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November 2014

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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.
Chair, Committee for Protection of Human Subjects (CPHS-1)
Professor, School of Optometry

Jane Mauldon, Ph.D.
Chair, Committee for Protection of Human Subjects (CPHS-2)
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Enc. CPHS Membership Roster 2013-2014

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, 2013 - June 30, 2014

## II. Executive Summary

In 2013-2014 the Office for Protection of Human Subjects (OPHS) and the Committee for Protection of Human Subjects (CPHS) reviewed and approved 1786 applications. Tani Prestage joined OPHS as Assistant Director in August 2013 and Melanie Hassel, IRB Coordinator, left OPHS in May 2014. OPHS workload in total number of protocols processed in the last five years overall continues to increase while the number of staff remains constant. This efficiency is the outcome of maintaining a highly skilled staff of IRB professionals.

In addition to serving research participants and investigators on this campus, CPHS is recognized as a leader in the human subjects protections profession for its provision of sound policy and guidelines for data use in the conduct of human subjects research. CPHS policy on Data Security is referenced in the Secretary's Advisory Committee on Human Research Protections (SACHRP) Considerations and Recommendations Concerning Internet Research and Human Subjects Research Regulations document. Additional contributions include CPHS's guidance on Internet Research, which is referenced in the Collaborative Institutional Training Initiative (CITI) human research Internet module.

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

The Committee is comprised of two panels: CPHS–1, which reviews the majority of UCB biomedical research, and CPHS-2, which reviews social-behavioral research. CPHS-1 convened 10 times and CPHS-2 convened 8 times in this period.

CPHS-1 included 12 members and CPHS-2 included 10 members (the 2013-2014 CPHS Membership List 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 are non-scientists, and three members are not affiliated with UCB.

Professor Robert DiMartino served as CPHS-1 Chair and Professor Jane Mauldon served as CPHS-2 Chair. Professor Oliver John served as CPHS-2 Vice Chair (there was not a Vice Chair for CPHS-1). OPHS Director Rebecca Armstrong served as a designated reviewer assisting with the expedited review of minor protocol amendments, continuing review/renewal applications, and deviations. Professor Shakar Kariv from the Haas School of Business served as designated reviewer for research involving the Haas School of Business eXperimental Social Science Laboratory (X-Lab).

## IV. Summary of Research Protocols Reviewed

### Approvals

Human subjects research review activity for CPHS and OPHS (new submissions, continuing reviews, and amendment applications) increased by approximately 100 protocols for 2013-2014. 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**

