

UC Berkeley

Human Research News



**Spring
2026**

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Issue 1**

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Spring 2026 Newsletter

Dear Members of the UCB Human Research Community,

While the semester may be winding down, our office continues to thrive and adapt to the changing research environment. For this issue of *UC Berkeley Human Research News*, we want to highlight many of the internal CPHS/OPHS changes that have been happening recently, as well as changes affecting the human subjects research (HSR) space throughout UC Berkeley, UC, and the country.

Please join us in congratulating Adrienne Tanner as our new Director of Research Subject Protection. Adrienne's team includes the following specialists and dedicated experts you have worked with in OPHS: Interim Assistant Director Suzanne Stone; CPHS-1 Administrator Daisy Lubag; CPHS-2 Administrator Colleen Kohashi; and our team of IRB Coordinators: Carrie Des Roches, Emily Harden-Antonio, Stacy Miladinovich, Ben Mooso, and Jason Silva.

While the OPHS is no longer housed on Fourth Street in Berkeley, our staff continue to work remotely and to support your research needs via email and Zoom.

Our new mailing address is:
Office for Protection of Human Subjects
Research Administration and Compliance
University of California, Berkeley
119 California Hall # 5940
Berkeley CA, 94720-1509

Contained in this newsletter you'll also find information about several updated policies and guidance documents, helpful HSR resources external to CPHS/OPHS, advice for newer researchers, Federal rules to be aware of, and some of our most frequently asked questions with their respective answers. We hope that you will find these articles both informative and helpful.

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(Letter from the Chairs continued)

On behalf of CPHS and OPHS, we thank you for working with us to facilitate and advance ethical, innovative research to address global challenges. Our research community continues to impress us with insightful research questions and advanced solutions with a sense of responsibility and dedicated academic excellence.

Sincerely,



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



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

Meet the OPHS Director and Interim Assistant Director

Since Rebecca (Becky) Armstrong's retirement from UCB early in 2025, OPHS staff have stepped up to fill the leadership role while a permanent OPHS Director was sought by RAC. While you may have been working with OPHS' new leadership already, we wanted to take this opportunity to formally introduce them to the human research community here at UCB.

Adrienne Tanner, MSL, CIP



Adrienne Tanner, MSL, CIP has assumed the role of Interim Director of Research Subject Protection and recently was formally selected to fill the permanent role of Director of Research Subject Protection going forward. A familiar face in Berkeley's research compliance landscape since 2008, Adrienne oversees the administrative units

and committees responsible for human subjects, animal care, and stem cell research. Her leadership focuses on aligning institutional policies with federal and state regulations and industry standards, while maintaining efficient, transparent administrative procedures for the campus research community. Whether she is liaising with federal agencies like the FDA and USDA or guiding faculty, students and staff through complex research compliance challenges, Adrienne

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remains dedicated to upholding the highest ethical standards while supporting the groundbreaking research being conducted across the UC Berkeley campus. Researchers can look to Adrienne and her teams (OPHS, OACU and SCRO) for expert consultation and support in navigating the IRB, ACUC, and/or SCRO review processes.

Suzanne Stone, MA, CIP

With more than 23 years of human subjects research ethics and compliance experience, Suzanne has shared her expertise with the UCB research community since 2012. In 2019, Suzanne expanded her role within OPHS, taking on an administrator role with the Stem Cell Research Oversight Committee and the SCRO Office. Since Becky's retirement, Suzanne has been our Interim Assistant Director for the OPHS and SCRO, supporting Adrienne's leadership and continuing to facilitate ethical, world class research.

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.



UCB's IRB Gets a Check-Up from the Feds

Earlier this year, UCB's IRB was assessed by the Bioresearch Monitoring Office (BIMO) of the Food and Drug Administration (FDA). The weeklong remote regulatory assessment (RRA) focused on FDA regulated studies being conducted here at UCB, which are overseen by OPHS/CPHS. After reviewing several studies, IRB meeting minutes, OPHS/CPHS policies, procedures, and guidelines, and countless study-related documents, the FDA inspectors made no official findings thus far. OPHS continues to be proud of the work our staff and the CPHS committees do in helping maintain regulatory compliance to promote the safety and ethics of the research conducted by our investigators and their teams.

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Policy & Guidelines Updates

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

Updated Policy: Training and Education for Investigators

During a recent review of this policy, we found that the policy and the current practices and requirements of OPHS/CPHS were not aligned. In order to ensure that the policy reflects current practice, we specifically added that the Group 1 Biomedical Research course and the Group 2 Social and Behavioral Research course do not expire. There may, of course, be other training requirements imposed by funders, sponsors, and/or collaborators, above and beyond what OPHS/CPHS requires. If this happens to you and you need a more current course completion date, just reach out to our office and we'll work with CITI so that you can take the course again. The full [Training and Education for Investigators Policy](#) can be found on the [OPHS website](#).

