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Attached is the 2015-2016 Annual Report for the Committee for Protection of Human Subjects. CPHS and OPHS strive to offer excellent customer service while ensuring the health, welfare and safety of subjects and supporting institutional regulatory compliance. CPHS and OPHS continue to lead the UC System in reviewing and revising our policies and practices and implementing increased flexibility for non-federally regulated, minimal-risk biomedical, social-behavioral, and educational research projects. This minimizes regulatory burden on many investigators and has been greatly appreciated by the faculty. CPHS and OPHS will continue to look for ways to streamline processes and reduce administrative workload for faculty conducting human subjects research.

Please contact us with questions or comments regarding this report:

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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

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

Enc. CPHS Membership Roster 2015-2016

Cc: 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, 2015 - June 30, 2016

II. Executive Summary

In 2015-2016, the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1673 applications, an increase from last fiscal year. New, continuing review, and amendment approvals were up almost 100 more than last year, especially amendments and continuing reviews overall and new submissions reviewed by the full board. Withdrawals and noncompliance submissions went up as well, along with official determinations of "not human subjects research" (NHSR). UC Berkeley research remains primarily social behaviorally focused, at 74% of total approved submissions. There was a 5% increase in federally funded studies.

In late 2015, UC Berkeley was the first UC System institution to roll out an Exempt Category #7. This new category permits 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. This benefits the researcher in many ways, from filling out a shorter application form, to not being required to submit consent documents, to no longer needing continuing review at all.

Furthermore, in April 2016, UC Berkeley extended its IRB approval period for qualifying expedited minimal risk research from 3 to 10 years. While appropriate oversight is maintained by requiring review of any amendments to such protocols, this 10-year approval period substantially reduces the burden on PIs for frequency of resubmission to CPHS. OPHS staff were delegated authority in mid-June 2016 to review minor amendments and continuing review applications to help reduce review timelines. The CPHS Executive Committee voted that action-based practitioner projects through the Leadership for Educational Equity Program (LEEP) in the School of Education do not need human subjects research review. Throughout the fiscal year, CPHS and OPHS revised and created several guidelines and revised two policies. The full listing can be found at the end of this report.

Professor Robert DiMartino finished his tenure as CPHS-1 Chair on June 30, 2016 and was succeeded by Dr. William Jagust. Dr. Jagust is a Professor in Public Health and Neuroscience. His research focuses on aging, dementia, and brain imaging.

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

The Committee is comprised of two panels, CPHS-1 and CPHS-2, and both review biomedical and social-behavioral research. CPHS-1 convened 10 times and CPHS-2 convened 9 times in this period. Both committees had 14 members (the 2015-2016 CPHS Membership List is attached).

