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 2016

VOLUME 3 ISSUE 1

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A Cornucopia of Changes

Dear Members of the UCB Human Research Community,

We welcome you to the latest issue of *UC Berkeley Human Research News*! This issue highlights a number of newly added resources and changes made by CPHS/OPHS this year in an effort to "lighten the load" on UC Berkeley investigators wherever possible. We continue our efforts to use the flexibility in UCB's Federalwide Assurance, while complying with regulations and maintaining our commitment to our primary mission – to protect the rights and welfare of those who participate as subjects in human research.

It has been a year of changes on many levels. In March, we welcomed our new Vice Chancellor for Research, Paul Alivisatos, PhD. In June, we bid thanks and farewell to Prof. Robert DiMartino, after five years of his dedicated service as Chair of CPHS-1, when he departed UC Berkeley to join the New England College of Optometry. (The co-signator of this letter, Prof. Jane Mauldon, notes that CPHS/OPHS felt fortunate when Dr. Bill Jagust agreed to take up the Chair baton again, having served before as Chair of CPHS-1 and as a member of both CPHS panels.) August saw another transition with the departure of the OPHS assistant director to UCSC; staff are working harder than ever until that position can be filled.

We hope you enjoy this newsletter, and encourage you to take advantage of the numerous ways in which CPHS and OPHS are striving to improve service to the research community and minimize regulatory burden.

Sincerely,

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

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

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New Resources & Time-Savers for UCB Researchers

PowerPoint for Training Your Staff – "Working with Research Study Participants: An Overview

CPHS/OPHS is proud to introduce a great resource for UCB researchers who conduct studies that engage external collaborating staff. Unless the collaborators can receive appropriate training in human subjects research through an affiliated institution, the UCB researcher must assure that such training takes place. Rather than impose CITI training on individuals with limited study responsibilities, UCB researchers often seek guidance on how to conduct the staff training themselves.

Help is here! To access our user-friendly PowerPoint presentation template, check out Working With Research Study Participants: An Overview, as well as the FAQ with informative notes on this topic.

Expanding Applicability of Exempt Category 1

Federal regulations at 45 CFR 46.101(b) describe six categories of research that may be eligible for exemption from expedited or full committee review. Category 1 reads: "Educational Practices: Research conducted in established or commonly accepted educational settings, involving normal educational practices such as: (i) research on regular and special education instructional strategies; or (ii) research on the effectiveness of, or the comparison among, instructional techniques, curricula, or classroom management methods." CPHS/OPHS has now expanded its interpretation of *"normal educational practices"* to include certain projects conducted by teachers for professional development purposes.

Reducing Submission Requirements

CITI certification: In the past, PIs were required to include CITI human subjects training reports for all study team members as attachments in their eProtocol submissions. OPHS recently lifted this administrative task from PIs; OPHS staff will check CITI records to verify training of all listed personnel.

Draft versions of certain study instruments acceptable: CPHS/OPHS currently requires that final content of all study instruments (e.g., surveys, questionnaires, interview guides) be included in the submission before approval can be given. Stay tuned to our website for upcoming details on instruments in minimal risk studies that can be accepted/approved with *draft* content.

Minor protocol changes to be made by OPHS staff with okay by researchers: Also coming soon: When minor changes are required by CPHS/OPHS during review, staff may revise the protocol directly as a time-saver for researchers.

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Finding Further Flexibility in UCB's Federalwide Assurance

Over the last several years, CPHS and OPHS have worked hard to find and implement changes related to flexibility in UCB's Federalwide Assurance (the written commitment we hold with OHRP in which UCB promises to comply with applicable federal regulations governing human subject research, and stipulates the procedures for doing so). Flexibility is sought to reduce administrative burden on campus investigators and increase efficiency of CPHS/OPHS, while continuing to honor our charge to protect participants in research. Improvements in the last year alone include:

-Authorized IRB staff to act as designated reviewers.
-Eliminated grant-protocol comparisons for non-federally funded studies.
-Removed requirement to submit study site permission letters.
-Transitioned to 10-year approval periods for qualifying studies.
-IRB Director delegated by VCR IO to sign inter-institutional agreements.

Goals, Actions, and Results to Date

***UCB Exempt Category 7:** Improve efficiency of IRB review by creating *Exempt Category 7* (in 2015), to allow minimal-risk studies that do not fit federal exempt categories 1-6 to be processed at the exempt level.

***Outcome (1 year)*:** 15% of new exempt studies approved under Category 7.

***Designated Review**: Reduce IRB member burden and shorten review times for expedited items by appointing IRB Director as an IRB member, and later appointing IRB staff as Director's alternates to review appropriate items.

***Outcome (3 months)*:** 16% reduction in review time for minor changes since staff became designated reviewers.

***Extended Approval Periods:** Reduce number of required continuing review submissions by implementing 3-year approval periods for most minimal-risk, non-federally funded research.

Outcome (1 year)*:** 58% decrease in renewal applications with no increase in noncompliances. Thus approval period for such studies extended to ***10 years.

***UC Collaborative Research:** Reduce administrative burden for multiple campus IRBs/PIs and encourage UC collaboration through use of a single IRB process – UC system-wide MOU (Memorandum of Understanding) program created.

***Outcome (3 years)*:** 133 new agreements executed.

***External Collaborative Research:** Reduce administrative burden of duplicative reviews for collaborative research through increased use of single-IRB process.

Outcome (3 years): 127 new inter-institutional agreements executed. (Also, stopped requiring signed IIAs for non-federally funded studies in 2014).

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Managing Editor:
Louise Tipton, EdM, CIP
Associate/Technical Editor:
Diana Holt, MS, CIP

Regulatory, Policy, and Guidance Updates

***NIH Policy on Good Clinical Practice (GCP) Training – Effective 1/1/17**

Last September, NIH issued its new Policy on Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trials, effective **January 1, 2017**. The Council on Government Relations (COGR) wrote to NIH with concern about investigators being able to complete required GCP training (and institutions being able to develop compliance infrastructure) in such a short amount of time. NIH has opted not to extend the January 1 implementation date, but did state:

"Institutions should not regard the policy's effective date as a deadline by which we would expect all staff involved in the conduct, oversight, and management of clinical trials to be GCP trained. Rather, as long as steps are being taken to meet the expectation, e.g., staff who have not yet been trained have signed up for a course, the training itself can be taken in a timely fashion after the effective date." NIH also plans to clarify the policy via FAQs in the near future.

NOTE: Investigators to whom the above pertains can now access the appropriate GCP training module via UCB's CITI program. Keep in mind that it is the *investigators' responsibility to select the correct training module* according to their clinical trial parameters.

***NCI – 2016 Best Practices for Biospecimen Resources**

To address roadblocks to cancer research progress, the National Cancer Institute (NCI) has released its Best Practices guidance. Based on extensive research and expert input, the NCI Best Practices outline the operational, technical, ethical, legal, and policy best practices for NCI-supported biospecimen resources (https://biospecimens.cancer.gov/bestpractices/).

***UC Safety Spotlight – 5 Safety Suggestions for Field Researchers**

Before you set off on your next research project to a remote or potentially hazardous location, be sure to check out these simple but smart tips to create a Field Safety Plan, courtesy of UCB's EH&S Office.

***More from NIH – Single IRB Policy for Review of Multi-Site Clinical Trials**

The NIH Policy on the Use of a Single Institutional Review Board (IRB) for Multi-Site Research sets the expectation that multi-site studies conducting the same protocol use a single IRB to carry out ethical review of the research. Implementation is now set for September 2017 – stay tuned for more details!

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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!