, Davis
Davis, CA
11. Project #: 12-08-0618 (Murphy)
Title: Healthcare-Associated Infections and Antimicrobial Use Prevalence Survey
PI: Joelle Nadle, MPH
California Emerging Infections Program
Oakland, CA
12. Project #: 12-07-0559 (Lowe)
Title: Pregnancy Outcomes of Veterans (PROVE)
PI: Ciaran Phibbs, PhD
Department of Veterans Affairs
Menlo Park, CA

13. Project #: 12-07-0533 (Dickey)
Title: Hospital Characteristics and the Quality of Cancer Care and Outcomes in California
PI: Kim Rhoads, MD, MPH
Stanford University
Stanford, CA
14. Project #: 12-08-0678 (Ruiz)
Title: Permanency Innovations Initiative(PII), Recognize Intervene Support Empower (RISE) Pilot Program and Study
PI: Curtis Shepard, PhD
L.A. Gay & Lesbian Center
Los Angeles, CA
Co-PI: George Gabel, MS, MA
Westat
Rockville, MD
15. Project #: 13-05-1216 (Murphy)
Title: Violent Behavior of Male and Female Inmates While in Custody: An Evaluation of Gender Responsive Anger Management Programs, With a Look at Motivation for Treatment and Treatment Outcomes Regarding Incidents of Violence While Incarcerated
PI: Stephanie Waldron,
California State University Stanislaus
Turlock, CA
16. Project #: 13-06-1255 (Murphy)
Title: Gestational Metabolic Conditions and Neurodevelopmental Disorders
PI: Cheryl Walker, MD
University of California, Davis
Sacramento, CA
17. Project #: 12-08-0673 (Lowe)
Title: Stress, Immunity & Cervical Cancer: Biobehavioral Outcomes of a Randomized Trial
PI: Lari Wenzel, PhD
Co-PI: Edward Nelson, MD
University of California, Irvine
Irvine, CA
18. Project #: 12-04-0161 (Murphy)
Title: Probabilistic Inference and Categorization Development in Infants
PI: Fei Xu, PhD
University of California, Berkeley
Berkeley, CA

19. Project #: 12-08-0590 (Dickey)
Title: Development of a Mid-trimester Screening Algorithm for Early-onset Preeclampsia
PI: Juan Yang, PhD
Sequoia Foundation
Richmond, CA
Co-PI: Martin Kharrazi, PhD
California Department of Public Health
Richmond, CA

F. Projects With Major Revisions Requiring Periodic Review

1. Project #: 12-07-0553 (Molitor/Trent/Bazzano)
Title: Abstract Concepts and Language Development
PI: David Barner, PhD
University of California, San Diego
La Jolla, CA
2. Project #: 13-09-1350 (Bazzano)
Title: Los Angeles Mommy and Baby Project Follow Up Project (LAMB Follow-up)
PI: Shin Chao, MPH, PhD
Los Angeles County
Los Angeles, CA
3. Project #: 12-11-0893 (Dickey)
Title: Pilot Study of Trends and Risks in Gestational Diabetes
PI: Assiamira Ferrara, MD, PhD
Kaiser Permanente
Oakland, CA
4. Project #: 13-01-1069 (Grabau)
Title: CCR-PAMF Linkage: Creating an Anonymized Dataset for Cancer Research
PI: Scarlett Gomez, PhD
Cancer Prevention Institute of California
Fremont, CA
5. Project #: 13-08-1334 (Murphy/Grabau)
Title: An Examination of Court Reports of Patients Found Incompetent to Stand Trial
PI: Barbara McDermott, PhD
University of California, Davis
Sacramento, CA

6. Project #: 12-05-0176 (Dickey)
Title: California Health Interview Survey
PI: Ninez Ponce, PhD
Co-PI: David Grant, PhD
University of California, Los Angeles
Los Angeles, CA
7. Project #: 13-12-1462 (Grabau/Lowe)
Title: Racial/Ethnic and Gender Differences in Early Stage Non-small
Cell Lung Cancer
PI: Lori Sakoda, MPH, PhD
Kaiser Permanente
Oakland, CA

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

None

H. 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).

None

I. Exemption/Determination Requests

None

J. Public Comments

K. Next Meeting

The next CPHS meeting is scheduled for Friday, December 5, 2014 in Sacramento.

L. 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 (5) 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.

The Committee for the Protection of Human Subjects (“CPHS”) encourages public attendance and participation at CPHS meetings. Additionally, CPHS established a toll-free telephone number for members of the public to monitor or participate in any CPHS meeting.

If interested, please call the telephone number and enter the access below when prompted.

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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.

California Health and Human Services Agency
Committee for the Protection of Human Subjects
400 R Street, Room 359
Sacramento, CA 95811
Phone: (916) 326-3660 Fax: (916) 322-2512
Lucila Martinez, Administrator
Lucila.Martinez@oshpd.ca.gov
cphs-mail@oshpd.ca.gov
CPHS website: www.oshpd.ca.gov/boards/cphs