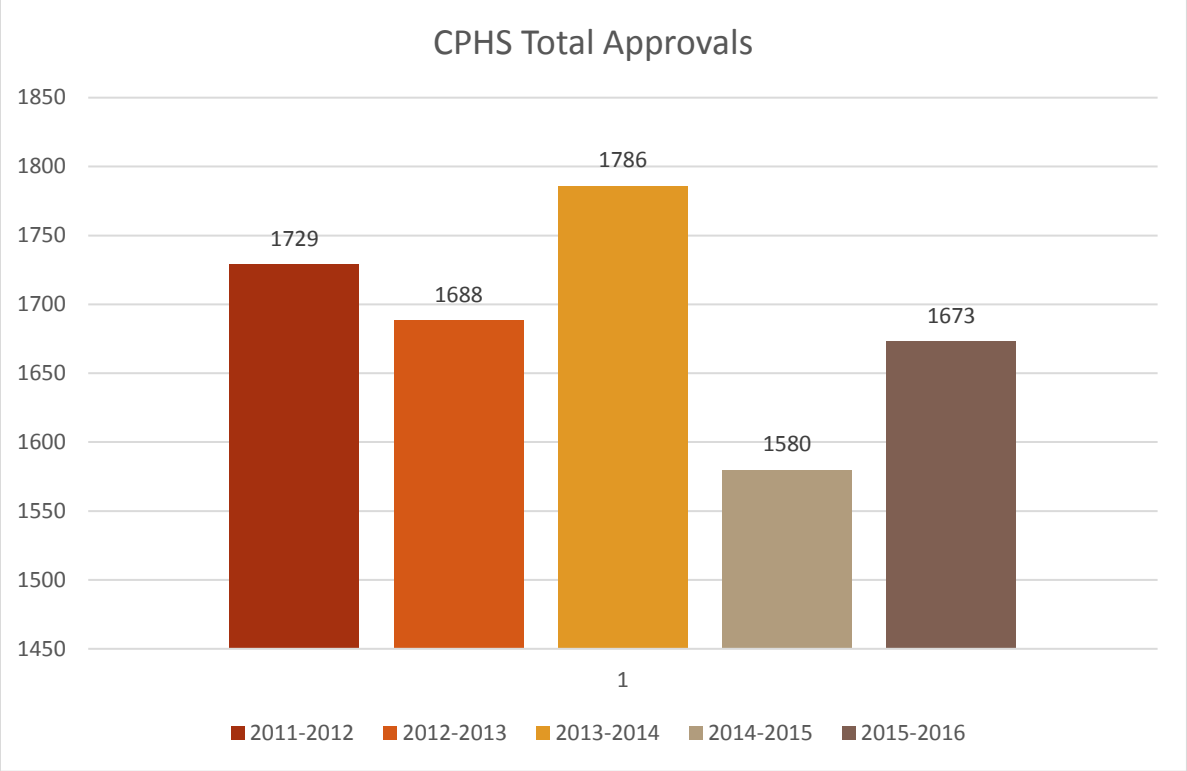
Professor Robert DiMartino served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Jack Lesch served as CPHS-1 Vice Chair and Professor Oliver John served as CPHS-2 Vice Chair. OPHS Director Rebecca Armstrong served as a designated CPHS reviewer assisting with the expedited 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.

IV. Summary of Research Protocols Reviewed

Approvals

The total human subjects research review activity for CPHS and OPHS increased by about 100 submissions for 2015-2016. There were almost 40 more new submissions than last year that received full board review, along with about 20 more new exempt submissions. Amendments were up at every review level compared to last year, with 70 more total amendments approved. Continuing reviews also increased for full board review and expedited review, with 29 more continuing review approvals. 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.

FIGURE 1. Total applications approved over 5 years



As the table below indicates, the drop in CPHS Total Approvals from 2013-14 to 2014-15 is entirely due to a sharp reduction in Continuing Reviews. This change came after CPHS revised its policies in April 2013 to extend approval periods for most protocols from one year to three years. This past year (in April 2016) CPHS further extended the standard approval period to 10 years. Once all three-year approvals have run their course, there will be very few Continuing Reviews, as almost no studies continue for ten years.

Of particular note is the number of new Full Board protocols in 2015-2016 – almost twice as many as were submitted and approved in the prior year. Expedited-level amendments continue to increase also. The decreased number of expedited approvals probably reflects in part CPHS/OPHS' roll out of Exempt Category #7, where non-federally funded or regulated expedited studies have been instead reviewed at the exempt level.

TABLE 1. Types of applications approved over 4 years

		2015-16	2014-15	2013-14	2012-13
New	Exempt:	200	178	205	210
	Expedited:	290	355	309	238
	Full Board:	81	44	29	27
	TOTAL	*571*	*577*	*539*	*475*
Amendment	Exempt:	132	116	100	74
	Expedited:	661	592	494	500
	Full Board:	19	34	27	14
	TOTAL	*812*	*742*	*621*	*588*
Continuing Review	Expedited:	260	235	603	582
	Full Board:	30	26	23	43
	TOTAL	*290*	*261*	*626*	*625*
Total Activity		*1673*	*1580*	*1786*	*1688*

Withdrawn applications

There are times when applications received by CPHS/OPHS are reviewed, 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 190 applications that were withdrawn this year, 75 were exempt applications, 96 were expedited applications, and 19 were full board applications.

