



UC BERKELEY HUMAN RESEARCH NEWS



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

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“Spring is the time of plans and projects.” (-Leo Tolstoy)

**SPRING
2017**

**VOLUME 4
ISSUE 1**

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Dear Members of the UCB Human Research Community,

We welcome you to this issue of *UC Berkeley Human Research News*, which brings you up to date on our latest “plans and projects,” and looks ahead to developments at UC Berkeley and the greater research world.

Inside, you will find information on newly reduced requirements for CPHS application attachments (e.g., surveys, questionnaires, and interview guides). We also alert you to recent updates of important CPHS guidance documents as well as guidelines/tools for ethical research from other sources, and discuss current status of major revisions to the Federal Policy for the Protection of Human Subjects (“the Common Rule”).

Big changes are afoot in the office this spring/summer, as four of our expert and valued staff members depart. CPHS-2 and CPHS-1 Administrators Louise Tipton (12 years) and Diana Holt (8 years) will both be retiring at the end of June. Analyst Alexis Clasca (7 years) is relocating to the East Coast, and analyst Carmen Lam (5 years) has been accepted to the UCB School of Law. We thank them all for their dedicated service, as OPHS Director Becky Armstrong moves to fill the four open positions as soon as possible!

On behalf of CPHS and OPHS, we hope that you will support us in our continued efforts to provide excellent education and service to our UCB researchers.

Sincerely,

William Jagust, M.D.
Chair, CPHS-1

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

More Resources & Time-Savers for UCB Researchers

» **Reduced Requirements for Study Instrument Attachments (e.g., Surveys, Questionnaires, and Interview Guides):** See our [new guidance](#) which allows CPHS protocol approval with attachment of draft (rather than final) versions of study instruments for qualifying submissions.

» **Reduced Requirements/Increased Privacy Protections re Pregnancy Exclusion in MRI Studies:** See our [updated guidance](#) on MRI (Magnetic Resonance Imaging) in Research, which removes the previous requirement that subjects of child-bearing potential must take a pregnancy test and give the results to researchers to prove eligibility for study participation. Under Revised guidelines, subjects will simply be informed of the exclusion and asked to affirm non-pregnancy.

» **Compensation of Research Subjects:** See our [updated guidance](#) which now provides clarification regarding legal aspects of using drawings (sometimes termed “lotteries” or “raffles”) as methods of compensation for subjects, and also gives information on the UC Berkeley Human Subject Prepaid Card Program (HSPC).

» **Secondary Analysis of Existing Data:** See our [updated guidance](#) for research involving the secondary use of existing data. This guidance includes a helpful “Secondary Data Matrix” with information and examples that can aid investigators in determining whether their planned study comprises “human subjects research (HSR)” per the regulations.

» **Attachment Checklists for Exempt and Non-Exempt Applications:** See our updated Attachment Checklists for [Exempt](#) and for [Non-Exempt](#) eProtocol applications for the latest information. In some cases, CPHS requirements for attachments have been reduced (e.g., study instruments and CITI training certifications).

COMING SOON! We are also at work on additional resources, e.g.:

» **Guidelines on Suicidal Ideation in Protocols:** New guidance is being developed to assist investigators in considering potential issues raised by including questions related to suicidality in research studies, and to clarify CPHS expectations.

» **Informed Consent, Child Assent, and Parent Permission Guidance:** Updated versions of guidelines and instructions, sample consent/assent/permission forms, and the online tool Consent Builder are in progress.

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Regulatory, Policy, and Guidance Updates

▪ **Status of Revisions to Federal Policy for the Protection of Human Subjects, 45 CFR 46 (the Common Rule)**

On January 19, 2017, long-awaited final Common Rule revisions were published in the Federal Register by the Office of Human Subjects Protection (OHRP). (See summary of revisions to the Rule [here](#).)

On January 20, 2017, the White House issued a memorandum to federal agencies freezing all pending federal regulations for 60 days. Although this 60-day period ended March 20, there have been no updates yet as to the status of the pending final revisions.

