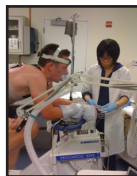
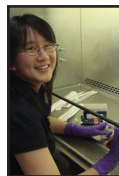




UC BERKELEY HUMAN RESEARCH NEWS



FALL
2017

Fall 2017 Newsletter

"There is nothing permanent except change." —Heraclitus

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Dear Members of the UCB Human Research Community,
Greetings, and welcome to the latest issue of *UC Berkeley Human Research News*!

Since our last issue, we've experienced a number of transitions in OPHS staff and CPHS membership. Notably, new staff members Daisy Lubag and Carrie Des Roches have joined the OPHS team, along with Diana Holt who has returned from retirement on a part-time basis. She is joined by Suzanne Stone, who has shifted from a contract role to part-time staff reviewer.

Our delight in welcoming (back) these team members is tempered, however, by mandatory campus-wide budget cuts that have eliminated one FTE in OPHS (a 10% reduction in staff). As a result, services such as phone consultations and educational outreach presentations are offered on a limited basis only, and protocol reviews may take a bit longer. We appreciate your patience and understanding as we strive to maintain services with less resources.

On the committees, we are pleased to welcome new members Silvia Bunge and John Flannery to CPHS-1, and Robert Merker and Sheila Santos to CPHS-2. We also extend our sincere thanks to all returning members for their continued service.

Big changes are in the works as we begin implementing revisions to 45 CFR 46 (the final Common Rule), that is supposed to go into effect on January 19, 2018. Among the most notable revisions are changes to the consent forms, exempt categories and level of review. It is rumored that the implementation date may be delayed so stay tuned for updates in the coming weeks.

Sincerely,

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

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

Regulatory, Policy, and Guidance Updates

• Updated Moore Clause Language Guidance – Effective 8/1/2017

[RPAC](#) updated the Moore Clause language for research with biospecimens and/or data from biospecimens. The language, to be included in informed consent documents, is as follows:

“Biospecimens (such as blood, tissue, or saliva) collected from you for this study and/or information obtained from your biospecimens may be used in this research or other research, and shared with other organizations. You will not share in any commercial value or profit derived from the use of your biospecimens and/or information obtained from them.”

[Consent Builder](#), the [template consent forms](#) for biomedical studies, and the [checklist](#) for genetic/genomic testing have all been updated.

See our [revised guidelines](#) on genetic and genomic research for more information.

• NIH Single IRB (sIRB) Policy – Effective 1/25/2018 for new NIH applications

The [NIH website](#) has resources to help PIs understand this new policy, summarized as follows: all domestic sites of multi-site studies involving non-exempt human subjects research funded by the NIH, where each site will conduct the same protocol, will use a single Institutional Review Board (sIRB) to conduct the ethical review required for the protection of human subjects. This policy does NOT apply to career development, research training or fellowship awards. Applicants will be expected to include a plan for the use of a sIRB in the grant applications and contract proposals they submit to the NIH (for due dates on or after January 25, 2018).

• Changes in NIH Policy on Certificates of Confidentiality

The NIH has updated its policy on issuing Certificates of Confidentiality (Certificate) for all biomedical, behavioral, clinical, or other NIH-funded research projects that collect and use identifiable, sensitive information. Effective October 1st, 2017, the NIH will automatically supply Certificates for new and non-competing NIH-award recipients conducting research applicable to this Policy. According to the NIH, Certificates “allow researchers to refuse to disclose names or other identifying characteristics of research subjects in response to legal demands.” Non-federally funded research projects may still apply and obtain Certificates as per current NIH policy. More details on the changes in Certificate policy are available at <https://humansubjects.nih.gov/coc/index>.

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More from NIH

• NIH Definition of a Clinical Trial – Effective 1/25/2018 for new NIH applications

The [NIH website](#) has resources to help you understand the new definition (for due dates on or after January 25, 2018):

“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.”

To determine whether your proposed research will meet the new definition of a clinical trial, use the following four questions:

- (1) Does the study involve human participants?
- (2) Are the participants prospectively assigned to an intervention?
- (3) Is the study designed to evaluate the effect of the intervention on the participants?
- (4) Is the effect being evaluated a health-related biomedical or behavioral outcome?

If the answers to all of these questions is “Yes,” the study is a clinical trial. If the answer to any of the questions is “No,” the study is NOT a clinical trial. Studies of surveys, questionnaires, user preferences, focus groups, educational settings to assess teaching method, and secondary research with biological specimens or health information are NOT clinical trials.

NOTE. As a reminder, all NIH-funded clinical investigators and clinical trial staff who are involved in the design, conduct, oversight, or management of clinical trials must be trained in Good Clinical Practice (GCP). The appropriate GCP training module can be found on [UCB’s CITI program](#).

Additionally, all NIH-funded clinical trials are expected to register and submit results information to [Clinicaltrials.gov](#) and the link to the study’s specific clinical trials website should be stated in informed consent documents.

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Resources and Time-Savers

• REMINDER - Include Data-sharing Information in Consent Forms

CPHS recommends that investigators include a statement regarding the sharing of data with others for future research purposes in all applicable consent forms. For example:

“Retaining research records: When the research is completed, I may save the [samples/ tapes and notes/ study records] for use in future research done by myself or others. I will retain this study information for up to XX months/years after the study is over. The same measures described above will be taken to protect confidentiality of this study data.”

If the consent form does not include a statement on retaining and sharing research records, study data (including de-identified data) may not be used in future research. By including this language investigators gain flexibility for later use of the data, even if they currently have no plans to do so.

• New Guidance – Suicidal Ideation in Protocols

CPHS has seen an increasing number of human research protocol submissions which involve identification of suicidal ideation in subjects. Such protocols raise particular concerns about potential risks for research participants. They can present ethical and practical challenges in evaluating and minimizing these risks – for investigators and IRB members alike. After careful consideration, the CPHS has developed general guidelines and a decision tree for investigators who wish to undertake such research. These resources are available through the CPHS website or this direct link: http://cphs.berkeley.edu/suicidal_ideation.pdf.

• Online Resources

With fewer OPHS staff available to respond to phone and email inquiries, the CPHS/OPHS website is your go-to resource for up-to-date information and guidance. We’ve recently revised and updated a number of documents in the Resources section. We suggest adding these pages to your browser’s bookmarks:

Website: <http://cphs.berkeley.edu/>

FAQs: <http://cphs.berkeley.edu/faqs.html>

Glossary: <http://cphs.berkeley.edu/glossary.pdf>

Guidelines: <http://cphs.berkeley.edu/guideline.html>

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