TABLE 2. Applications withdrawn by level of review

Reporting Period	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Exempt	54	61	60	54	75
Expedited	71	65	64	88	96
Full Board	12	6	5	16	19
Total:	*136*	*132*	*125*	*158*	*190*

Adverse Events and Unanticipated Problems

There were 12 potential unanticipated problems reported in the last year; however, none were determined to be unanticipated problems involving risk to subjects or others.

Noncompliance

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. Fifty-four cases of potential noncompliance were reviewed in the last year, none of which were found to be serious or continuing noncompliance.

TABLE 3. Noncompliance

Reporting Period	2011-2012	2012-2013	2013-2014	2014-2015	2015-2016
Noncompliance cases	22	36	66	46	54

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. If the request is made by email, OPHS issues a determination letter. Fourteen letters were issued this fiscal year. There were 43 determinations that were made in eProtocol for applications that were submitted. The eProtocol system provides a NHSR determination action within the system for researchers as proof of determination.

OPHS also processes requests for one 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 either review for or rely on another institution they are collaborating with. 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. Table 3 lists the number of MOUs and IIAs for the past four years.

TABLE 4. Memoranda of Understanding and Inter-Institutional IRB Authorization Agreements

Reporting Period	2012-2013	2013-2014	2014-2015	2015-2016
Reliances under UC MOU				
UCB Reviewed	88	97	87	124
UCB Relied	30	30	30	29
Total:	*118*	*127*	*117*	*153*
Reliances under IAAs				
UCB Reviewed	86	101	85	113
UCB Relied	20	15	18	27
Total	*106*	*116*	*103*	*140*

2015-2016 Turnaround times
The tables below show the amount of time 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 is measured in business 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.

Turnaround times for this period compared to last period went up modestly in each category. (We focus here on the median values – see table below.) On average, the time new submissions spent with CPHS/OPHS went up 3 days for exemptions, 8 days for expedited protocols, and 2 days for full board applications. Time with investigators (which is not under CPHS control) also went up in every category.

Table 5. Turnaround times for new protocols

		Days with CPHS/OPHS				Days with Investigator(s)	
		2015-16	2014-15	2013-14	2012-13	2015-16	2014-15
Exempt	Range	0 to 62	-	-	-	0 to 217	-
	Median	11	8	4	9	9	6
	Average	13	9	6	11	18	17
	# protocols	200	178	205	210		
Expedited	Range	0 to 229	-	-	-	0 to 242	-
	Median	46	38	29	35	14	12
	Average	47	39	33	39	26	25
	# protocols	290	355	309	238		
Full Board	Range	11 to 83	-	-	-	0 to 217	-
	Median	40	38	28	56	22	38
	Average	42	42	42	46	32	15
	# protocols	81	44	29	27		

Turnaround times for amendments only went up slightly, mainly on the investigator side, while turnaround time with CPHS/OPHS at full board level went down 3 days.