Updated Policy: Protocol Deviations and Noncompliances

The prior version of this policy required that all determinations related to noncompliances had to go through an IRB Chair or Vice Chair or be sent to the full board for review. In the current version, simple noncompliance reports may be handled by the OPHS Director in lieu of review by the IRB Chair, Vice Chair, or the full board. This change means that CPHS Chairs, Vice Chairs, and the committees can focus their time on the more substantial issues that get reported to OPHS while simple noncompliances can be handled administratively. The full [Protocol Deviations and Noncompliances Policy](#) can be found on the [OPHS website](#).

Updated Guideline: Reliance Agreements for Non-UCB Collaborators

As OPHS refines its practices around handling reliance agreements, guidelines for their use and execution continue to evolve. This guideline used to refer to collaborations between UCB investigators and non-UC collaborators, and a separate document instructed UCB investigators on how to go about obtaining a reliance agreement with collaborators external to UCB but still within the UC system. This updated guideline

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document represents a simplification of the reliance process where collaborations with any non-UCB collaborator are handled in a similar fashion so long as a commercial IRB is not involved. Some highlights of the updated guidelines include simplified terminology around types of reliance agreements, clarification of requirements for voluntary reliance agreements, and contact information for questions. The full [Reliance Agreements for Non-UCB Collaborators](#) guideline document can be found on the [OPHS website](#).

New Guideline: Activities Preparatory to Research

This new guideline has been developed to aid researchers in determining when to seek out IRB review and approval prior to engaging in activities preparatory to research. Though some regulation exists on the topic, much of the determination is made on a case-by-case basis, dependent on the activities to be conducted and how the information collected from those activities will be used. This new guidance document provides definitions, regulatory requirements, points to consider, and examples of activities which may be considered preparatory to research. As this is an ever-evolving topic, please feel free to contact OPHS at ophs@berkeley.edu for consultation on activities preparatory to research. The full [Activities Preparatory to Research](#) guideline document can be found on the [OPHS website](#).



Human Subjects Protections and External Resources

The OPHS/CPHS always strives to ensure that human subjects who participate in research are adequately protected and that the research conducted is as safe and ethical as possible. In working towards that goal, OPHS/CPHS often relies on the expertise of consultants outside of OPHS/CPHS with specific knowledge in that discipline. This is particularly true when it comes to Information Technology and the rapidly evolving landscape around how data is stored and used and how easy it can be to identify a specific individual. We wanted to share some of the more common resources that OPHS/CPHS relies on with you.

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(Human Subjects Protections continued)

UCB's [Research Data Management \(RDM\) Program](#) is a wealth of data knowledge covering everything from how to classify data, tools for collecting, managing, and sharing data, and even how to store and back up your data. For questions or consultations you can email RDM at researchdata@berkeley.edu or drop in to their [office hours](#).

UCB's [Compliance and Enterprise Risk Committee's Artificial Intelligence Risk Subcommittee \(CERC-AIR\)](#) is an institutional resource for risk determinations of AI systems. For questions about CERC-AIR and the risk assessment process, please contact CERC-AIR at cerc-air@berkeley.edu.

While not strictly IT related, UCB's [Intellectual Property & Industry Research Alliances \(IPIRA\)](#) office can help with transfers of knowledge, samples, and technology outside of UCB, as well as helping with startups, working with industry, and SBIR/STTR grants. To get started, you can complete the concierge form on [their website](#).

Another resource which researchers may find helpful is UCB's [Office of Environment Health & Safety \(EH&S\)](#). While this office is a mainstay of researchers working with hazardous chemicals, radiation producing equipment, flammables, and other hazards, EH&S also ensures safety when human samples which may contain pathogens and other infectious materials (e.g. blood, saliva, sputum, urine, etc.) are collected during human subjects research. For questions or to reach out to EH&S, please contact them using [this form](#) on their website.



Supporting New Researchers

We know that many of our faculty, lecturers, and staff mentor up-and-coming researchers through their academic careers, which may include conducting human subjects research. To help make the IRB submission process less stressful for you and your mentee, we have some tips to share:

Take advantage of IRB educational opportunities

OPHS partners with [D-Lab](#) once a semester to offer training in the eProtocol system and answer general questions about the IRB submission process. Encourage your mentees to sign up for this

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workshop and they can learn about the process and have their questions answered on the spot. In addition, OPHS staff work with undergraduate research scholar programs (e.g. Haas, Firebaugh, etc.) each semester to deliver trainings to the cohort. If your mentee is a part of one of these programs, encourage them to attend and hear from our staff about the submission and review process.

Don't wait until the last minute

This one is certainly easier said than done; however, it is important that mentees submit their applications in eProtocol as soon as they can to ensure a timely review and allow them to meet research goals and deadlines. While [published average turnaround times for review](#) are available on our website, it's important to remember that these are averages and may increase during times of particularly high volume as OPHS/CPHS works on a first come first served basis. It is always better to get an application submitted earlier than too late.

