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Should you have any questions or comments about our report, please contact one of us: Rebecca Armstrong, Director, Research Subject Protection; Robert DiMartino, CPHS-1 Chair; or Jane Mauldon, CPHS-2 Chair. Our contact information is as follows:

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Respectfully Submitted,

Robert DiMartino, O.D., M.S., F.A.A.O.
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Chair, Committee for Protection of Human Subjects (CPHS-2)
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Enc. CPHS Membership Roster 2012-2013
"Consent Builder relies on plain language templates" and "Templates could build better informed consent", IRB Advisor, April 1, 2013.

Cc: Robert DiMartino, CPHS-1 Chair
Jane Mauldon, CPHS-2 Chair
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, 2012 - June 30, 2013

II. Executive summary

In 2012-2013 the Office for the Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1733 applications. Carmen Lam and Jason Silva, IRB Coordinators, joined OPHS during this fiscal year and Maria Savage, Assistant Director of OPHS since 2005, left the university in March 2013, taking a new position at the University of Washington in Seattle.

On July 1, 2012 UC Berkeley (UCB) transitioned from a paper process to an online UC IRB Reliance Registry for all studies in which UCB relies on another UC campus or Lawrence Berkeley National Lab for IRB review, or in which other UC campuses rely on UCB for IRB review through a UC System Memorandum of Understanding (MOU).

CPHS revised its continuing review policy as of June 1, 2013 allowing investigators more flexibility available under our Federalwide Assurance (FWA). Research projects that are minimal risk (as defined by 45 CFR 46.102)and are not subject to federal oversight or federally funded may now be approved for a three (3) year period. In addition, as of March 1, 2013, OPHS no long applies a date stamp to approved consent documents, as it is not a regulatory requirement to do so.

OPHS Director Rebecca Armstrong and IRB Administrator Louise Tipton were interviewed in IRB Advisor magazine about their work on UCB's online tool Consent Builder, featured in the articles "Consent Builder relies on plain language templates" and "Templates could build better informed consent" (IRB Advisor, April 1, 2013).

OPHS and CPHS have been working with various colleges, departments, and programs to help improve undergraduate-initiated research projects that are submitted to CPHS for review.

III. Committee membership and number of meetings during the report period

The Committee is comprised of two panels: CPHS–1, which reviews primarily biomedical research, and CPHS-2, which reviews social-behavioral research. CPHS-1 convened 11 times, including two meetings in September. CPHS-2 convened 9 times.

CPHS-1 included 14 members and CPHS-2 included 15 members (the 2012-2013 CPHS Membership Roster is attached). Federal law requires that IRBs have at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated. Regulations also require that a non-scientist member, defined by our committee as a community member without scientific training or a faculty member from a department or school generally not associated with scientific research, be present at every meeting. Three members of CPHS unaffiliated with UCB serve as the community members or "non-affiliated" members.

Professor Robert DiMartino served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Rodolfo Mendoza-Denton served as CPHS-1 Vice Chair and Professor Oliver John served as CPHS-2 Vice Chair. OPHS Director Rebecca Armstrong served as a designated reviewer assisting with the expedited review of minor protocol amendments and continuing review/renewal applications and deviations.

IV. Summary of research protocols reviewed

Approvals

Human subjects research review activity for CPHS and OPHS (new submissions, continuing reviews, and amendment applications) slightly decreased for 2012-2013. 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 by 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