Table 6. Turnaround times for amendments

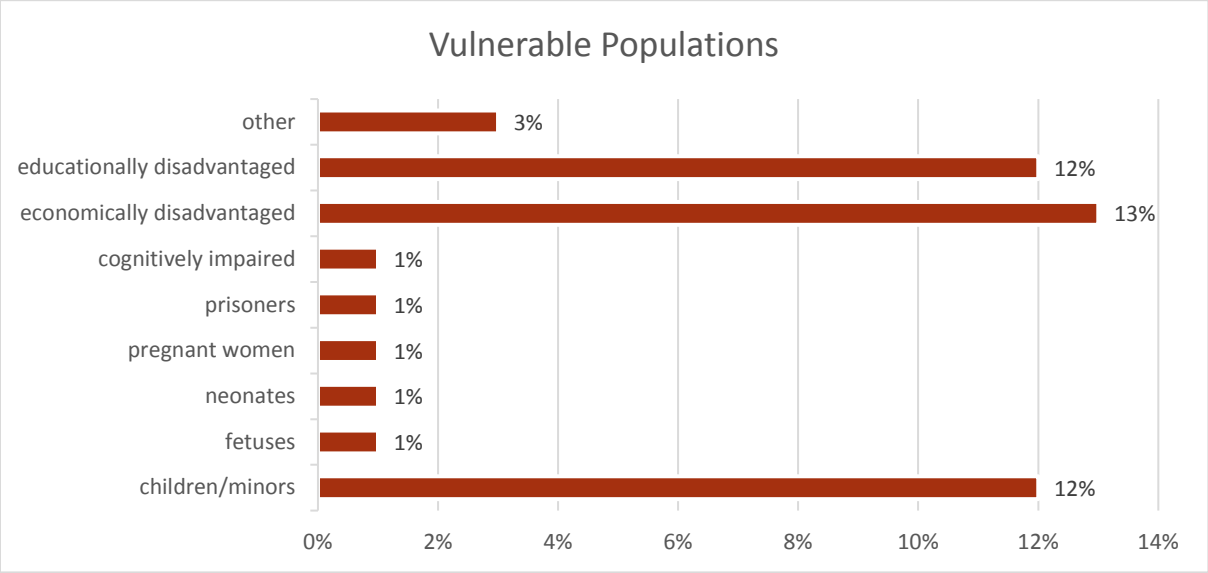
		Days with CPHS/OPHS				Days with Investigator(s)	
		2015-16	2014-15	2013-14	2012-13	2015-16	2014-15
Exempt	Range	0 to 56	-	-	-	0 to 176	-
	Median	4	2	2	6	1	-
	Average	5	4	3	8	9	15
	# protocols	132	116	100	74		
Expedited	Range	0 to 78	-	-	-	0 to 308	-
	Median	7	8	6	8	0	-
	Average	11	11	9	11	7	19
	# protocols	661	592	494	500		
Full Board	Range	0 to 41	-	-	-	0 to 41	-
	Median	7	7	6	9	0	-
	Average	10	13	10	13	4	15
	# protocols	19	34	27	14		

Significant details for 2015-2016 research

- *Social-behavioral vs. biomedical research:* 74% of protocols (new and continuing review applications) approved were for social-behavioral research.
- *International research:* 23% of the protocols reviewed and approved included international sites.

- *Federally funded research:* 37% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable subject populations:* 44% 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.

FIGURE 2. Vulnerable subjects 2015-2016



V. New Laws, Regulations, and Standards

NIH Single IRB Policy

The Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research issued June 2016 states that all domestic sites of NIH-funded non-exempt multi-site studies where the same research protocol is being conducted at more than one site must use a single IRB (sIRB) for review, while all other sites rely upon that single review. The policy does not apply to multi-site studies when the sites have different roles in carrying out the research. With certain exceptions, investigators must submit a plan to NIH stating which IRB is the sIRB. The policy will be enforced starting May 25, 2017. Until then, NIH will provide guidelines and resources regarding how to implement the new policy, including information on how to address associated costs, select the sIRB, develop the plan that needs submitted to NIH, qualify for an exception, and on requirements of reviewing and relying institutions.

NSF Notification Letter for 45 CFR 46.118 Determinations

Institutions may now submit notification letters to the National Science Foundation (NSF) for proposals lacking definite plans for involvement of human subjects. The notification letter indicates that the grant or protocol meets the requirements of 45 CFR 46.118 and stipulates that "one year from the date identified above, the Authorized Organizational Representative is required to either verify that the project continues to lack immediate plans for the involvement of human subjects, their data, or their specimens; or provide documentation to the cognizant NSF Program Officer to demonstrate that IRB approval has been obtained." OPHS will assist investigators and the Sponsored Projects Office with issuance of such letters for NSF awards lacking immediate plans for human subjects research.

Mobile Health Apps Interactive Tool

The Federal Trade Commission now provides researchers with a new Mobile Health Apps Interactive Tool website. The site provides regulatory guidance on mobile apps if investigators plan on creating and testing a mobile health app in a human subjects research project.

