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Attached is the 2019-2020 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.

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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

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Chair, Committee for Protection of Human Subjects (CPHS-2)
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Enc. CPHS Membership Roster 2019-2020

Cc: Pamela Miller, Interim 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, 2019 - June 30, 2020.

II. Executive Summary

From July 1, 2019 - June 30, 2020, the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1695 applications, down from 1866 applications approved during the prior fiscal year. The number of approvals for new protocols was down slightly, amendment approvals were up slightly, and continuing reviews decreased significantly (as expected given regulatory changes) compared to last year.

Noncompliance submissions decreased, official determinations of "not human subjects research" (NHSR) also decreased, and the number of withdrawn applications was down slightly, compared to last year. Overall, OPHS review turnaround times were reduced slightly (see tables 4 and 5). UC Berkeley's human subjects research portfolio remains primarily social-behaviorally focused at 78.2% of total approved submissions. Of the 1695 applications approved, 31.2% of them were federally-funded.

When the revised DHHS regulations governing human subjects research (45 CFR 46), went into effect on January 21, 2019, they expanded exempt categories, included new requirements for informed consent, and did away with the annual review requirement for minimal risk research. These changes allowed more research to be reviewed at the exempt level and expanded the number of protocols eligible to receive a ten year approval period, resulting in a reduced number of continuing review applications over the last fiscal year.

UC Berkeley (UCB) continues to take advantage of flexibility afforded by the regulations in terms of non-federally funded/regulated research. In late 2015, UCB 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 on January 21, 2019, 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 various ways, from filling out a shorter application form to reducing review times. During the 2019-2020 fiscal year, OPHS made 31 new category #70 determinations, saving time for both OPHS staff and for investigators.

The second half of the last fiscal year introduced unique challenges with the beginning of the COVID-19 public health crisis. OPHS staff began telecommuting 100% during the second week of March, and CPHS full committee meetings were held by Zoom starting with the 3/20/20 CPHS-2 meeting. On 3/13/20, investigators were advised to take measures to limit COVID-19 exposure and delay non-essential research; and, on 3/20/20, investigators were notified that they must cease all non-essential in-person research immediately. Where possible, investigators were encouraged to use remote forms of data collection, such as conducting interviews by Zoom. OPHS staff continued to handle their usual workloads and responsibilities while working from home, along with added pressure to perform rush reviews of COVID-19-related studies. By the end of June 30, 2020, OPHS had approved 105 COVID-related studies. OPHS has been in close communication with the VCRO on research resumption activities and have collectively created guidelines and research resumption forms to approve and track

research resumption activities on campus and in the field. See https://cphs.berkeley.edu/covid-19.html and below for more information.

Following Diana Holt's retirement at the end of June 2019, IRB Coordinator Suzanne Stone, who had been working under a part-time contract, was hired as a full time staff member as of 7/1/2019, and started sharing her job responsibilities between OPHS and the Office for Animal Care and Use (OACU) starting on 11/1/19. Before OPHS's newest staff member, Brenda Belcher, came on board on January 8, 2020, OPHS continued to operate with a reduced staff, down by 14% (i.e. 1.07 FTE). OPHS also absorbed Stem Cell Research Oversight (SCRO) Committee duties at the beginning of the 2019-2020 fiscal year, without an increase in staff.

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 '19-'20 fiscal year, CPHS-1 and CPHS-2 each convened 9 times. CPHS-1 had 14 regular members in the fall and 17 in the spring. CPHS-2 had 13 regular members in the fall and 16 in the spring (the 2019-2020 CPHS Membership List is attached).

Professor Bill Jagust, MD served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Ndola Prata, MD served as CPHS-1 Vice Chair and Professor Jeff Selbin served as CPHS-2 Vice Chair in the fall and Professor Oliver John served as CPHS-2 Vice Chair in the spring. OPHS staff are authorized as alternate members for OPHS Director Rebecca 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 down as compared to last year at 1695 approvals. New protocol approvals were down slightly in comparison to last year, with an increase in exempt determinations and a decrease in expedited and full board approvals. Exempt amendments were up, expedited amendments were up and full board amendments were down. Expedited continuing review applications were down significantly by 171 protocols, and full board continuing review applications remained steady. Three-year approvals for qualifying studies (e.g. non-federally regulated) were first granted in April 2013. In late April 2016, CPHS further extended the standard approval period to 10 years. While the revised Common Rule, which went into effect on January 21, 2019, 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: FDA-regulated research and, until April 2020, DOD-sponsored research must be reviewed annually, and industry-sponsored research must be reviewed at least once every 3 years. 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

