UC BERKELEY HUMAN RESEARCH NEWS

Committee for Protection of Human Subjects (CPHS) cphs.berkeley.edu
Office for Protection of Human Subjects (OPHS) ophs@berkeley.edu

FALL 2015

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Falling Into Place

Dear Members of the UCB Human Research Community,

We welcome you to the latest issue of *UC Berkeley Human Research News*, containing several topics of interest.

This fall there is big news for all those undertaking human research throughout the nation: in September, DHHS issued an NPRM (Notice of Proposed Rule Making), which proposes significant changes to the federal policy for the protection of human subjects (regulations found at 45 CFR 46).

This is in follow-up to the Advanced Notice (ANPRM) which DHHS released and solicited comment on over four years ago. Comments on the new proposals are again being requested, this time with a relatively short deadline set for December 7, 2015. (See article on page 2 for details.)

This issue also has features on "local" news and updates, including recently created and revised guidelines of various types offered as resources by CPHS and OPHS to assist UC Berkeley researchers. And of course, we note with pride a sampling of academic accolades received by our outstanding UCB investigators.

As usual, we hope that you enjoy the enclosed news and features, and Invite 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

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Regulatory, Policy, and Guidance Updates

- **DHHS Issues New NPRM (Notice of Proposed Rulemaking)**

On September 8, 2015, the U.S. Department of Health and Human Services (DHHS), along with 15 other federal departments and agencies, issued a Notice of Proposed Rulemaking. This NPRM proposes revisions to modernize, strengthen, and make more effective the Federal Policy for the Protection of Human Subjects (45 CFR 46), which was promulgated as "the Common Rule" in 1991.

The NPRM is in follow-up to the ANPRM (Advanced Notice) issued over four years ago. As stated by DHHS, the goal of these revisions is "to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for investigators." The proposed changes are designed to continue upholding the ethical principles which the Common Rule is based on, but apply them to the current social, cultural, and technological environment.

The NPRM proposes significant changes to 45 CFR 46, including:

- Designation of certain categories of activities as "excluded" from the need for IRB review (as they are not research or are inherently low risk).
- Addition of new categories of "exempt" research to recognize changes in the scientific landscape and better match review level to risk level. A new process would allow exempt determination without any administrative or IRB review.
- Elimination of renewal requirements for expedited approvals and studies where researchers have completed interventions and are only analyzing data or doing observational follow-up as part of standard clinical care.
- Establishment of new consent requirements for collecting biospecimens for future use/tissue repositories, such that waiver or alteration of consent for research involving biospecimens (regardless of identifiability) will occur only in very rare circumstances.
- Acceptance of single IRB review for multicenter clinical trials.

The 519-page Notice includes 88 questions for which DHHS is seeking public comment. DHHS set its deadline for comments on the NPRM as December 7, 2015. In response, UC Office of the President (UCOP) has asked for comments from the UC campus IRB directors and other main UC stakeholders. UCOP will use this input to develop system-wide comments on the proposed Rule.

Please note that investigators are free to respond on an individual basis as well. For further information on the NPRM, see the Office for Human Research Protections (OHRP) website at http://www.hhs.gov/ohrp/index.html.

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More Assistance/Guidance for UCB Researchers

- **Qualtrics for online surveys**

UC Berkeley has obtained a site license with Qualtrics that is available *at no cost* to UCB researchers. Qualtrics is an online survey software tool that can be used to create and launch surveys, store and analyze collected data, and provide reports. UCB personnel can create an account and get started with Qualtrics by visiting https://berkeley.qualtrics.com. For support/questions, please contact Qualtrics at support@qualtrics.com or the D-Lab at qualtrics-support@lists.berkeley.edu. To comply with UCB minimum security standards, researchers planning to conduct on-line survey research should use either UCB Qualtrics or Google Forms through UCB bDrive (see https://support.google.com/docs/answer/87809?hl=en and/or contact CSS IT at http://sharedservices.berkeley.edu/it/). When using either tool, the Confidentiality section of eProtocol should specify what the system's data security features are, and whether IP addresses (a potential identifier) will be collected.

- **Obtaining a Materials Transfer Agreement/Data Use Agreement (DUA)**

Researchers wishing to obtain data or specimens from other institutions need to contact the UC Berkeley Industry Alliance Office at iao@berkeley.edu for assistance in obtaining a Materials Transfer Agreement. This document, also known as a Data Use Agreement (DUA), may be required for submission to CPHS, depending on what specimens or data (e.g., a Limited Data Set from a HIPAA-covered entity) are being sought. Investigators should contact OPHS at 642-7461 for assistance on CPHS requirements for secondary data research or other relevant research proposals.

- **New and updated CPHS/OPHS Guidelines**

Over the last year, we've been hard at work on updates and new guidance in several important areas. Check out our CPHS/OPHS Guidelines page, which now includes:

***Major updates*:**

- Exempt Research (*with new UCB Category 7*)
- HIPAA and Human Subjects Research
- International Research (plus new web page – see below*)
- Internet-Based Research

New guidance:

- Drugs and Medical Devices in Research
- Electrical or Magnetic Brain Stimulation Research
- *Human Subjects Research in an International Setting

In progress/Coming soon:

- Genetics/Genomics Research
- Mandated Reporting
- Secondary Analysis of Existing Data

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Accolades for Our Investigators

We congratulate the deserving recipients of these recognitions:

- **Rodolfo (Rudy) Mendoza Denton**, Richard & Rhoda Goldman Professor of Psychology, was the recipient of UC Berkeley's 2015 Chancellor's Award for Advancing Institutional Excellence (CAAIE). As noted by Chancellor Dirks in announcing the award, Professor Mendoza-Denton "passionately embodies the spirit of the CAAIE through all aspects of his academic work, as well as his efforts to foster an equitable and inclusive climate on our campus. He is a pioneering scholar and public intellectual on issues of intergroup relations, stigma, prejudice, and inequity in educational contexts." (*October 2015*)

- Recipients of the 2015-16 Presidential Chair Fellows Curriculum Enrichment Grants included these human research investigators, who were part of faculty teams receiving grants to transform core areas of undergraduate curriculum:
  Malcolm Potts, Professor of Public Health – School of Public Health, Department of Community Health & Development: *Survival 101: Taking Control of Your Future.*
  Darren Zook, Lecturer of Peace and Conflict Studies – College of Letters and Sciences, International and Area Studies Academic Program: *A New and Coherent Design for Peace and Conflict Studies (PACS) Curriculum.*
  Eric Stover, Adjunct Professor and Faculty Director, Human Rights Center, School of Law: *Engaging Undergraduate Students in Human Rights Research*. (*August 2015*)

- **Na'ilah Nasir**, Professor in the School of Education and the Department of African American Studies, was appointed as UC Berkeley's next Vice Chancellor for Equity and Inclusion, beginning her term on November 1, 2015. The appointment was the culmination of a comprehensive national search. All agreed that "the combination of Professor Nasir's extraordinary academic credentials, significant administrative experience, and long-standing commitment to the cause of equity and inclusion uniquely position her to advance Berkeley's leadership role in the field." (*July 2015*)

- Faculty who are also human research investigators were honored with the 2015 Distinguished Graduate Student Mentoring Award:
  Edward Miguel, Professor of Economics, received the Award for Senior Faculty.
  Alison Post, Assistant Professor of Political Science and Global Metropolitan Studies, received the Award for Junior Faculty. (*April 2015*)

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