



UC BERKELEY HUMAN RESEARCH NEWS



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

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Autumn and the Annual Report

Dear Members of the UCB Human Research Community,

**OCTOBER
2014**

**VOLUME 1
ISSUE 2**

As a new academic year begins, we are happy to present the second issue of *UC Berkeley Human Research News*. Each year at this time, the UCB Committee for Protection of Human Subjects and the Office for Protection of Human Subjects submit our Annual Report to Vice Chancellor for Research Graham Fleming and the Research Compliance Advisory Committee. Once accepted, the report becomes available to the campus at large via the CPHS website.

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1 Letter from the
Chairs

This year's Annual Report (July 1, 2013 to June 30, 2014) reflects how human research is supported at UCB, including the effects of a policy change on approval periods. Utilizing flexibility in UCB's FWA (Federalwide Assurance), in June 2013, CPHS/OPHS began issuing *three-year approvals*, rather than one-year approvals, for all qualifying protocols – those found to be minimal risk, not federally funded, and meeting several other criteria.

2 Regulatory, Policy &
Guidance Updates

Numerous UCB investigators have benefitted from this revised policy. For full-Committee new and continuing reviews, 13 protocols out of 53 (25%) were approved as minimal risk and otherwise qualified for three-year approvals. For expedited new and continuing reviews, 644 out of 893 (a full 75%) received three-year approvals!

Did You Know?

3 Bioethics Webinar at
OPHS 10/7/14

As the Chairs of CPHS-1 and CPHS-2, we look forward to continuing our work with the expert, dedicated Committee members and OPHS staff we are fortunate to have, to guide and assist the UC Berkeley research community in upholding the highest standards of human research.

Spotlight On...
George Brooks'
Physiology Research

4 Accolades for Our
Investigators – 2014

We hope that you enjoy the enclosed news and features, and we welcome your feedback and ideas on what 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, Policy, and Guidance Updates

■ UCB human subjects training requirements updated to improve research compliance

In May 2014, the [CPHS Training and Education Policies and Procedures](#) were updated to ensure that all principal investigators, post docs, research staff, graduate and undergraduate students, and volunteer research staff who conduct human subjects research receive training in the ethics, regulations, guidelines, and policies that protect the rights and welfare of the participants. These updated education and training requirements bring UC Berkeley more in line with other major institutions carrying out human research.

Faculty (with limited exceptions as noted in the P&Ps), staff, and students wishing to engage in human subjects research must first complete either the biomedical or social-behavioral human research course (whichever is more germane) through the *Collaborative Institutional Training Initiative (CITI)* (see <http://cphs.berkeley.edu/training.html>). CITI course completion must be certified in the eProtocol application for all affected study personnel before CPHS will approve a new protocol, addition of personnel to an existing protocol, or a continuing review protocol.

■ Research records retention for UCB investigators

As now explained in our website FAQs (<http://cphs.berkeley.edu/fags.html>), research record retention rules for investigators vary depending on factors such as study sponsor, subject population, use of protected health information, federal regulations, and the Food and Drug Administration (FDA) regulations when applicable. Investigators should refer to the University of California Office of the President (UCOP) [Administrative Records Relating to Research: Retention and Disposition Requirements](#) document for more details.

■ FDA issues draft guidance on specific devices

In June 2014, the FDA issued draft guidance stating that it does not intend to enforce compliance with regulatory controls which apply to medical device data systems (MDDS), medical image storage devices, and medical image communications devices, due to the low risk they pose to patients and the importance they play in advancing digital health. CPHS will update UCB investigators when such guidance is finalized.

Did You Know? (More from our 2013-2014 Annual Report)

- *Crunching the numbers:* Human subjects research review/approval activity for CPHS and OPHS (new, continuing, and amendment applications) increased by close to 100 protocols (1688 to 1786), while OPHS staffing (9.5 FTE) remained constant.
- *Leadership in human subjects protection:* The CPHS policy on Data Security is referenced in the Secretary's Advisory Committee on Human Research Protections (SACHRP) document, "Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations."

Free Webinar on Bioethics in Management of Incidental and Secondary Findings – Tuesday Oct. 7, 2014 / 10-11:30 am (PDT)

Join us at OPHS as Elizabeth Pike, JD, LLM and Nicolle K. Strand, JD, M. Bioethics, from the Presidential Commission for the Study of Bioethical Issues (Bioethics Commission), present “Anticipate and Communicate for IRBs: Ethical Management of Incidental and Secondary Findings.” PRIM&R (Public Responsibility in Medicine and Research) and the Bioethics Commission have partnered to offer this thought-provoking webinar free of charge. Space is limited; **RSVP** to ophs@berkeley.edu or call 510-642-7461 to reserve your place.