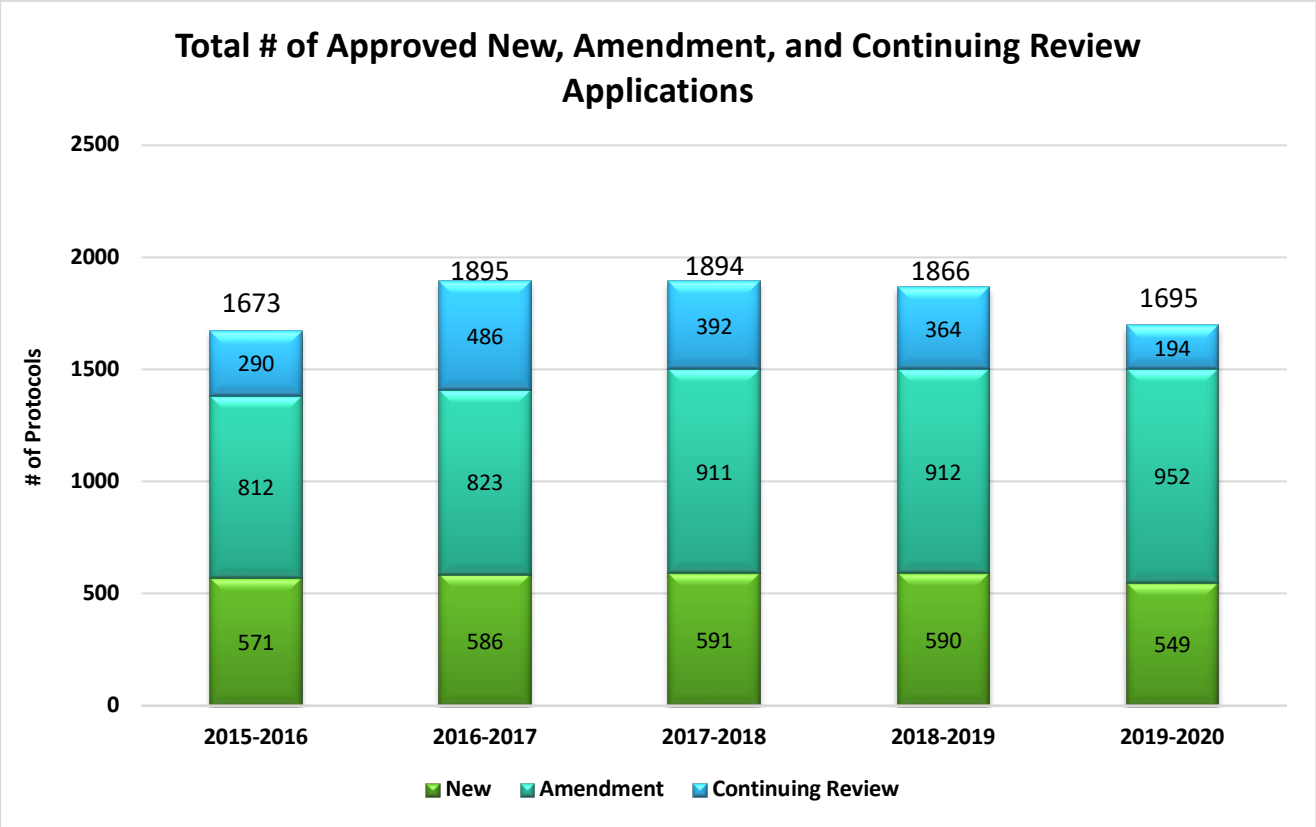

TABLE 1. Types of applications approved over 5 years

Application Type	Review Level	2015-16	2016-17	2017-18	2018-19	2019-20
New	Exempt:	200	244	224	258	265
	Expedited:	290	287	305	260	235
	Full Board:	81	55	62	72	49
	TOTAL	**571**	**586**	**591**	**590**	**549**
Amendment	Exempt:	132	131	137	162	192
	Expedited:	661	679	759	737	752
	Full Board:	19	13	15	13	8
	TOTAL	**812**	**823**	**911**	**912**	**952**
Continuing Review	Expedited:	260	453	356	339	168
	Full Board:	30	33	36	25	26
	TOTAL	**290**	**486**	**392**	**364**	**194**
Total Activity		**1673**	**1895**	**1894**	**1866**	**1695**

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 181 applications that were withdrawn this year, 80 were exempt applications, 90 were expedited applications, and 11 were full board applications.

