UNIVERSITY OF CALIFORNIA, BERKELEY

BERKELEY • DAVIS • IRVINE • LOS ANGELES • RIVERSIDE • SAN DIEGO • SAN FRANCISCO

SANTA BARBARA • SANTA CRUZ

OFFICE FOR PROTECTION OF HUMAN SUBJECTS
1608 Fourth Street, Suite 220
Berkeley, CA 94710

(510) 642-7461
ophs@berkeley.edu
cphs.berkeley.edu
FWA: #00006252

November 1, 2019

Research Compliance Advisory Committee
Office of Environment, Health and Safety
317 University Hall, #1150

Randy Katz
Vice Chancellor for Research
119 California Hall, #1500

Ula Taylor
Chair, Committee on Committees
Professor of African American Studies
660 Barrows Hall #2572

Attached is the 2018-2019 Annual Report for the Committee for Protection of Human Subjects (CPHS). CPHS and the Office for Protection of Human Subjects (OPHS) strive to offer excellent customer service while ensuring the health, welfare and safety of subjects and supporting institutional regulatory compliance.

Please contact us with any questions or comments regarding this report:

- Rebecca Armstrong, Director, Research Subject Protection
  Email: rda@berkeley.edu Tel: (510) 642-1180

- William Jagust, CPHS-1 Chair
  Email: jagust@berkeley.edu Tel: (510) 643-6537

- Jane Mauldon, CPHS-2 Chair
  Email: jmauldon@berkeley.edu Tel: (510) 642-3475

Respectfully Submitted,

William J. Jagust, M.D.

Chair, Committee for Protection of Human Subjects (CPHS-I)
Professor, School of Public Health and Helen Wills Neuroscience Institute

Jane Mauldon, Ph.D.
Chair, Committee for Protection of Human Subjects (CPHS-2)
Associate Professor, Goldman School of Public Policy

Enc. CPHS Membership Roster 2018-2019

Cc: Patrick Schlesinger, Assistant Vice Chancellor for Research Administration and Compliance
Rebecca Armstrong, Director, Research Subject Protection

Report to the Research Compliance Advisory Committee

I. Committee Title and Report Period

Committee for Protection of Human Subjects - Report for July 1, 2018 - June 30, 2019.

II. Executive Summary

From July 1, 2018 - June 30, 2019, the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1866 applications, down slightly from the number of applications approved last fiscal year. The number of approvals for new and amendment protocols remained relatively steady while continuing reviews decreased (as expected given regulatory changes) – compared to last year. Noncompliance submissions decreased, and official determinations of "not human subjects research" (NHSR) increased. The number of withdrawn applications was down compared to last year. Due to a continued heavy workload and reduced staff (see below for details), OPHS review turnaround times were up overall (see tables 4 and 5). UC Berkeley research remains primarily social-behaviorally focused, at 75% of total approved submissions. Of the 1866 applications approved, 32.5% of them were federally-funded. During the last fiscal year, UCB researchers utilized a commercial IRB (WIRB) for the first time with one study from the School of Optometry.

Big news in the IRB world over the last year included revisions to DHHS regulations governing human subjects research (45 CFR 46), went into effect on January 21, 2019. Among other changes, the revised regulations (also known as the Common Rule) expanded exempt categories, included new requirements for informed consent, and did away with the annual review requirement for minimal risk research. OPHS Staff were tasked with updating a large number of CPHS Policies & Procedures, guidelines, and webpages in preparation for the revised Common Rule's effective date (see below for the full listing of updated and new documents/resources). Staff also worked with Key Solutions, the software company responsible for CPHS's online application system, eProtocol, to update CPHS's online applications in preparation for the revised regulations. In consultation with the CPHS Executive Committee, OPHS staff developed a transition plan for UC Berkeley's research community and provided instructions and resources on the CPHS website: https://cphs.berkeley.edu.