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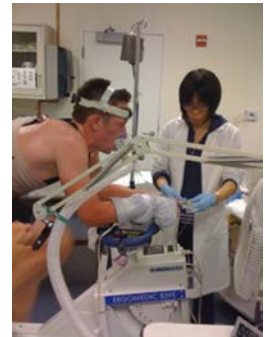
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Spotlight on... George Brooks' Physiology Research

A young man is doing some serious bike-pedaling on the UC Berkeley campus, but not with the usual purpose or destination. In fact, the pedaling is taking place in the lab of Professor George Brooks, and the young man has consented to participate as a subject in his study on exercise physiology and metabolism. Prof. Brooks designs and conducts research studies to investigate how the human body uses lactate, fatty acids, carbohydrates, and amino acids. This ongoing work has already had important practical applications.

As a track athlete in college, George Brooks began reading up on breathing, circulation, metabolism, and nutrition to understand his own performance. But he gradually realized that there were many deficiencies in the literature and determined to become an exercise physiologist. As he notes, “The more I learned, the more I realized that lessons learned on the track and in the research have vast implications for human health and disease.”



One working hypothesis to come from this research is the *Lactate Shuttle*, a mechanism that allows some muscles to produce lactate that is used by the heart and other muscles as a fuel source. A second hypothesis is the *Crossover Concept*, which describes how the body switches between fat and carbohydrate metabolism at different times, e.g., during exercise, sleep, or work on the computer.

Most recently, Prof. Brooks collaborated with UCLA neurosurgery researchers to understand how brain metabolism works in victims of traumatic brain injury. They discovered that the brain can use both lactate and glucose as energy sources, but after injury, the brain's ability to use glucose shuts down, while lactate can still be oxidized. Research continues on possible use of lactate to fuel the injured brain, improving chances for recovery. Moreover, this research has broad implications for healing in many types of injury and chronic illness.

Other aspects of his research might well help address the obesity epidemic in this country. Several years ago, Prof. Brooks was asked to serve on a scientific panel that proposed some significant changes, including exercise for at least one hour a day (twice that recommended in the 1996 Surgeon General's Report on Physical Activity and Health). In addition to ongoing research and teaching at UC Berkeley, Prof. Brooks has co-authored what is widely considered to be the best textbook in the field of exercise physiology and metabolism.

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Accolades for Our Investigators

Among the many UC Berkeley researchers whose achievements have been recognized in 2014, we congratulate:

- ✎ [Austin Roorda](#), Professor of Optometry and Vision Sciences and chair of the vision science graduate group. He was awarded a 2014 Guggenheim Fellowship, which is given for “impressive achievement in the past and exceptional promise for future accomplishment.” Prof. Roorda has pioneered and used advanced technology, including adaptive optics (AO), for studying the visual system, and is the inventor of the Adaptive Optics Scanning Laser Ophthalmoscope. In previous collaboration with UCSF researchers, he tested a treatment to slow retinal degeneration. [April 2014]
- ✎ [David Collier](#), Professor of Political Science. He won Uppsala University’s Johan Skytte Prize, described by the Swedish institution as “one of the greatest and most prestigious awards in political science,” for his contributions to concept development and qualitative analysis methods in political science. At UCB since 1978, Prof. Collier has served as chair of the political science department and the Center for Latin American Studies, and was founding co-director of the Berkeley-Stanford Program in Latin American Studies. [April 2014]
- ✎ [Edward Miguel](#), Professor of Economics and director of the Center for Effective Global Action. He is one of a number of inspiring UCB faculty, staff, and students who received the 2014 Chancellor’s Awards for Public Service. His research interests focus on African economic development and include economic causes and consequences of violence, impact of health status on education and productivity, and AIDS orphans. He has conducted field work in Kenya, Sierra Leone, Tanzania, and India. Prof. Miguel received the Chancellor’s Public Service Award for Research in the Public Interest. [May 2014]
- ✎ Among other UCB researchers honored for their public service were [Victoria Robinson](#) (Lecturer, Ethnic Studies, American Cultures; director, the American Cultures Engaged Scholars [ACES] program), who received the Service-Learning Leadership Award, and [Wendy Hernandez](#), (fourth-year American Studies major), who received the Mather Good Citizen Award. [May 2014]

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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.