



UC BERKELEY HUMAN RESEARCH NEWS



Committee for Protection of Human Subjects (CPHS)
Office for Protection of Human Subjects (OPHS)

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Welcome!

JANUARY
2014
VOLUME 1
ISSUE 1

Dear Members of the UCB Human Research Community,

We are happy to introduce the first issue of our newsletter for UC Berkeley's human research investigators, administrators, and all those interested in the vital endeavor of ethical research with human subjects.

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At UC Berkeley, human research encompasses a wide variety of studies from biomedical to social-behavioral, local to international, faculty-initiated to student-initiated. Almost all require review and approval by UCB's Institutional Review Board (IRB), the Committee for Protection of Human Subjects (CPHS-1 and CPHS-2), or by its administrative support team, the Office for Protection of Human Subjects (OPHS). Together, CPHS and OPHS strive to fulfill the mission set forth in human research regulations and policies at the federal, state, and university levels: to protect the rights and welfare of those who act as subjects in human research.

We take pride in serving as chairs of the two CPHS panels; our committees include faculty, staff, and community members, scientists and non-scientists, who possess a broad range of interests and expertise in the areas of research reviewed. Dr. Becky Armstrong, the director of OPHS, oversees an outstanding team of staff analysts who coordinate reviews and assist CPHS members and investigators with protocol and compliance issues. OPHS staff help researchers develop their human research applications and informed consent documents through website guidance, online, phone, and in-person assistance, as well as educational outreach. This newsletter is meant to serve as an additional resource to our human research community.

On behalf of the CPHS and OPHS, we hope you find the enclosed news and highlights informative and enjoyable. We welcome your feedback and suggestions for features you'd like to see in upcoming issues!

Sincerely,

Robert DiMartino, O.D., M.S., F.A.A.O.
Chair, CPHS-1

Jane Mauldon, Ph.D.
Chair, CPHS-2

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Regulatory Updates

■ Federal Drug Administration (FDA) audits UC Berkeley IRB

In early November 2013, FDA representatives informed OPHS Director Becky Armstrong that they would shortly begin conducting a formal audit of UC Berkeley's CPHS/OPHS procedures and records. (While the audit was not the result of any complaint or other "for cause" reason, it had been 10 years since the FDA's last audit of the UCB IRB.)

After a week-long, in-depth perusal of numerous CPHS protocols, meeting minutes, policies and procedures, and other requested documentation, the auditor found no serious violations. CPHS/OPHS was given five "Voluntary Action Indicated observations." We are currently addressing these items, in cooperation with investigators whose studies involve investigational drugs or devices or other factors requiring FDA oversight.

■ FDA issues final guidance on Mobile Medical Applications

The FDA issued a final guidance document, "[Mobile Medical Applications Guidance for Industry and Food and Drug Administration Staff](#)", on September 25, 2013. The guidance explains the agency's oversight of mobile medical apps (MMAs), applying a focused, risk-based approach to a small subset of mobile apps. These apps meet the regulatory definition of "device" and are intended to be used as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device. See: [Examples of MMAs that require FDA review](#) and [Examples of mobile apps unlikely to require FDA review](#).

■ OHRP offers Informed Consent clarification

In September 2013, the Office for Human Research Protections (OHRP) revised its response to an Informed Consent FAQ: "When does compensating subjects undermine informed consent or parental permission?"

The response now clarifies that remuneration to subjects may include compensation for risks associated with their participation in research and that compensation may be an acceptable motive for some individuals agreeing to participate in research. For a complete list, see [OHRP Informed Consent FAQs](#).

Did You Know? (Fun facts about CPHS/OPHS)

We seek to provide flexibility in IRB requirements for UCB investigators wherever permitted by regulations. Two recent examples:

- As of March 1, 2013, stamping of approved consent forms was discontinued. As long as the consent form retains the CPHS ID number, PIs may use **unstamped versions of currently approved forms**.
- As of June 1, 2013, CPHS/OPHS began issuing **three-year approvals** (rather than one-year approvals) to qualifying protocols that are minimal risk, not federally funded, and not under federal oversight.

Special Report: Student Research at UC Berkeley

UC Berkeley has a rich history of promoting research activities by students, whether postdoctoral, graduate, or undergraduate, and CPHS/OPHS has made ongoing efforts to support student researchers over the years. These range from individual consultations with the student and/or project faculty advisor to class presentations to tailored guidance in the [Student Investigators Guide](#), posted on our website in June 2012. More recently, we focused on issues that arise for undergraduate students in particular.