UC Berkeley continues to take advantage of flexibility afforded by the regulations in terms of non-federally funded/regulated research. In late 2015, UC Berkeley was the first UC System institution to roll out an exempt category #7. This new category permitted minimal risk, non-federally funded or regulated research studies, which formerly had to be reviewed under expedited level review processes, to now be reviewed under exempt level processes. With the implementation of the revised Common Rule, many of the studies that would have qualified for review under exempt category #7 now qualify under one or more of the revised federal exempt categories. However, there are still circumstances in which a study will not qualify for exempt review under the federal categories but will qualify under the UCB-specific category. Because the revised Common Rule included a new exempt category #7, CPHS renamed the UCB-specific category to category #70. This category continues to benefit researchers in many ways, from filling out a shorter application form to reducing review times. During the 2018-2019 fiscal year, OPHS made 68 new category #7/#70 determinations, saving time for both OPHS staff and for investigators.

The end of the 2018-2019 fiscal year marked some changes in staffing. IRB Coordinator Diana Holt, who had been recalled into a part-time position after retiring in June 2017, permanently retired from OPHS at the end of June 2019. IRB Coordinator Suzanne Stone, who had been working under a part-time contract, became a full time OPHS staff member on 7/1/2019. Other staffing changes that affected

OPHS' service in the past year included one staff member's absence due to maternity leave and a second staff member briefly left for a non-UCB position but then returned. In summary, OPHS has operated over the past couple years with a reduced staff, down by 14% (i.e. 1.07 FTE).

III. Committee Membership and Number of Meetings During the Report Period

The Committee is comprised of two panels, CPHS-1 and CPHS-2. While CPHS-1 tends to review more biomedical research and CPHS-2 reviews more social-behavioral research, both committees may review either type of research. During the '18-'19 fiscal year, CPHS-1 and CPHS-2 each convened 10 times. CPHS-1 had 17 regular members in the fall and 15 in the spring. CPHS-2 had 13 members (the 2018-2019 CPHS Membership List is attached).

Professor Bill Jagust, MD served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Jack Lesch served as CPHS-1 Vice Chair in the fall and Professor Ndola Prata, MD served as CPHS-1 Vice Chair in the spring. Professor Oliver John served as CPHS-2 Vice Chair. OPHS Director Rebecca Armstrong served as a designated CPHS reviewer assisting with the expedited review of minor protocol amendments (e.g., reviewing the addition of funding), continuing review/renewal applications, and deviation reports. OPHS staff were authorized as alternate members for Dr. Armstrong in order to complete IRB review and approval duties, as determined appropriate based on their experience and role in OPHS. Assistant Director Adrienne Tanner served as Dr. Armstrong's alternate at CPHS meetings, as needed.

IV. Summary of Research Protocols Reviewed

Approvals

The total human subjects research approval activities for CPHS and OPHS was slightly down as compared to last year at 1866 approvals. New protocol approvals remained steady in comparison to last year, with an increase in exempt determinations and full board approvals and a decrease in expedited approvals. Expedited amendment approvals were down, exempt amendments were up and full board amendments remained steady. Expedited continuing review applications were down by 28 protocols, and full board continuing review applications were down by about 10 protocols. Three-year approvals were first granted in April 2013. In late April 2016, CPHS further extended the standard approval period to 10 years effectively wrapping up six years of granting three-year expedited level approvals. While the revised Common Rule removed the requirement for continuing review of minimal risk research, CPHS decided to maintain 10 year approvals for minimal risk studies (and to implement this approval period for exempt projects which previously had no expiration date) for tracking/data-retention purposes moving forward. Certain exceptions apply including FDA-regulated research, which must be reviewed annually, and industry-sponsored research, which receives a 3-year approval. As we continue to grant 10-year approvals for most minimal risk research, we expect a continuing decrease in minimal risk renewal reviews.

Figure 1 shows the total number of applications approved over the last five years. Table 1 breaks down the applications approved over the same period of time based on the type of submission and level of review. These data exclude cases of potential noncompliance, adverse events, unanticipated problems, administrative actions, and withdrawn submissions, which are discussed later in this document.

