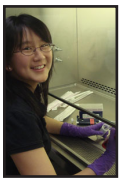
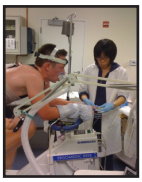
UC Berkeley Human Research News






Spring 2018

Volume 5 Issue 1

Inside This Issue

Spring 2018 Newsletter

Dear Members of the UCB Human Research Community,

Spring greetings! You may be wondering what happened to the impending revisions to 45 CFR 46 (the Common Rule) covering human subjects research. Weren't they supposed to go into effect on January 19th? Yes, but in an eleventh-hour filing, the "Interim Final Rule" (IFR) has now delayed both the effective and compliance dates until at least July 19, 2018.

While the delay provides regulated entities additional time to prepare to implement the revisions, it also postpones some of the anticipated burden-reducing benefits such as the elimination of continuing review requirements and grant-protocol comparisons, and expanded categories for exemption. However, the IFR does permit implementation of revisions that do not conflict with the current Common Rule.

Accordingly, we recommend that you begin using the updated Informed Consent templates for federally regulated research (more about these inside the newsletter), and that you revise the forms for studies that will be submitted for renewal. This will help facilitate review once the revised rule is truly "final."

We now turn to changes that *have* taken effect. OPHS has moved! Along with all of RAC, the OPHS offices are now at 1608 Fourth Street in Berkeley. This move allows us to substantially reduce costs without eliminating (even more) staff positions. One trade-off, however, is that in-person consultations are no longer convenient. When requesting assistance, we suggest that you utilize the OPHS/CPHS website and/or email ophs@berkeley.edu to schedule a phone consultation.

With Bill Jagust on sabbatical this semester, Silvia Bunge has stepped up to take on the responsibilities of CPHS-1 Chair. (Thanks, Silvia!) We also have a new Vice Chancellor for Research as of January 1st. Professor Randy Katz brings a formidable range of skills and expertise to provide leadership in this role, and we look forward to working with him to serve the UCB research community.

Read on for more news, resources, and updated guidelines. We hope you find the newsletter to be helpful, and we welcome your feedback for future issues.

Sincerely,

Silvia Bunge, Ph.D.
Chair, CPHS-1

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

UC Berkeley Human Research News

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Spring 2018

Volume 5 Issue 1

Inside This Issue

Determining What Needs CPHS/OPHS Review

IS IT "RESEARCH"?

New Resource — Take a Self-certification Questionnaire

In general, an activity must meet the definition of "research" and the research must involve "human subjects" in order to fall within the purview of CPHS/OPHS. However, determining whether or not an activity is "research" is not always so clear-cut.

> **Research** means a **systematic investigation**, including research development, testing and evaluation, **designed** to develop or contribute to **generalizable knowledge**.
>
> *Systematic investigation* means a study or examination involving a methodical procedure or plan.
>
> *Generalizable knowledge* means conclusions, facts, or principles derived from particulars (individual subjects, medical records, etc.) that are applicable to or affect a whole category (members of a class, kind, or group, a field of knowledge, etc.) and enhance scientific or academic understanding.
>
> *Design* refers to the purpose of the investigation. Some investigations are exploratory or are intended to train students and are not designed to produce generalizable knowledge.

Researchers often ask, "How do I know if I'm conducting research that requires CPHS/OPHS review?" In order to help researchers make that determination, OPHS has created the following self-certification questionnaire: **Am I Conducting "Research"?**

Depending on the answers, the user will be informed that either no review is needed because the project is not "research," or that CPHS review might be needed and users should contact OPHS for further guidance. The questionnaire can be found on CPHS' website: https://cphs.berkeley.edu/review.html.

IS UC BERKELEY "ENGAGED"?

Now Available — Guidelines to Determine Engagement in Human Subjects Research

In order to require review by CPHS, proposed projects must not only meet the definition of human subjects research, but also establish the "engagement" of UC Berkeley.

How is engagement determined? OPHS/CPHS applies the OHRP guidance on Engagement of Institutions in Human Subjects Research when making determinations. In an effort to make the process more "user friendly," we now have our own guidance document with scenarios designed to help UC Berkeley researchers: **https://cphs.berkeley.edu/engagement.pdf**.