VI. New or Modified Campus Procedures and Programs

UCB 10 year IRB approval periods

The Committee for Protection of Human Subjects (CPHS) and the Office for Protection of Human Subjects (OPHS) extended the IRB approval period for qualifying studies from 3 to 10 years through the flexibility available under UC Berkeley's Federalwide Assurance (FWA) starting April 15, 2016. This change relieves investigators from submitting continuing reviews more frequently without compromising human subject protections. The 10 year approval period applies to all studies except for:

1. Federally funded research, or research with funding from non-Public Health Service (PHS) agencies (e.g., foundations) that adhere to federal regulations in their award contracts. (For a current list of these agencies, see http://sites.nationalacademies.org/PGA/fdp/PGA_070596).
2. Research projects that CPHS determines are "greater than minimal risk" studies.
3. Research involving federal personnel or the Department of Veterans Affairs.
4. Research involving procedures, devices, or drugs subject to FDA oversight.
5. Research involving sponsor or other contractual restrictions that require annual review.
6. Research involving a conflict of interest (COI) for any study personnel.
7. Research involving a Certificate of Confidentiality.
8. Research involving a relying collaborating institution or investigator relying on UCB's review who does not accept this practice in writing (email acceptance okay).
9. Any industry-sponsored research or other individuals, entities, or institutions to which UCB charges a fee for IRB review.

Investigators must still amend these protocols for any changes in personnel, funding, data collection, etc., and report any unanticipated problems, serious adverse events, and/or protocol deviations per usual.

OPHS staff now approve minor amendments and continuing reviews

To help with review timelines and alleviate burden for IRB Chair/Vice Chair and OPHS Director review, OPHS staff were delegated as alternate IRB members in June 2016 so they could approve minor amendments and continuing reviews (versus assigning to the Chairs/Vice Chairs or Director once OPHS pre-review was completed). This process will save in total review time. In future, staff may be delegated to review other expedited items that are currently approved by designated IRB members.
Note: As of September 1, 2016 this change in CPHS/OPHS's review process has already reduced the average turnaround time for amendments by two days.

LEEP projects generally not human subjects research

The CPHS Executive Committee made a decision that action-based practitioner projects conducted by graduate students from the Leadership for Educational Equity Program (LEEP) in the graduate school of Education do not meet the definition of human subjects research and thus do not need IRB review.

CPHS Guidelines

OPHS and CPHS developed/updated the following guidelines for investigators:

- Compensation of Research Subjects
- Data Security Guidelines and Matrix
- Deception and Incomplete Disclosure in Research
- Exempt Research
- Genetic/Genomic Research
- International Research Checklist
- Internet-Based Research
- Mandated Reporting for Suspected Child, Elder, or Dependent Adult Abuse or Neglect
- Mechanical Turk for Online Research

CPHS Policies and Procedures
OPHS and CPHS developed/updated the following policies:

- Data Security
- Determination of Exemption

CPHS Website

- International Research Webpage was developed and added: http://cphs.berkeley.edu/international.html
- An FAQ page for Research Participants was developed and added: http://cphs.berkeley.edu/participant_faqs.html

VII. Agency Inspections and Enforcement Actions

No agency inspections or enforcement activity occurred in this time period.

VIII. Education and Outreach

Education of investigators
OPHS conducted 17 training sessions for the research community in the past year, a decrease from last year due to volume of protocol reviews. Below is a breakdown of where the presentations were given by school/college:

Sociology (1)
School of Public Health (3)
Education (1)
McNair Scholars (1)
Psychology (1)
Joint Medical Program (1)
RAC Forum for Research Administrators (1)
dLab (1)
Hass/SURF Scholars (1)
Engineering (1)
Law (1)
Graduate School (2)
Optometry (2)

Education/professional development of OPHS staff
Rebecca Armstrong, Diana Holt, and Louise Tipton presented at the 2015 Advancing Ethical Research Conference organized by Public Responsibility in Medicine and Research (PRIM&R) held in Boston. Director Rebecca Armstrong continued serving on the education committee for PRIM&R.

OPHS staff participated in the following webinars:

- Public Responsibility in Medicine and Research "Making Good Meetings Happen for IACUCs and IRBs" in May 2016; and
- Public Responsibility in Medicine and Research "New Ethical Challenges in Experimental Political Science" in June 2016.

General issues under discussion in the IRB world:

- Research using dark data and the dark internet
- Anticipation of OHRP/NIH issuing new regulations based on the Proposed Rulemaking notice released on September 7, 2015 to modify regulations protecting human subjects research
- Genomic research and identifiability
- Big Data