Figure 1. Total applications approved over 5 years

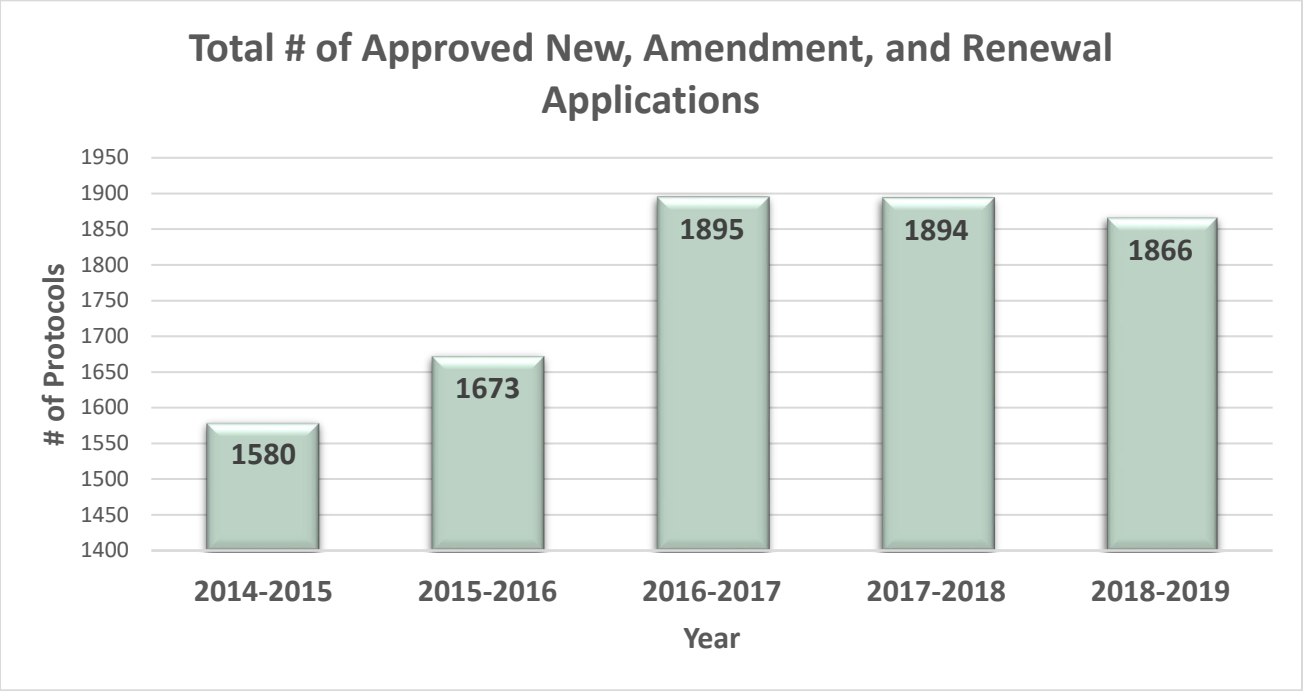

TABLE 1. Types of applications approved over 5 years

Application Type	Review Level	2014-15	2015-16	2016-17	2017-18	2018-19
New	Exempt:	178	200	244	224	258
	Expedited:	355	290	287	305	260
	Full Board:	44	81	55	62	72
	TOTAL	**577**	**571**	**586**	**591**	**590**
Amendment	Exempt:	116	132	131	137	162
	Expedited:	592	661	679	759	737
	Full Board:	34	19	13	15	13
	TOTAL	**742**	**812**	**823**	**911**	**912**
Continuing Review	Expedited:	235	260	453	356	339
	Full Board:	26	30	33	36	25
	TOTAL	**261**	**290**	**486**	**392**	**364**
Total Activity		**1580**	**1673**	**1895**	**1894**	**1866**

Withdrawn applications
There are times when applications received by CPHS/OPHS are reviewed and then later withdrawn from consideration by the researchers before final approval. The majority of these are new applications, but also include amendments, continuing reviews, and deviation submissions. Table 2 shows applications withdrawn over the last five years by level of review. Out of the 186 applications that were withdrawn this year, 84 were exempt applications, 97 were expedited applications, and 5 were full board applications.