Many undergraduate scholar programs include exciting and challenging research opportunities. In an effort to encourage ethical undergraduate human research endeavors, CPHS/OPHS developed extensive guidance documents for Undergraduate-Initiated Research Activities (UIRA) in 2013. The intent of UIRA guidance is to help maximize campus staff resources without sacrificing valuable research experiences for undergraduates. The two documents now available are:

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-[Ethical Issues in Undergraduate Research Activities with Human Participants](#), which outlines important points to take into consideration to protect human subjects. These include minimizing risks, protecting vulnerable groups, and ensuring voluntary participation.

-[Guidance on Designing Undergraduate-Initiated Research Activities \(UIRA\)](#), which thoroughly discusses common ethical issues and provides examples to minimize potential risks.

Spotlight on... Allison Harvey's Sleep and Mood Research

At any given time, staff analysts in OPHS are likely to be working on one of Allison Harvey's fascinating protocols. Harvey, a professor of psychology, clinical psychologist, and director of the Golden Bear Sleep and Mood Research Clinic at UC Berkeley, is a very busy investigator. Her research clinic is dedicated to improving treatments for insomnia and other sleep disturbances, as well as bipolar disorder and depression in teens and adults. Professor Harvey directs this program of treatment studies involving a number of NIMH-funded research protocols, all of which must undergo review by CPHS/OPHS on at least an annual basis.

One such project is the Teen Sleep Study, a response to the virtual epidemic of inadequate sleep and its fallout among adolescents today. The study is a unique four-year experiment to reset the circadian rhythms of "night owl" teens who have trouble going to sleep and waking up, and also suffer from emotional, social, behavioral, or academic problems (which are likely linked to their sleep patterns). Teen participants undergo six-week study sessions, including two sleepovers at the clinic where they join in motivational interventions, chronotherapy (controlling light and the timing of sleep cycles), and wind-downs such as meditation, yoga, or soaking up nature. Undergrad research assistants act as "sleep buddies," keeping the teens engaged and on task while collecting data and samples for the study.

Professor Harvey and her research program present hope for a sleep-deprived generation, and for finding new ways to help those who live with bipolar disorder and depression.

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Accolades for Our Investigators

2013 was an exciting year for UC Berkeley researchers! Among those recognized for their outstanding achievements, we congratulate:

- ✎ **William Jagust**, professor of public health and neuroscience and a leading authority on brain aging and dementia, was awarded the 2013 Potamkin Prize for Research in Pick's, Alzheimer's, and Related Diseases by the American Academy of Neurology and the American Brain Foundation. Professor Jagust received the prize for his research on plaques in the brain which may cause Alzheimer's disease. [March 2013]
- ✎ **Alison Gopnik**, professor of psychology, affiliate professor of philosophy, and a recognized pioneer in the study of children's learning and development, was named a member of the American Academy of Arts and Sciences. The AAAS is a prestigious 233-year-old national honorary society of leaders from academia, business, public affairs, and the humanities. [April 2013]
- ✎ **Alan Schoenfeld**, professor of education and mathematics, was given the 2013 Distinguished Contributions to Research in Education award by the American Educational Research Association (AERA). The prize is AERA's premier acknowledgment of outstanding achievement and success in education research, designed to publicize, motivate, encourage, and suggest models for education research at its best. [April 2013]
- ✎ **Roxanna Altholz**, assistant clinical professor of law and associate director of the International Human Rights Law Clinic, was awarded the 2013 Foundation for Change Thomas I. Yamashita Prize, which honors "a person whose work transforms the existing landscape and serves as a bridge between the academy and the community." Professor Altholz successfully represented families of individuals who were forcibly "disappeared" by Guatemalan security forces in the mid-1980's. [May 2013]
- ✎ **Meredith Minkler**, professor of health and social behavior, received the 2013 Tisch Research Prize, recognizing "a career of academic research on issues related to active citizenship." Professor Minkler was praised as one of the pioneers in community-based participatory research (CBPR), using this approach in studies of ethnic health disparities of midlife and older Americans and better health strategies for youth. [September 2013]

UC BERKELEY
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NEWS TEAM

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Please let us know about your achievements or those of your colleagues, so that we can feature them in future issues of our newsletter!

You are welcome to send any comments or suggestions regarding the UC Berkeley Human Research News to cphs_news@berkeley.edu.