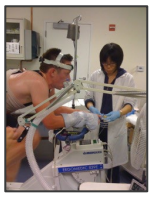
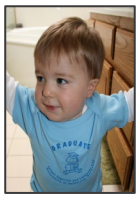
UC Berkeley Human Research News





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Fall 2026 Newsletter

Dear Members of the UCB Human Research Community,

Welcome back to a new academic year and fall semester here at UC Berkeley! We hope your summer has been both restorative and productive. In CPHS/OPHS, we are happy to welcome back returning faculty and students alike as well as the new faculty and students joining us at UC Berkeley for the first time.

In this edition of Human Research News, we have included several articles about changes within CPHS/OPHS including new guidance documents, consent templates, research recruitment opportunities, and learning resources available through CITI. We've also tried to tackle some of the most common questions we see regarding the review of human subjects research and provide the expectations of CPHS/OPHS.

More broadly, we also want to bring to your attention some of the developments in the human subjects research space nationally. This past summer, the federal Office of Management and Budget (OMB) opened up for comment their proposal "Regulation for Federal Financial Assistance" which would fundamentally change how federal grants are awarded and reviewed. The proposal received more than 500,000 comments including those from national organizations in the human subjects research community such as PRIM&R and NACHRP as well as the UC Office of the President advocating that the process for grant review remain politically neutral and based in scientific merit.

Looking ahead, the Department of Health and Human Services (DHHS) Office for Human Research Protections (OHRP) has notified the human subjects research community about an upcoming intent to publish a Notice of Proposed Rulemaking (NPRM) to update the Common Rule. While the notification does not describe the specific proposed changes, OHRP has stated "Changes are intended to uphold protections for human subjects while reducing burden and ambiguity for investigators, institutional review boards, and research institutions. Examples of changes include clarifying terminology, expanding exemptions for certain low-risk research activities, and enabling flexibilities for regulatory review of de minimis protocol changes." CPHS/OPHS will continue to monitor for any proposed changes and keep our local community informed as and when changes are enacted which affect our research community.

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(Letter from the Chairs continued)

Wishing you all a productive, educational, and ethical Fall 2026 semester!

Sincerely,

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

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

Selection of Permanent OPHS and SCRO Assistant Director

In our last edition of *UC Berkeley Human Research News*, we announced the selection of Adrienne Tanner as Director of Research Subject Protection and Suzanne Stone as the Interim Assistant Director for OPHS and SCRO. After a competitive hiring process, we are pleased to announce that Suzanne Stone has been selected to be the permanent Assistant Director for OPHS and SCRO. Suzanne officially dropped the "Interim" title on July 7th.

Both Adrienne and Suzanne look forward to continuing to work with the UCB human research community to facilitate ethical, and exemplary human subjects research designed to produce new knowledge and solve critical problems.

UC Berkeley Joins ResearchMatch

We are happy to announce that UC Berkeley is working with ResearchMatch to offer their free and secure tool to make it even easier to connect investigators with volunteers interested in participating in health research studies. Researchers can register with ResearchMatch and search their de-identified database for potential participants that match their study's eligibility criteria. If a match is found, investigators can send their contact message with details about the study through ResearchMatch directly to potential participants. Interested in learning more about using ResearchMatch to find participants? Please see our webpage: ResearchMatch for Investigators Seeking Participants

If you are interested in signing up as a volunteer participant, all you need to do is create a profile and you will then be sent the IRB approved recruiting message about studies you qualify for. Interested in learning more? Please see our webpage: ResearchMatch for Participants

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Guideline & Template Updates

Every so often we find that a guidance or template document doesn't fully cover what we want it to, needs to be, or simply needs to be updated as the world around us changes. With that in mind, we want to point your attention to one revised guideline and two wholly new templates we've developed:

Updated Guideline: Compensation of Research Subjects

Last year, the federal government's budget reconciliation package included a provision that affects reporting requirements for various types of income, including money offered as compensation for participating in research studies. These changes went into effect on January 1, 2026, and we've responded accordingly by updating our guideline document on Compensation of Research Subjects.

