

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

400 R Street, Room 369
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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

Friday, April 4, 2008
8:30 am – 5:00 pm

A. General Items

1. Administrator's Report
 - A. Review of new and revised forms on CPHS website
 - B. Electronic submission of research projects status report
2. Reports from members and staff on Research Forum (2/08/08)
3. Discussion on CPHS membership status
4. Policy on frequency of "facilitated review" for projects that CPHS relies on other IRBs to review
5. Office of Human Research Protection review of projects with Department of Health and Human Services funding and involving prisoners

B. Approval of Minutes

February 1, 2008 Meeting Minutes

C. Continuing Projects Calendar - Previously approved projects requiring full committee reapproval**Projects with major revisions and requiring periodic review****Projects requiring periodic review 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. 02-12-01 (Reviewer - Lowe)
Project Title: "Social and Moral Development in Twins"
Principal Investigator: Laura Baker, PhD
USC
Los Angeles, CA
2. Project No. 00-04-04 (Reviewer - Dickey)
Project Title: "California Health Interview Survey (CHIS)"
Principal Investigator: Richard Brown, PhD
UCLA
Los Angeles, CA
3. Project No. 05-06-51 (Reviewer - Snipes)

Project Title: "Identifying Risk Areas of West Nile Virus Transmission to Humans in California Using Dead Bird Reports and a Modified DYCAST Model"

Principal Investigator: Ryan Carney
CDPH
Richmond, CA

4. Project No. 06-04-04 (Reviewer - Harris)

Project Title: "A Longitudinal Study of Social Attention in Infants"

Principal Investigator: Gedeon Deak, PhD
UC San Diego
La Jolla, CA

5. Project No. 06-10-61 (Reviewer - Harris)

Project Title: "The Effects of Churning in California's Healthy Families Program: A Study Sponsored by the California Endowment"

Principal Investigator: Gerry Fairbrother, PhD
Cincinnati Children's Hospital Medical Center
Cincinnati, OH

6. Project No. 95-04-03 (Reviewer - Snipes)

Project Title: "Human Brainstem Frequency-Following Response During Attention"

Principal Investigator: Gary Galbraith, PhD
UCLA
Pomona, CA

7. Project No. 07-04-08 (Reviewer - Haris)

Project Title: "Part II – Stay Well and Healthy! Health Risk Appraisal Project – Further Tool Development"

Principal Investigator: Joan Earle Hahn, DNSc, APRN, BC, CDDN
UCLA
Los Angeles, CA

8. Project No. 03-04-03 (Reviewer - Mihordin)

Project Title: "Economic Costs of Rabies and Expected Benefits of Implementing a Skunk Oral Rabies Vaccination Program in California"

Principal Investigator: Michele Jay-Russell, DVM, MPVM, DiplACVPM
CDPH
Davis, CA

9. Project No. 90-04-02 (Reviewer - Lowe)

Project Title: "Natural History of Chromosome Abnormalities Diagnosed Prenatally"

Principal Investigator: Ernest Hook, MD
UC Berkeley School of Public Health
Berkeley, CA

10. Project No. 07-04-55 (Reviewer - Snipes)
Project Title: "Gene-Environment Factors in Childhood Brain Tumor"
Principal Investigator: Roberta McKean-Cowdin, PhD
USC/Norris Comprehensive Cancer Center
Los Angeles, CA
11. Project No. 07-04-06 (Reviewer - Kirkish)
Project Title: "The Development of Object Representation in Infancy"
Principal Investigator: Lisa Oakes, PhD
UCD
Davis, CA
12. Project No. 05-04-54 (Reviewer - Mihordin)
Project Title: "Evaluation of the Association between Geographic Distribution and Clustering of Exemptions and Outbreak of Vaccine Preventable Diseases"
Principal Investigator: Daniel Salmon, PhD, MPH
Johns Hopkins Bloomberg School of Public Health
Baltimore, MD
13. Project No. 07-04-62 (Reviewer - Harris)
Project Title: "The Relationship between Religious Delusions and Violence: An Exploratory Study"
Principal Investigator: Justine Schmollinger, JD, MA
Pacific Graduate School of Psychology
San Francisco, CA
14. Project No. 07-06-51 (Reviewer - Harris)
Project Title: "Sterilization Consents at California State Institutions, 1910s-1950s"
Principal Investigator: Alexandra Stern, PhD
University of Michigan
Ann Arbor, MI
15. Project No. 07-04-60 (Reviewer - Harris)
Project Title: "Evaluating Different Adherence Metrics in Asthma"
Principal Investigator: Thomas Tencer, MA
USC
Los Angeles, CA
16. Project No. 01-06-05 (Reviewer - Harris)
Project Title: "Linking California Infant Birth and Death Records to Evaluate the Relationship Between Air Pollution and Infant Mortality in California"
Principal Investigator: Tracey Woodruff, PhD, MPH
US Environmental Protection Agency
San Francisco, CA
17. Project No. 06-04-55 (Reviewer - Kirkish)
Project Title: "A Taxometric Analysis of Impression Management and Self-

