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Respectfully Submitted,

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Chair, Committee for Protection of Human Subjects (CPHS-2)
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Enc. CPHS Membership Roster 2014-2015

Cc: Robert DiMartino, CPHS-1 Chair
Jane Mauldon, CPHS-2 Chair
Rebecca Armstrong, Director, Office for Protection of Human Subjects

Report to the Research Compliance Advisory Committee

I. Committee Title and Report Period

Committee for Protection of Human Subjects - Report for July 1, 2014 - June 30, 2015

II. Executive Summary

In 2014-2015 the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1580 applications. The lower number reflects the regulatory flexibility policy of 3-year continuing reviews, easing the burden of submitting continuing reviews for researchers. Both new and amendment application reviews increased for OPHS staff and CPHS expedited reviewers, and workload also increased for all CPHS full board review applications. UC Berkeley continues to be a leader in flexibility within human subjects research regulations with the addition of a new exempt category for non-federally funded research in April 2015 that is increasingly being utilized. UC Berkeley also saw a slight increase in federally funded human subjects research for this period.

OPHS welcomed Emily Harden as IRB Coordinator in July 2014. Emily has previously worked as a Research Assistant for the University of Illinois at Chicago and received a Master degree in International and Multicultural Education with an Emphasis in Human Rights Education from the University of San Francisco. Many OPHS staff continued their professional contributions nationally with various presentations, posters, and articles detailed in this report.

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

The Committee is comprised of two panels: CPHS-1 and CPHS-2. Starting this fiscal year, both panels were staffed to review biomedical research and social-behavioral research. CPHS-1 convened 9 times and CPHS-2 convened 10 times in this period. Both committees included 13 members (the 2014-2015 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.

IV. Summary of Research Protocols Reviewed

Approvals

The total human subjects research review activity for CPHS and OPHS decreased by about 200 submissions for 2014-2015. This is due to the flexibility policy implementing 3 year renewal periods on qualifying studies which meant fewer annual continuing reviews. There were about 40 more new approvals compared with last fiscal year and over 100 additional amendments submissions compared with last fiscal year. Continuing reviews increased for full board review slightly. 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