TABLE 2. Applications withdrawn by level of review

Reporting Period	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Exempt	75	62	88	84	80
Expedited	96	82	101	97	90
Full Board	19	9	9	5	11
Total:	*190*	*153*	*198*	*186*	*181*

Adverse Events and Unanticipated Problems
There were 8 incidents reported in the last year. The majority of reports were not unanticipated problems involving risks to subjects. Of the very few 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 a 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. Forty-three 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	2015-2016	2016-2017	2017-2018	2018-2019	2019-2020
Noncompliance cases	54	62	79	62	43

Subject complaints
OPHS received nine subject complaints this past year, the majority of which were unsubstantiated or the issue was quickly resolved with the Principal Investigator.

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 12 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, 34 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 UCB 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, UCB is part of the group known as SMART IRB which is a mechanism by which multiple IRBs can rely on one IRB, known as an 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 31 new reliances under the UC MOU. UCB was the reviewing campus for 15 of those reliances and the relying campus for 16. Through IIAs for non-UC institutions, UCB entered into 27 new reliances as the relying IRB and approximately 65 as the reviewing IRB.

2019-2020 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, when needed. 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 for exempt protocols and decreased for expedited and full board 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, down 4 days for expedited protocols, and down 2 days for full board applications. Days with investigators (not under CPHS/OPHS control) went down for exempt and expedited protocols and up for full board 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)			
		2016-17	2017-18	2018-19	2019-20	2016-17	2017-18	2018-19	2019-20
Exempt	Range	0 to 47	0 to 50	1 to 48	0 to 64	0 to 159	0 to 216	0 to 176	0 to 189
	Median	17	12	13	14	6	5	4	3
	Average	17	13	14	16	13	12	11	12
	Protocol #	244	224	258	265				
Expedited	Range	3 to 130	3 to 124	4 to 188	0 to 88	0 to 206	0 to 234	0 to 98	0 to167
	Median	42	33	39	35	10	12	14	10
	Average	44	36	40	34	18	23	20	19
	Protocol #	287	305	260	236				
Full Board	Range	19 to 141	10 to 95	18 to 130	5 to 28	0 to 178	0 to 103	0 to 124	0 to 183
	Median	38	41	51	49	16	13	18	19
	Average	45	44	52	53	29	21	28	31
	Protocol #	55	62	72	48				

On the CPHS/OPHS side, turnaround times for amendments went up 3 days for exempt protocols, down 1 day for expedited protocols, and down 6 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 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)			
		2016-17	2017-18	2018-19	2019-20	2016-17	2017-18	2018-19	2019-20
Exempt	Range	0 to 29	0 to 67	0 to 27	0 to 26	0 to 223	0 to 56	0 to 131	0 to 163
	Median	5	4	3	6	0	0	0	0
	Average	7	6	5	7	5	4	4	3
	Protocol #	131	137	162	192				
Expedited	Range	0 to 73	0 to 66	0 to 106	0 to 115	0 to 228	0 to 155	0 to 166	0 to 130
	Median	8	6	7	6	0	0	0	0
	Average	11	9	10	11	5	5	4	5
	Protocol #	679	759	737	752				
Full Board*	Range	0 to 72	0 to 84	0 to 61	0 to 68	0 to 63	0 to 169	0 to 143	0 to 32
	Median	7	12	16	10	0	1	1	1
	Average	14	15	10	19	5	6	7	6
	Protocol #	13	15	13	8				

Details for 2019-2020 research

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

- *Social-behavioral vs. biomedical research:* 78.2% of protocols (new and continuing review applications) approved were for social-behavioral research.
- *International research:* 19.5% of the protocols reviewed and approved included international sites.
- *Federally funded research:* 31.2 % of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable subject populations:* 40.3% 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

Single IRB Requirement under the Revised Common Rule

The revised Common Rule (i.e., the 2018 Requirements) requires at 45 CFR 46.114(b) that all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency rely upon approval by a single IRB for the portion of the research that is conducted in the United States.

While the single IRB requirement was part of the revised Common Rule which went into effect on January 21, 2019, the compliance date for the single IRB requirement went into effect more recently on January 20, 2020. For studies subject to the 2018 Requirements:

- Reliance on a single IRB of record in cooperative research is optional before January 20, 2020, even for research subject to the 2018 Requirements.
- Reliance on a single IRB of record in cooperative research is required beginning January 20, 2020, unless the study meets the criteria for an exception described in §46.114(b)(2) of the 2018 Requirements.

The requirement for the use of a single IRB in cooperative research only applies to US institutions and the portion of the collaborative research conducted within the US.