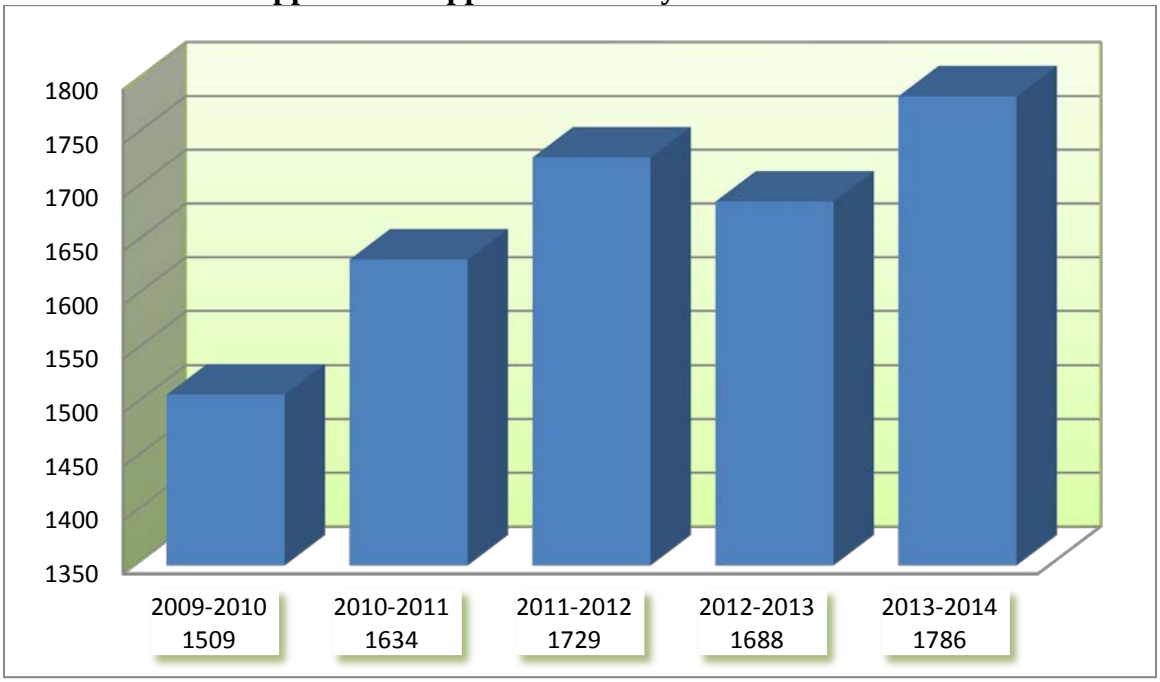



**TABLE 1. Types of applications approved over 5 years**

| **Reporting Period:** | **2009-2010** | **2010-2011** | **2011-2012** | **2012-2013** | **2013-2014** |
|---|---|---|---|---|---|
| | | | | | |
| **New** | | | | | |
| Exempt: | 211 | 198 | 181 | 210 | 205 |
| Expedited: | 241 | 296 | 310 | 238 | 309 |
| Full Board: | 71 | 55 | 29 | 27 | 29 |
| *Total:* | *523* | *549* | *520* | *475* | *539* |
| | | | | | |
| **Amendment*** | | | | | |
| Exempt: | 34 | 56 | 94 | 74 | 100 |
| Expedited: | 371 | 363 | 480 | 500 | 494 |
| Full Board: | 13 | 14 | 13 | 14 | 27 |
| *Total:* | *418* | *433* | *587* | *588* | *621* |
| | | | | | |
| **Continuing Review** | | | | | |
| Expedited: | 532 | 611 | 584 | 582 | 603 |
| Full Board: | 36 | 41 | 38 | 43 | 23 |
| *Total:* | *568* | *652* | *622* | *625* | *626* |
| | | | | | |
| ***Total Activity:*** | 1509 | 1634 | 1729 | 1688 | *1786* |

**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 four years by level of review. Out of the 125 applications that were withdrawn this year, 60 were new exempt applications, 64 were new expedited applications, and 5 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 | 2010-2011 | 2011-2012 | 2012-2013 | 2013-2014 |
|---|---|---|---|---|
| | | | | |
| Exempt | 91 | 54 | 61 | 60 |
| Expedited | 77 | 71 | 65 | 64 |
| Full Board | 7 | 12 | 6 | 5 |
| | | | | |
| ***Total:*** | *175* | *136* | *132* | *125* |

**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.

**Noncompliance**
Sixty-six (66) cases of potential noncompliance were reviewed in the last year, up from 36 (2012-2013), 22 (2011-2012), 29 (2010-2011), and 61 (2009-2010) in the preceding years. One case of serious noncompliance was reported to university officials, the Office for Human Research Protections (OHRP), and the program officer of the funding agency.

**Administrative actions**
OPHS makes “not human subjects research” (NHSR) determinations for researchers who need documentation (e.g., it is required by a sponsor or a journal). OPHS made 40 NHSR determinations in 2013-2014. 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 | 2010-2011 | 2011-2012 | 2012-2013 | 2013-2014 |
|---|---|---|---|---|
| | | | | |
| **Reliances under UC MOU** | | | | |
| UCB Reviewed | 12 | 18 | 88 | 97 |
| UCB Relied | 31 | 54 | 30 | 30 |
| *Total:* | *43* | *72* | 118 | 127 |
| | | | | |
| **Reliances under IAAs** | | | | |
| UCB Reviewed | - | 32 | 86 | 101 |
| UCB Relied | - | 16 | 20 | 15 |
| *Total* | - | 48 | 106 | 116 |