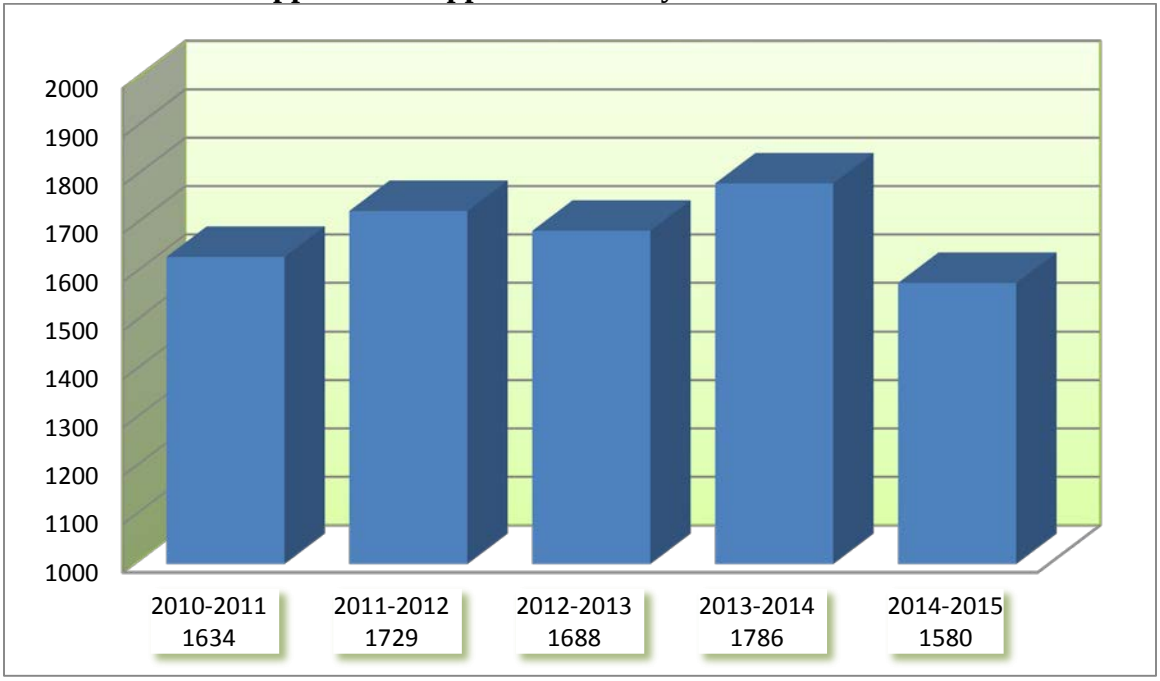


TABLE 1. Types of applications approved over 5 years

Reporting Period:	**2010-2011**	**2011-2012**	**2012-2013**	**2013-2014**	**2014-2015**
New					
Exempt:	198	181	210	205	178
Expedited:	296	310	238	309	355
Full Board:	55	29	27	29	44
Total:	*549*	*520*	*475*	*539*	*577*
Amendment					
Exempt:	56	94	74	100	116
Expedited:	363	480	500	494	592
Full Board:	14	13	14	27	34
Total:	*433*	*587*	*588*	*621*	*742*
Continuing Review					
Expedited:	611	584	582	603	235
Full Board:	41	38	43	23	26
Total:	*652*	*622*	*625*	*626*	*261*
Total Activity:	*1634*	*1729*	*1688*	*1786*	*1580*

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 158 applications that were withdrawn this year, 54 were exempt applications, 88 were expedited applications, and 16 were full board applications.

TABLE 2. Applications withdrawn by level of review

Reporting Period	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Exempt	91	54	61	60	54
Expedited	77	71	65	64	88
Full Board	7	12	6	5	16
Total:	*175*	*136*	*132*	*125*	*158*

Adverse Events and Unanticipated Problems
There were 28 potential unanticipated problems reported in the last year; however, none were determined to be unanticipated problems involving risk to subjects or others.

TABLE 3. Noncompliance

Reporting Period	2010-2011	2011-2012	2012-2013	2013-2014	2014-2015
Noncompliance cases	29	22	36	66	46

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. Often these are simple cases of noncompliance, such as exceeding the number of total subjects. Forty-six cases of potential noncompliance were reviewed in the last year, down from sixty-six last year.

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. Seven letters were issued this fiscal year. There were 28 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. A signed inter-institutional IRB Authorization Agreement (IIA) is used where federal funding is involved. As part of UCB's flexibility policy, signed IIAs are no longer required for non-federally funded research unless a sponsor or other institution requires it; therefore in cases where UCB relies on another institution's IRB review, OPHS no longer retains documentation of the reliance. Eighteen signed IIAs were obtained for this period. Table 3 lists the number of MOUs and IAAs for the past four years.

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

Reporting Period	2011-2012	2012-2013	2013-2014	2014-2015
Reliances under UC MOU				
UCB Reviewed	18	88	97	87
UCB Relied	54	30	30	30
Total:	*72*	*118*	*127*	*117*
Reliances under IAAs				
UCB Reviewed	32	86	101	85
UCB Relied	16	20	15	18 signed IIAs
Total	*48*	*106*	*116*	*103*

2014-2015 Turn-around 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 by 9.44 days for exempt, 6.72 days for expedited, and 2.3 days for full board.

Table 5. Turn-around times for new applications*

		Days with CPHS/OPHS	Days with Investigator(s)	Total
Exempt	Range	0 to 46	0 to 240	
	Median	8	6	
	Mode	8	0	
	Average	8.49	17.25	25.74
Expedited	Range	0 to 118	0 to 259	
	Median	38	12	
	Mode	26	1	
	Average	39.18	24.64	63.82
Full Board	Range	10 to 95	1 to 263	
	Median	38	19	
	Mode	38	3	
	Average	41.8	28.6	70.4

*****2 outlier protocols were kept out of the report in order to not skew 'Total No. of Working Days with PI': one at 812 days (new study approved) and one at 993 days (new study withdrawn).