TABLE 2. Applications withdrawn by level of review

Reporting Period	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Exempt	54	75	62	88	84
Expedited	88	96	82	101	97
Full Board	16	19	9	9	5
Total:	*158*	*190*	*153*	*198*	*186*

Adverse Events and Unanticipated Problems
There were 5 incidents reported in the last year. The majority of reports were not unanticipated problems involving risks to subjects. Of the reports that were directly related to the research, steps were taken to prevent similar incidents from happening in the future.

Noncompliances
Whenever a study deviates from the approved protocol, or when activities occur outside of an approval, this is deemed noncompliance and must be reported to CPHS. Most often these are found to be cases of simple noncompliance, such as exceeding the approved total number of subjects. Sixty-two cases of potential noncompliance were reviewed in the last year, none of which were found to be a serious or continuing noncompliance.

TABLE 3. Noncompliance

Reporting Period	2014-2015	2015-2016	2016-2017	2017-2018	2018-2019
Noncompliance cases	46	54	62	79	62

Subject complaints
OPHS received ten subject complaints this past year, the majority of which were unsubstantiated or the issue was quickly resolved with the Principal Investigator. Several of the aforementioned complaints came in as whistleblower complaints and they are still under investigation.

Administrative actions
OPHS provides consultation on whether an activity is or is "not human subjects research" (NHSR). At times a journal or sponsor may require an official determination of NHSR. OPHS issued six official NHSR determination letters last year. Many more determinations were issued informally by email through ophs@berkeley.edu.

If a protocol is submitted through eProtocol that is *not* found to meet the threshold definition of human subjects research, OPHS makes a NHSR determination. Last year, 38 determinations were made in eProtocol. The eProtocol system provides a NHSR determination action notification for researchers as proof of determination.

IRB Reliances

OPHS also processes requests for an institution to rely on the IRB review of another. The process helps prevent duplicative IRB reviews of collaborative projects that involve more than one institution. Investigators can make use of the UC System Memorandum of Understanding (MOU) that permits one campus to rely on the IRB review of another. Outside of the UC system, investigators may request that UC Berkeley serve as the IRB of record for a collaborating institution or vice versa. These requests must be reviewed and approved by the OPHS Director. For non-UC collaborations, institutions may enter into Inter-Institutional IRB Authorization Agreements (IIAs), either formally documented with an IIA form or listed on a spreadsheet, depending on protocol specifics.

In addition, during this past year, UCB joined the group known as SMART IRB which is a mechanism by which multiple IRBs can rely on one IRB, known as a sIRB (single IRB). The development of this group, the associated software and processes has been driven by NIH's requirement of sIRB review for multisite, clinical trials. To date, UCB has chosen to use SMART IRB only for qualifying multisite clinical trials and, in doing so, does not serve as the IRB of record.

Over the last fiscal year, UCB entered into 44 new reliances under the UC MOU. UCB was the reviewing campus for 14 of those reliances and the relying campus for 30. Through IIAs for non-UC institutions, UCB entered into 22 new reliances as the relying IRB and approximately 20 as the reviewing IRB.

2018-2019 Turnaround times

Accuracy of turnaround times data is dependent on the accuracy of the reporting function in eProtocol.

The tables below show the amount of time (in number of calendar days) that a new application or amendment spent with CPHS/OPHS and the amount of time spent with the investigator(s) between submission and approval. Time spent with CPHS/OPHS includes the time taken to assign the submission to an OPHS analyst, time the analyst spent on the preliminary review, and time spent by the convened IRB or designated reviewer. Time spent with the designated reviewer may take 5-7 days, or longer. Time is measured in calendar days and a value of "0" indicates that action was taken by that party in less than 24 hours. Continuing review turnaround times are not included as they are processed by expiration date.

On the CPHS/OPHS side, turnaround times for this period compared to last period increased slightly over last year for all application types. (We focus here on the median values – see table below.)

Days spent with CPHS/OPHS for new submissions went up 1 day for exemptions, up 6 days for expedited protocols, and went up 10 days for full board applications. Days with investigators (not under CPHS/OPHS control) went down slightly for exempt protocols and up for full board and expedited applications.