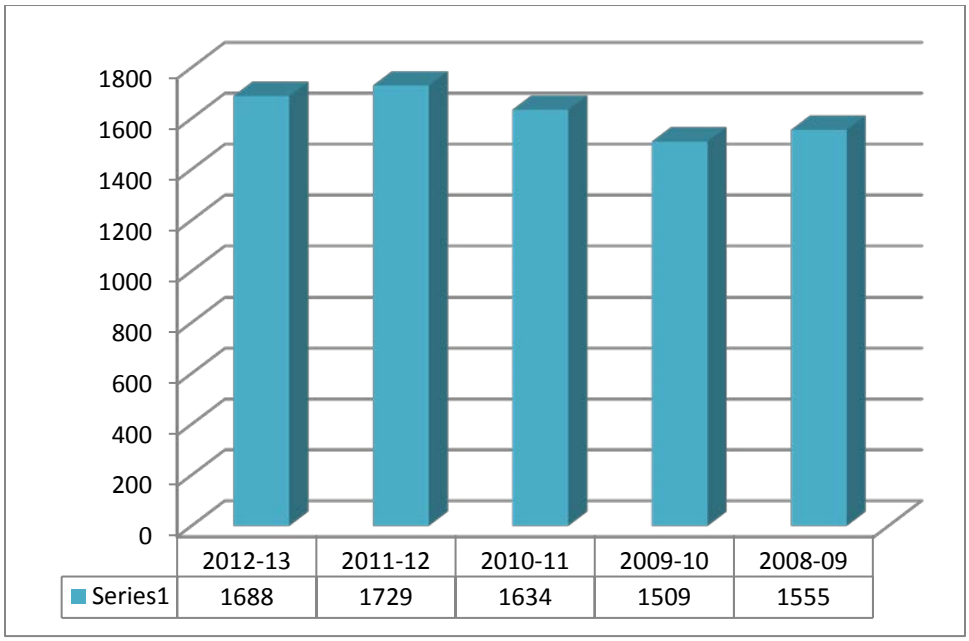


TABLE 1. Types of applications approved over 5 years

*Note: Prior to 2009-2010 exempt and expedited amendments are combined due to data limitations

Reporting Period:	**2012-2013**	**2011-2012**	**2010-2011**	**2009-2010**	**2008-2009**
New					
Exempt:	210	181	198	211	271
Expedited:	238	310	296	241	325
Full Board:	27	29	55	71	52
Total:	*475*	*520*	*549*	*523*	*560*
Amendment*					
Exempt:	74	94	56	34	-
Expedited:	500	480	363	371	-
Full Board:	14	13	14	13	31
Total:	*588*	*587*	*433*	*418*	*435*

Continuing Review					
Expedited:	582	584	611	532	526
Full Board:	43	38	41	36	34
Total:	*625*	*622*	*652*	*568*	*560*
Total Activity:	*1688*	*1729*	*1634*	*1509*	*1555*

Withdrawn Applications
Occasionally, applications are received by CPHS/OPHS and then later withdrawn from consideration. The majority of these are new applications. Table 2 shows applications withdrawn over the last 3 years by level of review (data prior to 2010 is unavailable). Out of the 132 applications that were withdrawn this year, 57 were new exempt applications, 45 were new expedited applications, and 2 were new full board applications. The remainder was comprised of amendments, continuing reviews, and deviation submissions.

TABLE 2. Applications withdrawn by level of review

Reporting Period:	**2012-2013**	**2011-2012**	**2010-2011**	**2009-2010**
Exempt:	61	54	91	-
Expedited:	65	71	77	-
Full Board:	6	12	7	-
Total:	*132*	*136*	*175*	-

Adverse Events and Unanticipated Problems
There were three potential unanticipated problems and five subject complaints reviewed in the last year. Two cases were reported to university officials; since they had no federal funding they were not reported to regulatory authorities.

Noncompliance
Thirty-six (36) cases of potential noncompliance were reviewed in the last year, compared with 22 (2011-2012), 29 (2010-2011), and 61 (2009-2010) in the preceding years. One case of serious noncompliance from 2011-2012 continues to have monitoring of human subjects research activities for the 2012-2013 fiscal year.

Administrative Actions
OPHS and CPHS make “not human subjects research” (NHSR) determinations for researchers who need documentation (e.g., it is required by a sponsor or a journal). OPHS made 60 NHSR determinations in 2012-2013. This number reflects determinations that were made for applications that were submitted and does not include NHSR determinations that were made in response to inquiries received by phone or email.

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 establish an inter-institutional IRB Authorization Agreement (IAA) between UC Berkeley and the outside entity to rely on the review of another. Table 3 lists the number of MOUs and IAAs for the past four years.