COVID-19

In early March 2020, UCB responded to growing public health concerns surrounding the emergence of the COVID-19 virus. On March 13, 2020, the VCR and CPHS issued a notice to UC Berkeley researchers recommending that study investigators plan to take and implement specific actions to limit transmission of the virus by delaying or otherwise modifying non-essential interactions with human subject research participants. In particular, PIs were encouraged to delay research involving group meetings or appointments – especially with subject populations who may be more vulnerable to the COVID-19 virus – or use alternative interactions via electronic means. OPHS staff also started working remotely 100% at that time.

On March 20, 2020, the VCR and CPHS issued further guidance indicating that, in light of new guidance at the state and national level, all in-person research interactions must cease immediately. The notice stated that only research that is essential to the health of the participant may continue to include

in-person interactions. This notice applied to all research conducted within the U.S. and abroad. It further clarified:

If your approved protocol involves in-person interactions:

• You may modify your procedures to continue your research and remotely interact with subjects using telephone or internet means.
• If you cannot modify your research to eliminate in-person contact, you must put your research on hold.

Pausing research does not require an IRB amendment or other notification.

If you choose to make risk-reducing changes by eliminating in-person contact, you may do so immediately without waiting for CPHS approval. You must still submit a protocol amendment and, if you change your protocol prior to CPHS review and approval, submit a deviation report to CPHS/OPHS as soon as you can. Any infection-reducing deviations will be viewed as minor.

CPHS and the VCR also provided guidance on appropriate screening measures to limit COVID-19 exposure/transmission for essential, in-person research activities.

Starting in June 2020, UC Berkeley implemented a phased plan for resuming research and bringing subjects back on campus, with the clear message that any research that can be conducted remotely must be.

Between March and June 2020, CPHS/OPHS received 125 COVID-19 related submissions, both new and amendments, with most being time-sensitive. By the end of June 2020, CPHS/OPHS had approved 105 COVID-19 related protocols.

The NIH, NSF, and FDA all published guidance related to the COVID-19 public health emergency. The FDA also provided FAQs on Testing for SARS-CoV-2.

In addition, on March 17, 2020, the U.S. Department of Health and Human Services (HHS) issued a Declaration, under the Public Readiness and Emergency Preparedness Act (PREP Act), providing immunity to certain covered persons against claims of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of drugs, biologics, diagnostics, devices, and vaccines used to treat, diagnose, cure, prevent, or mitigate COVID-19. In order to be covered under the PREP Act, the product must be used under an FDA-approved mechanism, such as through an Emergency Use Authorization (EUA), Investigational New Drug Application (IND), or Investigational Device Exemption Application (IDE).

FDA Guidance on Humanitarian Device Exemption Program

On September 6, 2019, the Food and Drug Administration issued final guidance on the Humanitarian Device Exemption (HDE) Program. This guidance reflects changes to the HDE Program resulting from the amendments made by the 21st Century Cures Act. The Cures Act amended the Food, Drug and Cosmetic Act (FD&C Act) to increase the maximum number of patients affected by a disease or condition that a Humanitarian Use Device (HUD) is designed to treat or diagnose to "not more than 8,000 individuals" in the United States." Amendments to the FD&C Act also allow either an institutional review board (IRB) or "an appropriate local committee" approve the use of a HUD to treat or diagnose patients at a facility.

California Consumer Privacy Act (CCPA)

The California Consumer Privacy Act (CCPA) was signed into law on June 28, 2018 by Governor Brown and is incorporated into the California Civil Code at Section 1798.11 et seq. It grants California residents1 ("consumers") rights with respect to the collection and use of their personal information by businesses.

Specifically, it gives consumers: (1) the right to know what personal information is being collected about them and how it is being used and shared; (2) the right to control how their personal information is used; and (3) the right to equal service and price, even if they exercise their privacy rights.
The CCPA calls upon the California Attorney General to issue regulations governing compliance with the new law. As of the date of release of this Alert, a proposed final version of these regulations ("Proposed Regulations") is before the California Office of Administrative Law for review. The Proposed Regulations instruct businesses on compliance obligations with respect to notice to consumers, handling consumer requests, verification of those requests, and requirements regarding minors and non-discrimination.

The CCPA went into effect on January 1, 2020, with enforcement by the California Attorney General allowed beginning July 1, 2020.

Since UC is not a business, the CCPA does not directly apply to UC. However, CCPA may apply to UC's for-profit ventures and commonly branded public-private partnerships. Some of UC's suppliers and research sponsors may also require compliance with certain provisions of the Act.

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.

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."

VI. New or Modified Campus Procedures and Programs

OPHS staff updated and/or created a large amount of content on https://cphs.berkeley.edu over the last fiscal year to aid investigators and research participants alike.