**2013-2014 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.

**Table 4. Turn-around times for new applications**

| | | Days with CPHS/OPHS | Days with Investigator(s) | Total |
|---|---|---|---|---|
| **Exempt** | Range | 0 to 142 | 0 to 188 | - |
| | Median | 4 | 2 | - |
| | Mode | 1 | 0 | - |
| | Average | 6.2 | 10.1 | 16.3 |
| **Expedited** | Range | 2 to 177 | 0 to 261 | |
| | Median | 29 | 12 | |
| | Mode | 19 | 0 | |
| | Average | 33.2 | 23.9 | 57.1 |
| **Full Board** | Range | 13 to 221 | 0 to 100 | |
| | Median | 28 | 19 | |
| | Mode | 27 | 46 | |
| | Average | 41.6 | 26.6 | 68.1 |

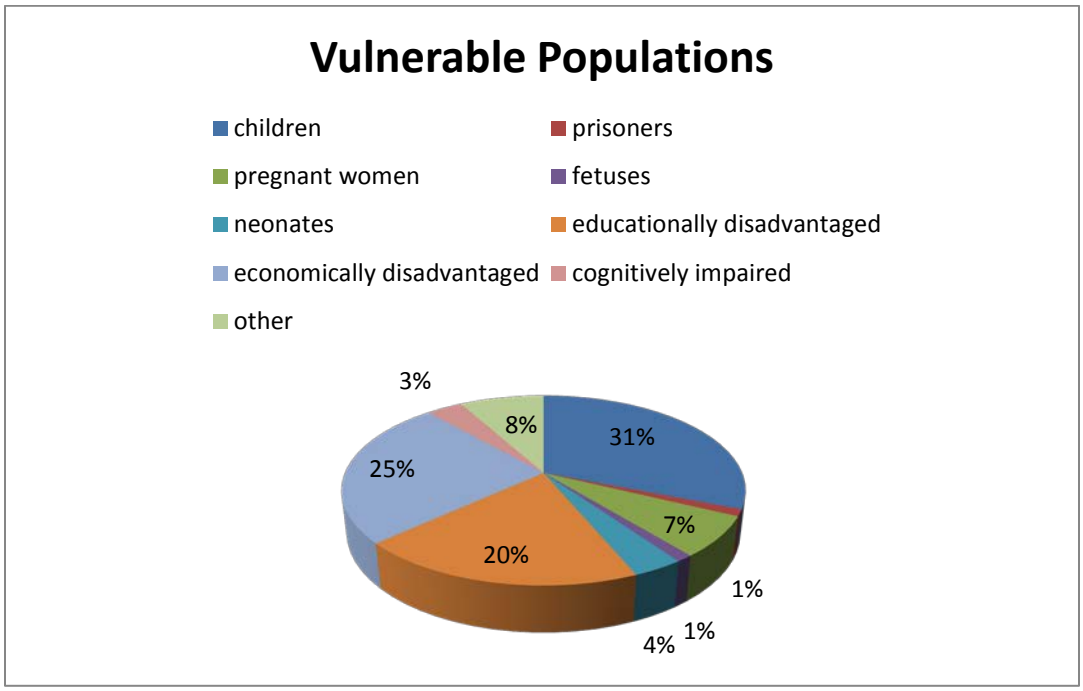
**Table 5. Turn-around times for amendments**

| | | Days with CPHS/OPHS | Days with Investigator(s) | Total |
|---|---|---|---|---|
| **Exempt** | Range | 0 to 43 | 0 to 62 | - |
| | Median | 2 | 0 | - |
| | Mode | 1 | 0 | - |
| | Average | 3.2 | 3.7 | 7 |
| **Expedited** | Range | 0 to102 | 0 to 168 | |
| | Median | 6 | 0 | |
| | Mode | 6 | 0 | |
| | Average | 8.7 | 5.3 | 14 |
| **Full Board** | Range | 0 to 112 | 0 to 237 | |
| | Median | 6 | 0 | |
| | Mode | 6 | 0 | |
| | Average | 10.2 | 11.3 | 21.5 |

**Significant details for 2013-2014 research**

- *Social-behavioral vs. biomedical research:* 75% 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:* 28% of the protocols reviewed and approved indicated that they were supported by federal funds.
- *Research with vulnerable populations:* 38% 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 2013-2014.

**FIGURE 2. Vulnerable subjects 2013-2014**




## V. New Laws, Regulations, and Standards

The Office for Human Research Protections (OHRP) revised its FAQ regarding compensation to allow, in some circumstances, remuneration to subjects for risks associated with their participation in research, and compensation as an acceptable motive for some individuals agreeing to participate in research.