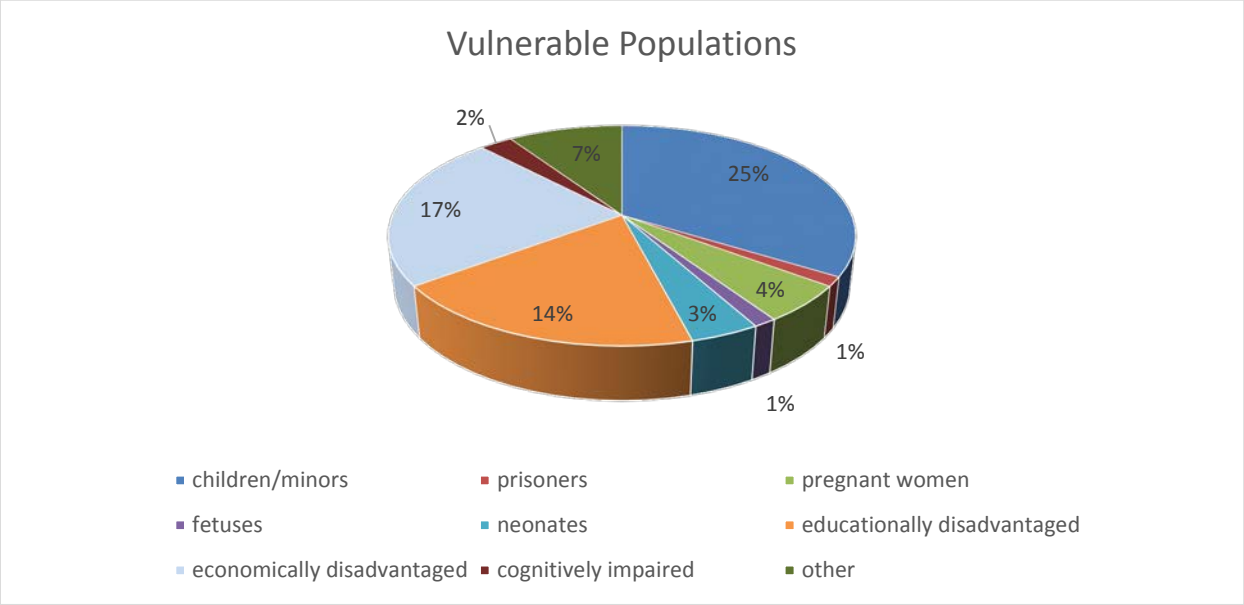
Table 6. Turn-around times for amendments

		Days with CPHS/OPHS	Days with Investigator(s)	Total
Exempt	Range	0 to 38	0 to 111	
	Median	2	1	
	Mode	1	0	
	Average	3.57	5.18	8.75
Expedited	Range	0 to 153	0 to 205	
	Median	8	1	
	Mode	1	0	
	Average	10.71	7.89	18.6
Full Board	Range	1 to 81	0 to 88	
	Median	7	0	
	Mode	1	0	
	Average	13.27	7.19	20.46

Significant details for 2014-2015 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:* 33% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable populations:* 39% of the protocols reviewed and approved included vulnerable populations. Figure 2 shows the percentages of the different vulnerable populations amongst all protocols reviewed and approved in 2014-2015.

FIGURE 2. Vulnerable subjects 2014-2015



V. New Laws, Regulations, and Standards

The NIH Genomic Data Sharing (GDS) Policy was issued on August 27, 2014 and applies to those at UCB who are obtaining genetic data for research using NIH funding, including genome-wide association studies (GWAS). The policy requires investigators to submit genomic data sharing plans and have appropriate security measures.

The Newborn Screening Saves Lives Reauthorization Act of 2014 went into effect on March 16, 2015. The law requires that all research funded pursuant to the Public Health Service Act using newborn dried blood spots be considered human subjects research and requires researchers using newborn blood spots obtained after March 18, 2015 in federally funded research receive IRB approval and obtain parent permission for research use.

In November 2014 OHRP released draft guidance *Disclosing Reasonable Foreseeable Risks in Research Evaluating Standing of Care*. In March 2015 the FDA issued the draft guidance Electronic Informed Consent in Clinical Investigations.

VI. New or Modified Campus Procedures and Programs

UCB creates exempt category 7 under flexibility model

The Committee for Protection of Human Subjects (CPHS) and the Office for Protection of Human Subjects (OPHS) announced a new UCB category for exempt review in April. This category is allowed within the flexibility available under UC Berkeley's Federalwide Assurance (FWA) and was created to reduce researcher burden.

UCB Exempt Category 7 is comprised of minimal-risk activities that will not induce distress beyond that of daily life and that could not reasonably place the subject at risk of criminal or civil liability, be damaging to the subject's financial standing, employability, insurability, or reputation, or be stigmatizing in any other way. This research category also is not applicable for studies that are:

- under Federal funding or personnel supported by federal training, center, or program grants; or funding from non-Public Health Service (PHS) agencies that adhere to federal regulations in their award contracts;
- FDA-regulated;
- have an NIH Certificate of Confidentiality;
- involve prisoners or children;
- involve Federal personnel or the Department of Veterans Affairs;
- involve invasive biomedical procedures or clinical interventions;
- involve deception or incomplete disclosure;
- contain identifiable, private existing data; or
- include researchers with a financial conflict of interest.

Exempt Category 7 activities may include, but are not limited to, non-physically invasive interventions or performance of tasks such as: reading/writing/drawing tasks; physical activities such as walking, sitting, or manipulating an object; computer tasks and/or Internet searches; talking and/or listening to words, then making selections, or "think-aloud" exercises; viewing media; role-playing; completing a specific physical or mental action ("imagining"); passive monitoring of space (environment) with sensors; playing a game; and height/weight measurements.