Under the previous rules, if a participant was going to receive more than $600 in compensation over the course of a calendar year, researchers needed to collect additional information about the participant so that the participant could be issued a 1099 tax form in January of the following year. Under the new rule, the limit has been increased to $2000 and will change each year based on inflation. Accordingly, Section F of our guideline document has been updated to match the revised requirement and now includes a link for researchers to check the current threshold amount for reporting when it is updated by the IRS annually.

In addition, Section G of the guideline document which describes the UC Berkeley Human Subject Prepaid Card Program now offers two payment options: Instant Issue Plastic and Virtual Payment. The guidance has been updated to reflect these two methods. The full Compensation of Research Subjects guideline document can be found on the OPHS website

New Guideline: Behavioral Observation FAQ

OPHS often receives questions about studies where behavioral observation of participants is an included research procedure. These questions range from whether behavioral observation is even considered human subjects research to whether consent is required for behavioral observation. The new FAQ includes definitions specific to behavioral observation, discusses when behavioral observation is human subjects research, provides examples of when exempt or non-exempt review is required for behavioral observation, describes when consent is required for behavioral observation, and details special confidentiality considerations when including behavioral observation as a part of research activities.

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(Continued from Guideline & Template Updates)

To serve as a resource for researchers, OPHS has created a Behavioral Observation FAQ webpage with all this information which can be found on our general Guidance website.

New Templates: Plain Language Social-Behavioral Study & Biomedical Study

To make consent forms more accessible to a wide range of participants, OPHS/CPHS has developed a plain language consent template for both social-behavioral and biomedical studies. These new templates are written in more lay-friendly language and reorganized to provide information about studies in more bite-sized chunks which are more easily understood. These new templates still contain all of the required language to satisfy Federal, State, and UC Berkeley requirements and provide a wide range of suggested language to address everything from various risks to confidentiality provisions.

Our new Plain Language Social-Behavioral Template and Plain Language Biomedical Template can be found on our Informed Consent website.

Resources At CITI You Might Not Be Aware Of

As a part of UC Berkeley's CITI account, UC Berkeley staff, students, faculty, and affiliates have access to over 150 CITI webinars. Topics generally center on various facets of research and are not limited to topics in human subjects research. Even better, webinars may be eligible for Continuing Education (CE) credits based on the accrediting body.

Notable topics include:

- Artificial Intelligence (AI) and Human Subject Protections
- Conducting a Literature Search for Animal Use Alternatives
- Effectively Communicating Research Results to Non-Scientific Audiences
- Generative AI and Science Communication
- I've Been Funded, Now What?
- Partnering with Technology Companies
- Research Equity and the Part We Play
- Survey Research Fraud
- Writing Your First R01

And so many more!

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(Continued from Resources At CITI You Might Not Be Aware Of)

If you're interested in adding one or more of these webinars to your CITI training or just want to see the webinars that are available, login to www.citiprogram.org. Then on your home screen click the "View Courses" button. On the next screen, scroll to the bottom and click "Add a course". On the next screen, scroll down to Question 11 to view the webinars available to you and select the ones you'd like to add.

NIH Reclassifies BESH Studies

The National Institutes of Health (NIH) recently announced that Basic Experimental Studies Involving Humans (BESH) will no longer be classified as clinical trials. Effective for grant applications submitted for due dates **on or after May 25, 2026**, BESH projects, which focus on fundamental biological or behavioral mechanisms rather than direct health outcomes, are exempt from NIH clinical trial requirements.

Most notably for researchers, these basic studies will no longer require registration or results reporting on ClinicalTrials.gov. Going forward, applicants proposing BESH research should submit proposals under funding opportunities designated as *Clinical Trial Not Allowed* or *Clinical Trial Optional*. Standard human subject protections remain unchanged—including IRB review, informed consent, and compliance with the NIH Data Management and Sharing (DMS) Policy—and existing BESH awards will continue under their current terms.