TABLE 3. Memoranda of understanding and inter-institutional IRB authorization agreements

Reporting Period:	**2012-2013**	**2011-2012**	**2010-2011**	**2009-2010**
Reliances under UC MOU				
UCB Reviewed:	88	18	12	20
UCB Relied:	30	54	31	17
Total:	*118*	*72*	*43*	*37*
Reliances under IAAs				
UCB Reviewed:	86	32	-	-
UCB Relied:	20	16	-	-
Total:	*106*	*48*	-	-

2012-2013 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, the time the analyst spent on the preliminary review, and the 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.

Table 4. Turn-around times for new applications

		Days with CPHS/OPHS	**Days with Investigator(s)**	**Total**
Exempt	Range	0 to 38	0 to 212	-
	Median	9	1	-
	Mode	8	0	-
	Average	10.49	13.83	24.32
Expedited	Range	1 to 138	0 to 234	
	Median	35	8	
	Mode	27	0	
	Average	39.2	23.85	63.05
Full Board	Range	18 to 144	0 to 138	
	Median	55.5	18.5	
	Mode	33	5	
	Average	55.9	32.56	88.46

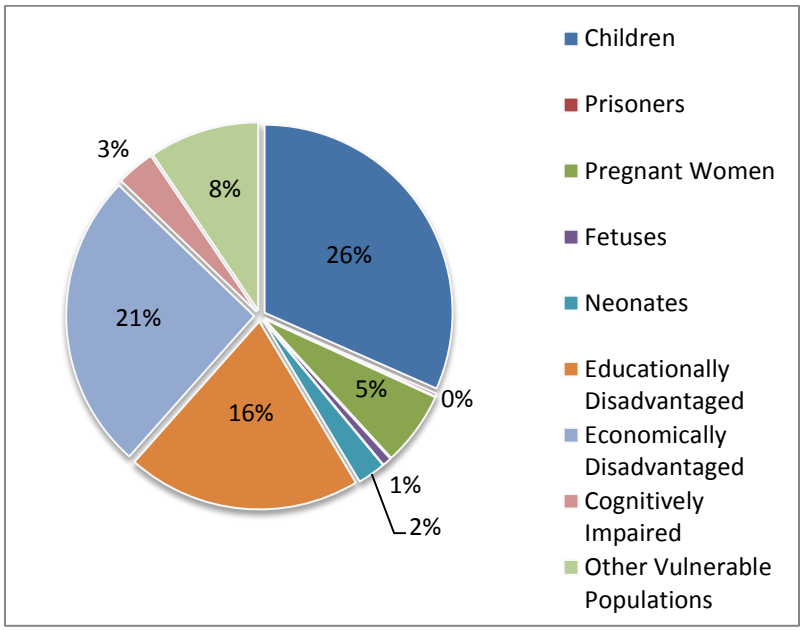
Table 5. Turn-around times for amendments

		Days with CPHS/OPHS	Days with Investigator(s)	Total
Exempt	Range	0 to 43	0 to 191	-
	Median	6	0	-
	Mode	1	0	-
	Average	7.46	3.47	10.93
Expedited	Range	0 to 85	0 to 337	
	Median	8	0	
	Mode	1	0	
	Average	11	6.59	17.59
Full Board	Range	0 to 59	0 to 123	
	Median	9	0	
	Mode	1	0	
	Average	12.76	8.02	20.78

Significant Details

- *Social-behavioral vs. biomedical research:* 91.14% of protocols (new and continuing review applications) approved in 2012-2013 were for social-behavioral research.
- *International research:* 24% of the protocols reviewed and approved included international sites.
- *Federally funded research:* 27% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable populations:* 40% 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 2012-2013.

FIGURE 2. Vulnerable subjects 2012-2013



V. New laws, regulations or standards

OHRP Archives Guidance Document on IRB Knowledge of Local Research Context
On August 3, 2012, the Office for Human Research Protections (OHRP) archived "IRB Knowledge of Local Research Context" guidance as it is no longer in effect. Please see http://www.hhs.gov/ohrp for more information.