Table 4. Turnaround times for new protocols (in number of calendar days)

Application Type		Calendar Days with CPHS/OPHS				Calendar Days with Investigator(s)			
		2015-16	2016-17	2017-18	2018-19	2015-16	2016-17	2017-18	2018-19
Exempt	Range	0 to 62	0 to 47	0 to 50	1 to 48	0 to 217	0 to 159	0 to 216	0 to 176
	Median	11	17	12	13	9	6	5	4
	Average	13	17	13	14	18	13	12	11
	Protocol #	200	244	224	258				
Expedited	Range	0 to 229	3 to 130	3 to 124	4 to 188	0 to 242	0 to 206	0 to 234	0 to 98
	Median	46	42	33	39	14	10	12	14
	Average	47	44	36	40	26	18	23	20
	Protocol #	290	287	305	260				
Full Board	Range	11 to 83	19 to 141	10 to 95	18 to 130	0 to 217	0 to 178	0 to 103	0 to 124
	Median	40	38	41	51	22	16	13	18
	Average	42	45	44	52	32	29	21	28
	Protocol #	81	55	62	72				

On the CPHS/OPHS side, turnaround times for amendments went down 1 day for exempt protocols, up 1 day for expedited protocols, and up 8 days for full board protocols. Turnaround times on the investigator side remained steady across all application types. Note: multiple factors impact whether an amendment to a full board protocol goes through full committee review. If an amendment is minor, it may be reviewed at the expedited level. eProtocol reports, however, do not always capture these nuances.

Table 5. Turnaround times for amendments (in number of calendar days)

Application Type		Calendar Days with CPHS/OPHS				Calendar Days with Investigator(s)			
		2015-16	2016-17	2017-18	2018-19	2015-16	2016-17	2017-18	2018-19
Exempt	Range	0 to 56	0 to 29	0 to 67	0 to 27	0 to 176	0 to 223	0 to 56	0 to 131
	Median	4	5	4	3	1	0	0	0
	Average	5	7	6	5	9	5	4	4
	Protocol #	132	131	137	162				
Expedited	Range	0 to 78	0 to 73	0 to 66	0 to 106	0 to 308	0 to 228	0 to 155	0 to 166
	Median	7	8	6	7	0	0	0	0
	Average	11	11	9	10	7	5	5	4
	Protocol #	661	679	759	737				
Full Board*	Range	0 to 41	0 to 72	0 to 84	0 to 61	0 to 41	0 to 63	0 to 169	0 to 143
	Median	7	7	12	16	0	0	1	1
	Average	10	14	15	10	4	5	6	7
	Protocol #	19	13	15	13				

Details for 2018-2019 research

The below information has remained relatively consistent across the last several years.

- *Social-behavioral vs. biomedical research:* 75% of protocols (new and continuing review applications) approved were for social-behavioral research.
- *International research:* 22.5% of the protocols reviewed and approved included international sites.
- *Federally funded research:* 32.5% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable subject populations:* 38.5% of the protocols reviewed and approved included at least one vulnerable population. Economically and educationally disadvantaged subject populations are often present in the same study.

V. New Laws, Regulations, and Standards

Revised Common Rule

Changes to regulations governing human subjects research, as outlined in the Common Rule, 45 CFR 46, were published in the Federal Register in January 2017. These amended rules are the first significant changes to human subjects regulations since 1991.

The rule changes were originally scheduled to take effect on January 19, 2018, but were delayed until July 19, 2018. Based on feedback from the research compliance community, the rule was modified to permit implementation of a few aspects of the changes but full implementation was further delayed until January 21, 2019. On January 21, 2019, the revised Common Rule (also known as the 2018 Common Rule requirements) went into effect. As noted in the Executive Summary above, major changes included new/expanded exempt categories, new informed consent requirements, and the elimination of the continuing review requirement for minimal risk research. See the following overview page on the CPHS website for more information: https://cphs.berkeley.edu/guide/commonrule.html

Overall, given the flexibility CPHS/OPHS had already implemented in our policies and procedures, most investigators experienced little change in the conduct of their research and this transition was seamless for them. The biggest impact of this regulatory change was on the staff in ensuring all documentation about the conduct of human subjects research was revised, current, and available to the research community.