Thus, UC Berkeley’s IRB (and others across the nation) are waiting to hear when and how the new Common Rule revisions will be adopted and implemented. Until then, UCB will follow the current Common Rule.

If and when these final revisions are adopted, some of the changes that may affect our campus include:

- * Changes to the consent form process to provide subjects with a better understanding of the research.
- * New exempt categories of research based on level of risk.
- * Removal of requirement to conduct continuing review of ongoing research studies where such review does little to protect subjects.

We will continue to closely track the status of the Rule revisions, and will keep campus investigators and other stakeholders informed as soon as new information becomes available.

▪ **Updated “International Ethical Guidelines for Health-Related Research Involving Humans”**

In December 2016, the Council for International Organizations of Medical Sciences (CIOMS), in collaboration with the World Health Organization (WHO), published [these guidelines](#) to replace guidance last issued in 2002. If you are an international researcher with medical-related projects, be sure to check [here](#) for up-to-date resources.

▪ **“Navigating Ethics in the Digital Age: Introducing Connected and Open Research Ethics (CORE), a Tool for Researchers and IRBs”**

Emerging technologies in the past decade have spawned the fields of mHealth and digital medicine, but also created new ethical and regulatory challenges. See this interesting [article](#) about the recently launched CORE initiative, which involves researchers and IRB affiliates in developing dynamic and relevant ethical practices to guide these new areas of research.

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Accolades for Our Investigators

CPHS and OPHS add our congratulations to these 2017 award recipients:

☞ **David Card**, PhD, Class of 1950 Professor of Economics at UC Berkeley and Director of the Labor Studies Program at the National Bureau of Economic Research, is one of the winners of the 2017 Carol D. Soc Distinguished Graduate Student Mentoring Awards. Card's research interests include inequality, racial disparities, education, and immigration. For his various CPHS protocols, he has acted both as principal investigator and faculty sponsor for student-initiated projects.

☞ **Karen Chapple**, PhD, Professor of City and Regional Planning, has been awarded a 2017 Chancellor's Award for Public Service, in the category of Faculty – Research in the Public Interest. Chapple studies the governance, planning, and development of regions in the US and Latin America, with a focus on housing and economic development. As a faculty affiliate of the Institute of Governmental Studies and the Institute for Research on Labor & Employment, she is currently engaged in three research projects related to sustainability planning.

☞ **Khalid Kadir**, PhD, an Institute of Governmental Studies Affiliated Faculty member and Lecturer at UC Berkeley, has received UCB's Distinguished Teaching Award, the campus' highest honor for teaching. Kadir teaches courses in the Global Poverty & Practice (GPP) program, Political Economy, and the College of Engineering. He has gained recognition from both students and colleagues for his accomplishments and service to others. His course evaluations reflect his students' overwhelming enthusiasm for his engaging yet challenging instruction.

☞ Joint recipients of the 2017 UC Berkeley Faculty Service Award are:
David Lieberman, PhD, James and Isabel Coffroth Professor of Jurisprudence. Lieberman's service includes contributions as a member and co-chair of the Committee on Research, as associate dean of the Law School, and as head of the Legal Studies undergraduate program. He also headed the Task Force on Jewish Studies, successfully turning around and re-vitalizing the program.

Trond Petersen, PhD, Professor of Sociology. Petersen's service includes chair of the Department of Sociology, associate dean for Social Sciences, and chair of Status of Women and Ethnic Minorities. He has also made big contributions to the campus in the area of international education, building the Berkeley International Study Program and founding the Peder Sather Center.

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NEWS STAFF

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EDITOR'S NOTE: As of July 1, 2017, I will be retiring after almost 30 years of service with UC, the last 12 at Berkeley. I would like to express my deep admiration to the CPHS members and my OPHS colleagues for the vital work they do in protecting research subjects, and my gratitude for the opportunity to contribute to this endeavor!