CPHS Guidelines
OPHS and CPHS updated the following guidelines for investigators:
- Mechanical Turk (MTURK) for Online Research
- Data Security Guidelines and Matrix
- Engagement in Human Subjects Research
- HIPAA and Human Subjects Research
- Exempt Research
- Secondary Analysis of Existing Data

OPHS and CPHS developed the following new guidelines for investigators:
- Legally Authorized Representative (LAR): Use of Surrogate Consent in Research

CPHS Policies and Procedures
OPHS and CPHS updated the following policies:
- IRB Membership
- Data Security
- Training and Education for Investigators

CPHS Website
OPHS staff added or updated the following resources, as noted:
- Added a new long-form FAQ on HIPAA vs. FERPA: Secondary Use of Student Health Records at Postsecondary Institutions
- Added a new long-form FAQ on Informed Consent in Exempt Level Research
- Added a new long-form FAQ on Data Retention and updated the Maintenance and Stewardship of Research Data
- Added an FAQ on selecting an online survey platform
- Added an FAQ on data sharing without consent
- Added COVID-19 Guidance for Human Subjects Research
- Updated the Secondary Use of Existing Data long-form FAQ
- Updated the "What if I will be sharing data with non-UC Berkeley investigators/institutions?" FAQ
- Updated the FAQ on using electronic signatures for documented consent
- The "Am I Conducting Research" questionnaire was updated to a more comprehensive, "Am I Conducting Human Subjects Research" questionnaire
- Updated the General Data Protection Regulation (GDPR) page
- Updated the Working with Research Study Participants: An Overview PowerPoint presentation
- Updated the HIPAA PHI website text
- Updated the Training and Education page
- Updated the CITI training log-in instructions

VII. Agency Inspections and Enforcement Actions

No inspections took place between 7/1/19 and 6/30/20.

VIII. Education and Outreach

Education of UCB's research community

OPHS conducted 5 training sessions for the research community in the past year, the same number as last year. 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
D-Lab Working Group	1
Graduate Student Workshop (combined group)	1
McNair Scholars/SURF/Haas Scholars (combined group)	1
School of Public Health (combined group)	1
JMP IRB Orientation for 1st Year Students	1

Educational and Professional Staff Development

OPHS staff participated in the following webinars:

- CITI, "Research with Native American Communities: Important Considerations When Applying Federal Regulations," August 2019.
- CITI, ""Ethics & Policy Issues in CRISPR Gene Editing," August 2019
- Flex Coalition Webinar, August & March 2020
- PRIM&R, "SBER Network Virtual Roundtable: Piloting a System-Based Exemption Process," September 2019.
- OHRP, "SMART Talk: Getting Ready for the 2020 Single IRB Requirements," September 2019.
- SMART IRB: "October SMART Talk: Operationalizing an HRPP under Single IRB: what's different, what's the same, and the known unknowns," October 2019.
- CARE-Q: "sIRB: When Institutions are relying on another IRB," October 2019.
- PRIM&R, "SBER Network's Virtual Roundtable: GDPR and SBER," February 2020.
- PRIM&R, "COVID-19: How HRPPs are Preparing and Responding—A Discussion Forum," March 2020
- OHRP, "OHRP Guidance on Response to COVID-19," April 2020

OPHS staff member Colleen Kohashi and OPHS Director Rebecca Armstrong, attended PRIM&R's 2019 Social, Behavioral, and Educational Research Conference (SBER19) in Boston where they presented the following:

Armstrong, R., & Brooke-Cholka, C. (2019, November). *From Flexible to More Flexibility: What's left to review?* Paper presented at the SBER meeting of Public Responsibility in Medicine and Research, Boston, MA.

Kohashi, C. & McGee, M. (2019, November). *Incentives and Compensation for Subjects in SBER***.** Paper presented at the SBER meeting of Public Responsibility in Medicine and Research, Boston, MA.

OPHS Assistant Director Adrienne Tanner and OPHS Director Rebecca Armstrong attended PRIM&R's Advancing Ethical Research conference in November 2019 in Boston where Adrienne presented the following:

Tanner, A. (2019, November). *A Flexible Approach to Exempt Review.* Poster session presented at the annual meeting of Public Responsibility in Medicine and Research, Boston, MA.

Certified IRB Professional (CIP) Certification:

Carrie Des Roches, Sarah Donnelly, and Adrienne Tanner (recertifying) took and successfully passed the CIP exam in fall 2019, and Brenda Belcher took and successfully passed the CIP exam in spring 2020.

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
- Data sharing and data ownership
- Genetic research
- Right to Try/Expanded Access
- GDPR and related privacy laws