VI. New or modified campus procedures or programs

UC IRB Reliance Registry: Online system for processing reliances under the UC MOU fully implemented
UCOP's web-based application was fully implemented across all campuses for the submission, review and approval of reliances under the UC System-wide Memorandum of Understanding on July 1, 2012. Registries for all studies in which our investigators rely on another UC campus or Lawrence Berkeley National Lab for IRB review, or vice versa, by means of the UC System Memorandum of Understanding (MOU) must use the online registry.

UCB provides flexibility of approval periods for investigators
As of June 1, 2013, OPHS began offering flexibility to investigators consistent with UC Davis and UCSF by allowing three-year approval periods for qualified human subjects research . Studies that are deemed minimal risk research (as defined by 45 CFR 46.102), not subject to federal oversight, not federally funded, are not requesting a Certificate of Confidentiality, and not restricted under a reliance or a conflict of interest (COI) may now be approved for a three-year period.

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

- Children in Research
- Clinical Laboratory Testing in Human Subjects Research
- Compensation of Research Subjects
- Data Security Guidelines Matrix
- Recruitment
- Subject Pools, Recruitment Registries and Databases

CPHS Policies and Procedures
OPHS and CPHS updated/revised the following policies and procedures:

- Amendment Review
- Continuing Review
- Data Security
- Expedited Review
- General Requirements and Documentation
- Initial Review

VII. Agency inspections and enforcement actions

There were no inspections or enforcement actions by any regulatory authorities in 2012-2013.

VIII. Education and outreach

Education of Investigators
Director Rebecca Armstrong and OPHS staff conducted 22 training sessions for undergraduate and graduate students in the past year. The training sessions covered the fundamentals of human subjects research review and approval, the eProtocol submission processes, use of secondary data, and issues germane to social and behavioral research. This educational outreach provides the research community information to help improve and expedite their protocol submission process. Below is a breakdown of where the presentations were given by school/college:

Optometry (1)
School of Public Health (5)
Haas Scholars (2)
McNair Scholars (1)
Psychology (1)
Sociology (2)
Joint Medical Program (1)
Fogarty Recipients (1)
International Studies (3)
Humanities (1)
Language, Literacy, & Culture (1)
Undergraduate Fellowship (1)
Informatics (1)
City and Regional Planning (1)

Education of OPHS Staff
Members of the OPHS staff along with the Director attended the 2012 Advancing Ethical Research Conference organized by Public Responsibility in Medicine and Research (PRIM&R) in San Diego, CA. (Director Armstrong, Diana Holt, and Adrienne Tanner also presented at this conference.) Melanie Hassel and Carmen Lam attended the PRIM&R February 2013 regional conference co-hosted by UC Berkeley and UC San Francisco. In addition, the following webinar was purchased for OPHS staff to view: *Convergence of Biomedical and Social/Behavioral Research: Implications for IRBs and Investigators* by PRIM&R on June 11, 2013.

IX. Significant campus events during the report period

The shift of administrative activities being provided by Campus Shared Services continues to impact the UCB research community.

X. Broader issues

- The federal budget sequestration that began in 2011 cut $1 trillion in discretionary appropriations through lower annual spending caps over a nine-year period, and an additional $1.2 trillion in cuts began March 1, 2013, which will impact federally funded research.

- On March 23, 2013, The New York Times reported that once again, Henrietta Lacks' cells were used in research without consent. As chronicled in the 2010 book The Immortal Life of Henrietta Lacks, Ms. Lacks was an African American woman who died of cervical cancer in 1951; her cells were previously collected without her knowledge. The rare cells (later dubbed HeLa) had an amazing ability to replicate, and were and still are used by scientists around the world for research. European scientists sequenced the genome of the HeLa cells this year, which led to a backlash from her surviving relatives concerned about privacy and not being asked permission. Upon receiving word from the family, the scientists apologized and removed the data from the internet.

General issues under discussion in the IRB world:

- Possible deregulation of stem cell research
- Ethical issues of trials conducted in India
- Advanced Notice of Proposed Rulemaking (ANPRM) for Revision to Common Rule remained inactive
- Increased use of one IRB review of record for multisite research
- Data security, particularly as it pertains to personal genetic information