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.

<table>
<thead>
<tr>
<th>Project #</th>
<th>Title</th>
<th>PI</th>
<th>Co-PI</th>
<th>University</th>
</tr>
</thead>
<tbody>
<tr>
<td>14-07-1642</td>
<td>Characterizing the Epidemiology of Patients Presenting to California Emergency Departments with Traumatic Brain Injuries</td>
<td>Bharath Chakravarthy</td>
<td>Ahmed Elrefaie</td>
<td>University of California, Irvine</td>
</tr>
<tr>
<td>14-05-1584</td>
<td>SEER Pharmacy Data Linkage Pilot</td>
<td>Sally Glaser, PhD</td>
<td>Dennis Deapen, DrPH</td>
<td>University of Southern California</td>
</tr>
<tr>
<td>14-07-1655</td>
<td>Emerging Infections Program (EIP) Innovations Evaluation of Antibiotic Prescribing Quality in Hospitalized Patients</td>
<td>Joelle Nadle, MPH</td>
<td></td>
<td>California Emerging Infections Program</td>
</tr>
<tr>
<td>14-08-1588</td>
<td>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</td>
<td>Stephen Nitch, PhD</td>
<td>Kayla Kinworthy, MA</td>
<td>Loma Linda University</td>
</tr>
</tbody>
</table>
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.

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