Don't let perfect be the enemy of good

OPHS requires that eProtocol applications be submitted with sufficient detail and completeness so that our staff and reviewers can understand what is being proposed, how the research will be accomplished, who will be involved, what the risks are, and how those risks will be mitigated. Applications submitted without this basic level of detail and completion are returned to the research team to be completed and fleshed out before they can be reviewed so that OPHS can keep review times as low as possible. At the same time, some mentees stress and delay their submissions in an effort for their submissions to be perfect so that they don't get disapproved.

It's important to note that the IRB will not disapprove of a research study over mistakes in an application. Disapproval is rare and only happens in instances where there are serious concerns with the design of the research. Please help mentees understand it's better to get their detailed and complete application submitted for feedback rather than stress over minor details.

Additionally, while we appreciate a well-thought-out and put together application, the IRB review process is rarely one in which a submission is approved upon first review. More typically, the IRB review process is

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iterative with a reviewer sending back comments and mentees replying to them and making requested revisions over the course of 1-3 cycles of review. As such, it is imperative that mentees develop detailed and complete submissions the first time to ensure a smooth and efficient review process.

When in doubt, reach out!

Have a question from a mentee you'd like to discuss? Don't know under which category your mentee's work should be submitted? Not finding the answer you need on the [OPHS website](#)? Email us (or have your mentee email us) at OPHS@berkeley.edu. We'll be happy to address any questions.



Federal Data and Specimen Rule Updates

Last year, the Department of Justice (DOJ) and the National Institutes of Health (NIH) issued new requirements for the security and safeguarding of human data and specimens:

DOJ Bulk Data Rule

As of July 8, 2025, this rule (found at [28 CFR 202](#)) is intended to prevent countries of concern from accessing various types of sensitive data about Americans including data on health, biometrics, genomes, and geolocation. Notably, the rule applies regardless of whether the data are identifiable. UCOP has issued a [compliance alert](#) providing a breakdown of the rule and additional guidance. UC Berkeley's Research Security Office has developed a [checklist](#) to aid researchers in determining whether their research triggers the bulk data rule.

NIH Data Specimen Security Policy

As of October 24, 2025, this policy (found in notice [NOT-OD-25-160](#)) prohibits NIH-supported US biospecimens from being distributed to anyone in countries of concern with some limited exceptions. The "NIH-supported" portion of this policy kicks in any time that NIH funds are used to collect, process, store, use, or distribute the biospecimens irrespective of whether they are identifiable or not.

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While OPHS/CPHS are not directly involved in the enforcement of compliance with these rules for the UCB community, we want to bring these to our researchers' attention as they have bearing on human subjects research which may be being conceived or is already ongoing. Additionally, we expect that more information about these rules will become available in the coming year so please watch for future updates in future newsletters.

If you have questions about countries of concern, sending specimens or data abroad, or other export control matters, we encourage you to learn more by going to the [Export Control website](#) or contacting export control using their [service request form](#).

If you need help with getting a Data Use Agreement (DUA) or Material Transfer Agreement (MTA) in place to send or receive data or specimens, please refer to the [Intellectual Property & Industry Research Alliances \(IPIRA\) website](#) or fill out [IPIRA's concierge form](#).



Frequently Asked Questions

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

What is the most common reviewer comment in eProtocol applications?

Consistency. OPHS/CPHS reviewers often find that applications will describe a procedure or plan in one section and then completely change or forget that procedure or plan in another section. For example, an eProtocol application might indicate in the General Checklist that there isn't a plan to compensate participants but then describes offering a gift card to subjects later in the protocol. These inconsistencies are not just limited to the free-text sections in eProtocol either. The informed consent document, recruitment materials, and even instructions to subjects may contain information that is inconsistent with the eProtocol application or other supporting documents. These inconsistencies are the most common error reviewers see.

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To avoid this error, take a moment to read through your application and supporting documents fully one last time before hitting that submit button.

How can I make sure I meet all the requirements for informed consent?

OPHS/CPHS offers several resources for this on our [Informed Consent page](#). It covers everything from informed consent checklists, to guidelines, to current templates for various types of research.

Pro Tip: When developing a new consent form for a study, always start with the template on our webpage. That will ensure you have the most current required language and formatting. If you use an older consent form template or a previously approved form from another study you risk introducing inconsistencies, copy/paste errors, and outdated/incorrect language.

Where can I get information about securely collecting and storing my research data?

OPHS/CPHS provides some information in our [Data Security Guidelines and Matrix](#) guidance document. However, for more in depth questions about approved systems, available resources, and determining the security level of your data, we encourage you to reach out to the [Research Data Management](#) team.

Is there such a thing as a "no risk" study?

No. All studies involve some risk. Surveys, interviews, focus groups, and observations may make people feel uncomfortable even if the topic isn't sensitive. Blood draws, physical exams, and eye exams also pose risks, though often rare and minimal. And there is always the possibility of a breach of confidentiality even if data is collected without directly identifiable information (e.g. names, addresses, voices, etc.). All of these fall into what we call "Minimal Risk". This means that these studies, while presenting some risk to participants, present no more risk than a normal person would face in their everyday life.

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.