Deception on the MMPI-2 and Rorschach among a Criminal
Forensic Population”

Principal Investigator: Nicole, Yell
Pacific Graduate School of Psychology
Walnut Creek, 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.**

18. Project No. 02-06-08 (Reviewer - Lowe)

Project Title: “Evaluation of the Substance Abuse and Crime Prevention Act
(SACPA III)”

Principal Investigator: Darren Urada, PhD
UCLA
Los Angeles, CA

19. Project No. 08-02-04 (Reviewer - Ruiz)

Project Title: “Study of Air Pollution, Genetics and Early Life Events, SAGE”

Principal Investigator: Kathleen Mortimer, ScD, MPH
UC Berkeley
Berkeley, 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. 08-04-01 (Reviewers – Harris)

Project Title: “Evaluation of a Mindfulness-Based Stress Reduction
Program for Parents and Caregivers”

Principal Investigator: Alicia Bazzano, MD, MPH
Westside Regional Center
Culver City, CA

2. Project No. 08-04-02 (Reviewer – Dinis, English and Spanish)

Project Title: “TeenSMART Outreach (TSO) Evaluation: Use of Wed-
Based Strategies to Increase Adolescent Enrollment in
Family Planning Clinics”

Principal Investigator: Claire Brindis, PhD
UCSF
San Francisco, CA

3. Project No. 08-04-03 (Reviewer – Ward)

Project Title: “Adolescent and Young Adult Experience of Care”

Principal Investigator: Rosemary Cress, DrPH

CDPH/PHI
Sacramento, CA

4. Project No. 08-04-04 (Reviewer – Kirkish)
Project Title: “Cognitive Functioning after Breast Cancer Treatment”
Principal Investigator: Patricia Ganz, MD
UCLA
Los Angeles, CA
5. Project No. 08-04-05 (Reviewer – Ruiz, English and Spanish)
Project Title: “Forteo Post-Approval Surveillance Study: Case Series”
Principal Investigator: Alicia Gilsenan, PhD
RTI-HS
Research Triangle Park, NC
6. Project No. 08-04-06 (Reviewer – Galbraith)
Project Title: “Child Development Study: Individual Difference Factors”
Principal Investigator: Gail Goodman
UC Davis
Davis, CA
7. Project No. 08-04-07 (Reviewer – Murphy)
Project Title: “Emotion-based Mediation of Cancer-related Attitudes and Behavioral Outcomes in Adolescents: Impact of the Re-Mission Videogame”
Principal Investigator: Jana Haritatos, PhD
HopeLab
Redwood City, CA
8. Project No. 08-04-08 (Reviewer – Kirkish)
Project Title: “De-activating Command Hallucinations”
Principal Investigator: Joseph Malancharuvil, PhD, MS, ABPP
DMH Patton State Hospital
Patton, CA
9. Project No. 08-04-09 (Reviewer – Dickey)
Project Title: “National Survey of Child and Adolescent Well-Being II (NSCAW II), Baseline Study”
Principal Investigator: Kathryn Dowd, PhD
RTI International
Research Triangle Park, NC
10. Project No. 08-04-10 (Reviewer – Dickey)
Project Title: “The Effect of a Single Dose of Azithromycin on *Neisseria meningitidis* Carriage”
Principal Investigator: Kathleen Harriman, PhD, MPH, RN,9
CDPH
Richmond, 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.

1. Project No. 08-04-52 (Reviewer – Snipes)
Project Title: “Prenatal Identification of Congenital Heart Defects: An Opportunity for Mediation of Associated Morbidity and Mortality Risks”
Principal Investigator: Laura Jelliffe-Pawlowski, PhD
CDPH
Richmond, CA
2. Project No. 08-04-55 (Reviewer – Ward)
Project Title: “Perinatal Regionalization and Quality of Care”
Principal Investigator: Scott Lorch, MD, MSCE
University of Pennsylvania
Philadelphia, PA
3. Project No. 08-04-60 (Reviewer - Ward)
Project Title: “Vehicle Pollutant Emissions and Adverse Birth Outcomes”
Principal Investigator: Justin Gallagher, MPP
UC Berkeley
Berkeley, 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)

H. Exemption Request

Project Title: “Descriptive Epidemiology of Birth Defects in California”
Principal Investigator: Gary Shaw, DrPH
March of Dimes

I. Next Meeting

The next CPHS meeting is scheduled for June 6, 2008 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.

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