



UC BERKELEY HUMAN RESEARCH NEWS



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

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Spring Things: New UCB Exempt Category 7 and CPHS Membership

APRIL
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VOLUME 2
ISSUE 1

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Dear Members of the UCB Human Research Community,

Once again, we are happy to introduce the latest issue of *UC Berkeley Human Research News*. In this letter, we'd like to call your attention to several important topics related to human subjects research at UC Berkeley.

The first item will be great news to investigators who wish to conduct minimal-risk research that appears to be "exempt" but does not fit any of the six categories for exemption described in the federal regulations on human research (45 CFR 46).

A seventh category of exempt research activities has been defined by CPHS and OPHS, using flexibility in UCB's Federalwide Assurance. Projects may qualify per the *inclusion/exclusion criteria* outlined in our new *Exempt Research* guidelines and *Policies & Procedures* documents. This updated guidance is now available on the CPHS/OPHS website (<http://cphs.berkeley.edu>) and has been incorporated into the eProtocol application system. See the article inside and check out our website for more details!

The second item is an invitation to UCB faculty to join CPHS-1 or CPHS-2. At this time of year, we are always looking for members to replace those who are rotating off the committees. If you wish to share your expertise, acquire and apply knowledge about ethical and regulatory issues, and "give back" to our dynamic UC Berkeley research community, we encourage you to contact OPHS Director Becky Armstrong for further information in this regard.

As always, we hope that you enjoy the enclosed news and features, and welcome your feedback for upcoming issues.

Sincerely,

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

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

Regulatory, Policy, and Guidance Updates■ **UCB Exempt Category 7 joins federal Exempt Categories 1 to 6**

A new UCB category for exempt review is now available! Using the flexibility under UC Berkeley's Federalwide Assurance (FWA), CPHS and OPHS have delineated a seventh UCB category for research activities that are minimal-risk and meet other inclusion standards for exemption, but do not fit into any of the six exempt categories defined in the federal human research regulations. Our intent is to reduce regulatory burden on researchers.

*Activities that fit into **Category 7** may include* (but are not limited to): non-physically invasive interventions or performance of tasks such as reading, writing, or drawing; physical activities such as walking, sitting, or manipulating an object; computer tasks or Internet searches; talking and/or listening to words, then making selections, or "think-aloud" exercises; viewing media; role-playing; completing a specific physical or mental action ("imagining"); passive monitoring of space (environment) with sensors; playing a game; and/or height or weight measurements.

To qualify for exemption under UCB Category 7, a research project must be comprised of minimal-risk activities *only*. It will not qualify if any other specified exclusions apply, including involvement of federal funding or regulation, vulnerable subject populations (such as children or prisoners), biomedical or clinical interventions, or deception of subjects. A **complete list of exclusions** is outlined in our CPHS [Exempt Research](#) Guidelines as well as the [Determination of Exemption](#) Policies & Procedures. Be sure to read these updated guidance documents for details about what activities may or may not be included in all seven exemption categories.

Please note: Individual investigators do not have the authority to determine that their own research qualifies for exempt status; this decision must be made by OPHS staff, upon review of a Request for Determination of Exempt Status application submitted by the investigator.

■ **OHRP drafts "standard of care" guidance**

Responding to the storm of controversy surrounding a 2013 NIH-funded trial of oxygen saturation levels in preemies, the HHS Office for Human Research Protections (OHRP) has developed guidance on how risks posed by "standard of care" studies like the oxygen trial should be disclosed to potential participants. The draft guidance, published 10/24/14, reaffirms the basic precepts of informed consent as a foundation of ethical conduct in research, says OHRP Direct Jerry Menikoff. (See <http://www.hhs.gov/ohrp/index.html>.)

■ **NIH changes general definition of "clinical trial"**

Effective 1/25/15, NIH defines "clinical trial" as "a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes." The new definition is "designed to make the distinction between clinical trials and clinical research studies clearer, and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials."

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Brains at Berkeley!

A small sampling of intriguing news about UCB research on the human brain:

■ BRAIN Initiative research grants - major awards to UCB researchers

On 9/30/14, National Institutes of Health (NIH) announced its first research grants related to President Obama's Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative, including awards to UC Berkeley totaling nearly \$7.2 million over three years:

[John Ngai](#), Professor of Neuroscience and director of the QB3 Functional Genomics Lab, and his UCB colleagues will **profile brain cells**, using new techniques for identifying and isolating different neurons, then sequencing their genes. [David Feinberg](#), Adjunct Professor of Neuroscience, and his collaborators at UCSF, Harvard, and Duke Universities will increase the detail of magnetic resonance imaging (MRI) more than 30 times over today's most powerful MRI scanners. A new technique, MR Corticography, will be used for **surface imaging of the brain**. [Richard Kramer](#), Professor of Molecular and Cell Biology and chair in Molecular Biology of Diseases, and [Ehud Isacoff](#), Professor of Molecular and Cell Biology and director of the Helen Wills Neuroscience Institute, will add **photoswitches** to the neurotransmitter receptors in the brain so they can be turned on or off with light to study their roles in brain circuits.