For complete details, review the official announcement in NIH Guide Notice NOT-OD-26-067.

Frequently Asked Questions

While the OPHS website includes a section for Frequently Asked Questions, we wanted to highlight some of the common questions/mistakes we see in applications.

Can I add new UCB personnel by just updating the Personnel Information section?

When adding new UCB personnel to a study, you will always need to update the Personnel Information section of the eProtocol application through an amendment application.

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(Frequently Asked Questions continued)

If you're adding personnel to an Exempt application, then you'll also want to look at Section 7b to see if any changes need to be made there. If you're adding personnel to a Non-Exempt application, then you'll need to discuss their expertise and role(s) on the study in Section 4a, and you'll want to look at Section 13(c)(i)/17(d)(i) to see if any changes need to be made there. These are the common sections that need to be updated.

In all cases, you should carefully look over the other sections of the eProtocol application, consent forms, and any attachments to ensure that if there are sections where individuals are listed, that list is up to date and appropriate based on the roles personnel will have on the study.

How can I have OPHS/CPHS approval determinations extend to non-UCB collaborators?

First, you will need to determine which of your non-UCB collaborators (if any) are engaged in the human subjects research. Some collaborative activities, while engaging collaborators in the overall research project, do not engage them in the human subjects research aspect of the study. To help determine whether your collaborators are engaged or not, please review our engagement guidance document.

Next, if you determine that your collaborators are engaged in the human subjects research, you'll need to include information about your collaborators, their human subjects research activities, and their human subjects training in Section 3 of the eProtocol application. You'll also need to include information about what activities your collaborators will participate in throughout the eProtocol application, where indicated. Lastly, you'll need to include a completed Request to Review form in Section 8/9 (for exempt applications) or Section 17/22 (for non-exempt applications) for review.

The OPHS Director will review the request and determine whether CPHS/OPHS can agree to serve as the IRB of Record for the study and the collaborating investigators/institutions.

If the Director determines that the reliance needs to be documented (common for non-exempt applications), OPHS staff will provide you with a template agreement and, where applicable, a Local Context Questionnaire for you to provide your collaborators. Your collaborators will then need to work with their IRB or compliance office/officer to complete the documents and return them to OPHS staff will provide you with a template agreement and, where applicable, a Local Context Questionnaire for you to provide your collaborators. Your collaborators will then need to work with their IRB or compliance office/officer to complete the documents and return them to OPHS for counter signature.

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(Frequently Asked Questions continued)

Only when all steps have been completed and the eProtocol application is approved are your collaborators considered to be covered by CPHS/OPHS's review and determinations and can begin conducting human subjects research activities.

For more information, please visit our Collaborative Research page.

How long does OPHS/CPHS review take?

OPHS/CPHS review timelines hinge on several factors: complexity of the project, type of review (i.e. exempt or non-exempt), and current submission volume. As OPHS/CPHS generally operates on a first-come, first-served basis, when we have more submissions our review times will generally increase. As such, as described on our Types of Review webpage, new exempt protocols typically take 3-4 weeks for review while new non-exempt protocols qualifying for expedited review take 6-8 weeks for review. New non-exempt protocols requiring full board review will also generally take 6-8 weeks for review; however, that assumes that the protocol is submitted by the appropriate committee deadline and is complete.

How can I find my approval letter?

Once OPHS/CPHS review is complete and it's determined that the study can be approved, the eProtocol system will send an automated notification to your email with the approval letter for the study attached. This is probably the easiest way to get your approval letter. Of course, if that email gets deleted, sent to spam, or lost in the internet, you can also always download the approval letter directly out of eProtocol itself. To do so, please see our quick guide on viewing an approval letter.

Have a question you're not seeing?

Check out our FAQs page for more questions. Still not seeing the question you're trying to answer? Write to us at OPHS@berkeley.edu.