UCB lessens requirements for collaborative research
In order to ease researcher burden without effect on protection of human subjects, CPHS no longer requires signed Inter-institutional IRB Agreements for collaborative studies with non-UC institutions unless the study is greater than minimal risk, supported by federal funds or subject to federal oversight, is FDA-regulated, is seeking an NIH Certificate of Confidentiality, or the other institution requires it. The researcher still must submit a request to rely on another institution's IRB review to the OPHS mailbox and the research personnel must complete required human subjects research training. If the researcher is requesting that UCB review for non-UCB personnel, this request is listed in eProtocol. Collaborations within the UC system still use the online UC system reliance registry. Reliances cannot occur if any researcher on the project has a financial conflict of interest.

UCB updates confidentiality and privacy questions on eProtocol non-exempt applications
The non-exempt eProtocol applications were revised in August 2014 to reword privacy and confidentiality questions for better clarity and reduced redundancy. This affected both newly created and existing forms that need revision for amendment and continuing review submissions.

CPHS Guidelines
OPHS and CPHS developed/updated the following guidelines for investigators:
- Electrical and/or Magnetic Brain Stimulation in Research
- eProtocol Attachments Check List for Exempt Applications
- eProtocol Attachments Check List for Non-Exempt Applications
- Exempt Research
- HIPAA and Human Subjects Research
- Protocol Deviations and Noncompliances

CPHS Policies and Procedures
OPHS and CPHS developed/updated the following policies:
- Composition of the IRB
- Determination of Exemption
- IRB Meeting Administration
- IRB Reliance

- Protocol Deviations and Noncompliances
- Training and Education

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 27 training sessions for the research community in the past year. Due to volume of protocol reviews, spring and summer sessions were limited to those who were mandated to have training by their funding agency. Below is a breakdown of where the presentations were given by school/college:

Sociology (1)
School of Public Health (7)
City and Regional Planning (1)
McNair Scholars (1)
Psychology (1)
Joint Medical Program (1)
Haas Institute for a Fair and Inclusive Society (1)
Optometry (1)
dLab (4)
R.W. Johnson scholars (1)
Blum Center (1)
Environmental Sciences (2)
Business (1)
Latin American Studies (1)
Graduate School (2)
Libraries (1)

Additional educational resources
Along with extensive information offered on the CPHS/OPHS website, Fall 2014 and Spring 2015 editions of the CPHS/OPHS online newsletter, *UC Berkeley Human Research News* (with OPHS staff Louise Tipton as editor), were issued to the campus human research community. The newsletters included timely regulatory and local updates, e.g., roll-out of UCB's Exempt Category 7.

Education/professional development of OPHS staff
Members of the OPHS staff attended the 2014 Advancing Ethical Research Conference organized by Public Responsibility in Medicine and Research (PRIM&R) held in Baltimore, MD. At the conference Colleen Kohashi, Tani Prestage, and Adrienne Tanner exhibited a poster titled *University of California IRB reliance registry: Facilitating human subjects review for multi-campus studies in the UC system* along with Dragana Nikolajevic of The Office of the President and Colleen presented on the panel *Innovations in institutional collaborations.* Adrienne and Colleen exhibited a poster titled *Creating data security policy and guidance at the University of California, Berkeley.* Rebecca Armstrong and Tani delivered a collaborative presentation titled *Empowering staff, sharing workload: Integral staff involvement in review process* with Washington University in Saint Louis' Martha Jones and Jeanne Velders.

Director Rebecca Armstrong continued serving on the education committee for the Public Responsibility in Medicine and Research (PRIM&R) and wrote the article *Getting ahead of the wave: MOOC's and human subjects research* in PRIM&R's blog 'amp&rsand' in July 2014. Rebecca and Assistant Director Tani Prestage were interviewed for IRB Advisor's November 2014 articles *IRB workload sharing strategy reduces board member fatigue,* and *Success with IRB staffing begins with interview process.*

Emily Harden attended PRIM&R's IRB Administrator 101 in San Diego in February 2015.

OPHS staff viewed the following webinars:

- Office for Human Research Protections "Reporting Incidents" in July 2014;
- Public Responsibility in Medicine and Research "Anticipate and Communicate for IRBs: Ethical Management of Incidental and Secondary Findings in October 2014; and
- Public Responsibility in Medicine and Research "The Future of Internet Research: What We Can Learn from the Facebook Emotional Contagion Study" in October 2014.

General issues under discussion in the IRB world:

- Internet research without consent: The Facebook Emotional Contagion Study
- Recruitment on social media
- Notice of Proposed Rulemaking (NPRM) to modify regulations protecting human subjects research was released on September 7, 2015