FDA guidance on the Impact of the Revised Common Rule

On 10/12/18, FDA released the following guidance: *Impact of Certain Provisions of the Revised Common Rule on FDA-Regulated Clinical Investigations*

For studies that fall under the purview of both regulations (e.g., the trial is supported by HHS and involves an FDA-regulated product), the agency states that, "where the regulations differ, the regulations that offer the greater protection to human subjects should be followed."

NIH's Revised Clinical Trial Policies

Implementation of New NIH Clinical Trial Definition and Procedures:

In 2014, NIH began a multi-faceted effort to enhance the quality, relevance, feasibility, and transparency of NIH-funded clinical trials. A key element of these stewardship reforms was the development of a clearer, more comprehensive definition of clinical trial. Currently, the NIH clinical trial definition is:

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 (https://grants.nih.gov/policy/clinical-trials/definition.htm).

The revision is designed to make the distinction between clinical trials and clinical research studies clearer and to enhance the precision of the information NIH collects, tracks, and reports on clinical trials.

All NIH applications proposing clinical trials that are submitted on or after 1/25/2018 must be submitted under a funding opportunity announcement (FOA) designated specifically for clinical trials.

On July 20, 2018, NIH issued a notice on Delayed Enforcement and Short-Term Flexibilities for Some Requirements Affecting Prospective Basic Science Studies Involving Human Participants (NOT-OD-18-212). There is concern among the research community that the NIH clinical trial case studies broadened the agency's definition of "clinical trial" to include basic science studies involving human participants. NIH, in response, has released this notice (NOT-OD-18-212), which delays enforcement of registration and reporting policies for prospective basic science studies involving human participants under NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NOT-OD-16-149). Per the notice, "through September 24, 2019, NIH will continue to expect registration and reporting for prospective basic science studies involving human participants, with additional flexibility to allow reporting on existing basic science portals, with the expectation that data will eventually be transported to ClinicalTrials.gov."

General Data Protection Regulation (GDPR)
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 European Economic Area (EEA). Effective May 25, 2018, any research that involves subjects located in the EEA must comply with GDPR or face heavy penalties (up to 20 million Euros or 4% global revenues).

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://gdpr-info.eu/

OPHS created a guidance page for the UC Berkeley research community:
https://cphs.berkeley.edu/guide/gdpr.html

Marijuana Research
Proposition 64, the initiative that legalized adult-use marijuana under state law, but which did not alter federal law in this area, has raised questions in regards to policies related to marijuana and industrial hemp research conducted at the UC. In response, UCOP has created an updated guidance document on Conducting Marijuana Research at the University of California, published July 24, 2018. As before, this document affirms that UC research remains subject to the same federal laws and regulations as before the passage of Proposition 64.

VI. New or Modified Campus Procedures and Programs

OPHS staff updated and/or created a large amount of content on http://cphs.berkeley.edu over the last fiscal year to aid investigators and research participants alike. Many of these updates were made in response to the revised Common Rule:

CPHS Guidelines
OPHS and CPHS updated the following guidelines for investigators:
- Child Assent and Parent Permission
- Engagement in Human Subjects Research
- Exempt Research
- HIPAA and Human Subjects Research
- Informed Consent
- Secondary Analysis of Existing Data

OPHS and CPHS developed the following new guidelines:
- Certificate of Confidentiality

CPHS Policies and Procedures
OPHS and CPHS updated the following policies:
- Signatory Authority
- Determination of Exemption
- IRB Meeting Administration
- Initial Review
- Expedited Review
- Continuing Review
- Monitoring Ongoing Research
- Categories of Action
- Intrainstitutional Communication
- General Requirements and Documentation
- Waivers of Informed Consent
- Assent and Parent/Guardian Permission

CPHS Checklists and Worksheets
OPHS and CPHS updated the following checklists and worksheets:
- Criteria for IRB Approval of Research
- Informed Consent Checklist
- Waiver of Child Assent
- Waiver of One or More Elements of Informed Consent
- Waiver of Parent or Guardian Permission
- Waiver of Requirement for Documented Consent