■ Research finds neural compensation in people with Alzheimer's-related protein

According to a recent study led by UCB's [William Jagust](#), the human brain is capable of a neural workaround that can compensate for a buildup of beta-amyloid, a destructive protein associated with Alzheimer's disease. As Dr. Jagust, who holds joint appointments at Helen Wills Neuroscience Institute, the School of Public Health, and Lawrence Berkeley National Lab, explained about the exciting findings, "This study provides evidence that there is plasticity in the aging brain that appears to be beneficial, even in the face of beta-amyloid accumulation." Though it remains unclear why some people are better at using different parts of their brain than others, Jagust said, "I think it's very possible that people who spend a lifetime involved in cognitively stimulating activity have brains that are better able to adapt to potential damage." (See [full UCB Newscenter article](#) here.)

■ What babies tell us about artificial intelligence

At the annual World Economic Forum in Davos, Switzerland in January, [Alison Gopnik](#) was a panel member of an "SRO" discussion on artificial intelligence. Professor Gopnik drew on her extensive research and expertise in developmental psychology and philosophy to share some insights on a hot topic: can/might computers make decisions better than people? [In her related post](#), Gopnik quotes Alan Turing, who not only proposed "the imitation game" to test if a machine is intelligent, but also noted that the real secret to human intelligence is our ability to learn, and thus a key achievement would be to design a machine that was like a child, not an adult. Gopnik describes how research in the last 15 years has shown three things even very young children can do which are far ahead of anything done by current computers, which can only process the data they are given: 1) Children are good at *choosing or creating a hypothesis* (out of infinite possibilities) *and then testing it*. 2) Children can *explore the world around them*, a crucial part of scientific learning. 3) Children can *learn by getting information from the other people around them in a number of surprisingly sophisticated ways*.

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More on brain research and bioethics...

The Presidential Commission for the Study of Bioethical Issues (**Bioethics Commission**) has just released *Gray Matters: Topics at the Intersection of Neuroscience, Ethics, and Society*. This is the second volume of the Commission's two-part response to President Obama's request related to the BRAIN Initiative.

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Accolades for Our Investigators

We add our congratulations for these well-deserved recognitions:

- ✎ Evelyn Nakano Glenn, Professor of Gender and Women's Studies and Ethnic Studies, and Mark A. Richards, Professor of Earth and Planetary Science, were the recipients of UC Berkeley's 2014 Chancellor's Award for Advancing Institutional Excellence. As noted by Chancellor Dirks in announcing the awards, the CAAIE is presented to UCB faculty "who have an extraordinary record of accomplishment in promoting diversity while advancing equity and inclusion through their scholarship, research, teaching, and public service." Professor Glenn is internationally recognized as a sociological scholar, and has done groundbreaking research on women's work, US labor and citizenship, comparative race and ethnic studies, and Japanese American experience. She is the Founding Director of UCB's Center for Race and Gender, a highly regarded student mentor, and has long been involved in a wide range of diversity and social justice initiatives. Professor Richards has provided visionary campus and national leadership in increasing diversity in the STEM fields during his 12-year tenure as Dean of Berkeley's Mathematical & Physical Sciences Division. He has designed and promoted numerous innovative and widely acclaimed programs, and has played a pivotal role in increasing diversity both in the Mathematical & Physical Sciences faculty and students earning PhDs in STEM. (November 2014)

- ✎ The [UC Berkeley Human Rights Center](#) was recognized by The MacArthur Foundation with a 2015 [MacArthur Award for Creative and Effective Institutions](#). From gathering evidence of Saddam Hussein's abuse of Iraqi Kurds to interviewing former Guantanamo detainees about torture and documenting the needs of sexual violence survivors, the Human Rights Center has conducted research on war crimes and other serious human rights violations for more than 20 years. The center has trained hundreds of students and advocates as well. "We have been on the frontlines providing local non-governmental organizations and international criminal courts with the scientific and technological tools to hold perpetrators accountable, reintegrate child soldiers, and reunite families separated by war," said faculty director Eric Stover, who has led this remarkable organization since 1996. The award comes with \$1 million, which the center will use to establish an endowment and to expand its sexual violence program. (February 2015).

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