Spring 2018

Volume 5
Issue 1

Inside This Issue

Regulatory, Policy & Guidance Updates

Do you, or will you, collect data from people in EUROPE?

GENERAL DATA PROTECTION REGULATION (GDPR) — EFFECTIVE MAY 25

How will GDPR affect UC researchers? Scheduled for enforcement starting on May 25, 2018, any research that involves subjects ***located*** in the European Union (EU) must comply with GDPR or face heavy penalties (up to 20 million Euros or 4% global revenues).

GDPR was approved by the EU Parliament on April 14, 2016, replacing and repealing the Data Protection Directive 95/46/EU, and intends to strengthen and unify data protection for all individuals within the EU.

GDPR protects the processing of a natural person's personal data, including any information relating to an identified or identifiable natural person such as: name, identification number, location data, online identifiers (e.g., IP address), and any data element specific to the physical, physiological, genetic, mental, economic, cultural, or social identity of that natural person.

Among other requirements, GDPR stipulates that personal data must be processed pursuant to a lawful basis, collected for legitimate purposes, limited to what is necessary, and kept in a secure form permitting identification for no longer than necessary. Subjects must give free and informed consent for the collection/use of their personally identifiable information, and must be given the right to withdraw consent at any time.

See the following website for additional information: https://www.eugdpr.org/

NEW TEMPLATES for Informed Consent for Federally Funded Research

If you have federally-funded research, please consider using the new templates for informed consent for federally regulated research: **https://cphs.berkeley.edu/informedconsent.html**.

These may be required as of July 19th, but can be implemented prior to that date. The main revision from the other informed consent templates is the addition of "Key Information," which should come at the beginning of the forms. In addition, there are a few additional statements in the Confidentiality section of the forms. Please contact OPHS if you have any questions about the revised informed consent requirements. *Please note that our online Consent Builder has not yet been updated to include the new template.*

NCI BEST PRACTICES for Biospecimen Resources

The National Cancer Institute (NCI) has released **NCI Best Practices for Biospecimen Resources**, which outlines the operational, technical, ethical, legal, and policy best practices for NCI-supported biospecimen resources (https://biospecimens.cancer.gov/bestpractices/).

This resource is intended to be adapted based on the specific biospecimens and scientific needs, as the current principles are optimized for cancer research.

Spring 2018

Volume 5 Issue 1

Inside This Issue

UC Berkeley Human Research News Staff

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More News and Resources

Consent Forms — Save for 10 Years

In order to meet the University's data retention requirements, signed consent forms must be retained for 10 years after the end of the calendar year in which the research is completed, unless otherwise specified in the award agreement.

If protocols do not already indicate compliance with the records retention requirements, investigators will be asked to add that information to the Confidentiality section. CPHS recommends providing for storage in digital format when describing records retention procedures in the protocol.

Attention Tolman Hall Units

If your department is moving to a new location, you may need to update protocols that list Tolman Hall as a study location. Please prepare and submit an amendment application for approval prior to conducting human subjects research at a new location.

Educational Outreach

OPHS has a long history of providing educational presentations on human subjects research to UCB students at the request of faculty and staff. Lately, we've been in the unfortunate position of having to decline most requests, due to campus budget reductions and consequent loss of OPHS staff. In an effort to maximize our limited resources and meet the needs of the campus research community, we will try to coordinate a small number of presentations this fall with combined groups of students from various disciplines.

If you are interested in having your students participate in one of the presentations, please send an email to OPHS@berkeley.edu noting your school or department, potential dates, and the approximate number of students who would attend. As space will be limited, please include only those students who are likely to be conducting human subjects research.

Recently Updated CPHS Guidelines

- Electrical and/or Magnetic Brain Stimulation in Research
(CPR training no longer required to administer TMS.)

- Mechanical Turk for Online Research
(New information on the Notify Workers function.)

- Informed Consent for Federally Regulated Research
- Child Assent and Parent Permission for Federally Regulated Research
(Updated to incorporate new Common Rule requirements.)

- International Research
(Link to listing of social-behavioral research standards from around the world.)