CPHS Website
- OPHS Staff created a webpage to explain changes associated with the revised Common Rule (45 CFR 46), UCB's transition process, and related links: https://cphs.berkeley.edu/guide/commonrule.html
- "What Needs CPHS/OPHS Review" was updated to account for changes associated with the revised Common Rule: https://cphs.berkeley.edu/review.html
- The OPHS/CPHS glossary was updated to account for modified definitions associated with the revised Common Rule: https://cphs.berkeley.edu/glossary.html
- With the revised Common Rule, CPHS/OPHS changed "Exempt Category 7" to "Exempt Category 70." The related quick guide was updated: https://cphs.berkeley.edu/guide/exemptcategory70.html

- The "Ten-Year Approval" quick guide was updated to account for changes associated with the revised Common Rule: https://cphs.berkeley.edu/guide/tenyear.html
- OPHS Staff created a guidance page on the General Data Protection Regulation (GDPR) as well as related consent template language.
- CPHS published a Fall 2018 newsletter with information on the updated Common Rule: https://cphs.berkeley.edu/newsletter/2018fall.pdf

VII. Agency Inspections and Enforcement Actions

No inspections took place between 7/1/18 and 6/30/19.

VIII. Education and Outreach

Education of UCB's research community

OPHS conducted 5 training sessions for the research community in the past year, down from last year's 11 presentations. The drop in presentations was due to the continuing reduced staffing level and a subsequent lack of availability to prepare, travel to campus, and give presentations. However, OPHS combined presentation requests in order to reach as many investigators as possible. See a breakdown of presentations by unit in the below table.

Table 6. Education Outreach

College/School/Department	# of Presentations
Blum Center for Developing Economies	1
Graduate Student Workshop (combined group)	1
McNair Scholars/SURF/Haas Scholars (combined group)	1
Optometry	1
School of Public Health (combined group)	1

Educational and Professional Staff Development

OPHS staff participated in the following webinars:

- PRIM&R, "When SBER Involves Drugs and Devices: Cases to Clarify FDA Oversight," September 2018
- PRIM&R, "Data Sharing in SBER: Balancing Transparency and Human Research Protections," May 2019
- PRIM&R, "Wearing Multiple Hats in Your Research Compliance Program," May 2019
- PRIM&R, "Expectation vs. Reality: Reporting Obligations to the IRB," June 2019
- PRIM&R, SBER Network Virtual Roundtable, "Postapproval Monitoring: Ideas for What to Do Instead of Continuing Review," June 2019

In August 2018, OPHS Assistant Director Adrienne Tanner attended the UCOP-sponsored People Management Conference hosted by UCLA.

In October 2018, OPHS staff members Sarah Donnelly and Carrie Des Roches attended PRIM&R's IRB Administrator Boot Camp in Chicago.

OPHS staff members Colleen Kohashi, Daisy Lubag, Suzanne Stone and Adrienne Tanner, along with OPHS Director Rebecca Armstrong, attended PRIM&R's Advancing Ethical Research conference in November 2018 in San Diego where staff members (as noted below), presented the following:

Tanner, A. & Kohashi, C., (2018, November). *Square Peg, Round Hole: When Community Based Ethnographic Research Meets the Federal Regulations.* Poster session presented at the annual meeting of Public Responsibility in Medicine and Research, San Diego, CA.

Gloeckner., G, Jach, E., Kohashi, C. (2018, November). *Navigating Uncertainty: Research with Undocumented/Unauthorized Immigrants.* Paper presented at the annual meeting of Public Responsibility in Medicine and Research, San Diego, CA.

Certified IRB Professional (CIP) Certification:

Colleen Kohashi and Jason Silva took and successfully passed the CIP exam in spring 2019, recertifying and becoming OPHS' newest CIP-certified staff member, respectively.

IX. General issues under discussion in the IRB world (in addition to items described above regarding new regulations, policies and definitions):

- Implementation of revised Common Rule
- Single IRB requirement under the revised Common Rule (scheduled to go into effect in January 2020)
- Data sharing and data ownership
- California Consumer Privacy Act of 2018 (beginning January 1, 2020)
- Genetic research
- Right to Try/Expanded Access