In August 2013, the Food and Drug Administration published *Guidance for IRBs, Clinical Investigators, and Sponsors: IRB Responsibilities for Reviewing the Qualifications of Investigators, Adequacy of Research Sites, and the Determination of Whether an IND/IDE Is Needed*. The guidance assists those involved in research with determining if their research involves FDA-regulated products and if so, what the requirements are.

In May 2014 the Food and Drug Administration published *Guidance for IRBs, Clinical Investigators, and Sponsors: Considerations When Transferring Clinical Investigation Oversight to Another IRB*. The guidance discusses responsibilities and requirements involved when a clinical investigation review is transferred from one institution's IRB to another.

## VI. New or Modified Campus Procedures and Programs

**UCB "flexible continuing review period" reaches anniversary**
CPHS began issuing three (3)-year approval periods for qualifying protocols on June 1, 2013. For the fiscal year, 25% of the initial and continuing full board reviews were approved for a 3-year period, and 72% of the initial and continuing expedited reviews were approved for a 3-year period. To qualify for a 3-year approval period, a study must not be greater than minimal risk, under federal funding or oversight, have a sponsor requiring annual review, be FDA-regulated, have an NIH Certificate of Confidentiality, or include researchers with a financial conflict of interest.

**UCB updates human subjects research training requirements**
CPHS significantly revised its Training and Education policy, expanding education requirements for research personnel. In addition to students, faculty (with some exceptions), staff, and post-docs engaged in human subjects research must complete either the biomedical or social-behavioral human research

course through the online Collaborative Institutional Training Initiative (CITI), depending upon which is most germane to the research. Please reference Section 1.1 of the CPHS policy Training and Education to view the new requirements.

**OPHS publishes first newsletter**

OPHS launched the first edition of its CPHS/OPHS online newsletter, *UC Berkeley Human Research News*, in January 2014. With analyst Louise Tipton as editor, the newsletter includes regulatory updates, a report on student research, and features highlighting UCB researchers. A second edition is planned for Fall 2014.

**CPHS Guidelines**

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

- Amendments
- Clinical Laboratory Testing in Human Subjects Research
- Data Security Guidelines and Matrix
- Deception and Incomplete Disclosure in Research
- Exempt Research
- Internet-Based Research
- Recruitment
- Secondary Analysis of Existing Data
- Student Investigators Guide
- Undergraduates: Ethical Issues in Undergraduate Research Activities with Human Participants
- Undergraduates: Guidance on Designing Undergraduate-Initiated Research Activities

**CPHS Policies and Procedures**

OPHS and CPHS developed/updated the following policies:

- Amendment Review
- Composition of the IRB
- Continuing Review
- Data Security
- IRB Meeting Administration
- IRB Member Conflict of Interest
- IRB Membership
- IRB Reliance
- Review for a Determination of Exemption
- Suspension and Termination of Human Subjects Research
- Training and Education

## VII. Agency Inspections and Enforcement Actions

The Food and Drug Administration conducted a not-for-cause inspection of UCB's active FDA-regulated research, focusing in depth on device studies, in November 2013. Three deviations were cited on FDA Form 483. As a result, CPHS made minor updates to policies and procedures and some researchers were required to modify consent documents and/or protocols as a result of the observations. In addition, CPHS members underwent continuing education regarding FDA-regulated research.

## VIII. Education and Outreach

### Education of investigators

Director Rebecca Armstrong and OPHS staff conducted 28 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, medical devices, data security, program evaluation, collaborative research, and other issues germane to social and behavioral research. This educational outreach provides the research community with information to help improve the quality and speed of their protocol submission process. Below is a breakdown of where the presentations were given by school/college:

Optometry (1)
School of Public Health (3)
Lawrence Hall of Science (3)
McNair Scholars (1)
Psychology (1)
Sociology (2)
Joint Medical Program (1)
Terraswarm (1)
Blum Center (1)
dLab (6)
R.W. Johnson scholars (1)
Political Science (1)
Film and Media (1)
Summer undergraduate research fellows (1)
Latin American Studies (1)
Graduate School (2)
Education (1)

### Education/professional development of OPHS staff

Members of the OPHS staff attended the 2013 Advancing Ethical Research Conference organized by Public Responsibility in Medicine and Research (PRIM&R) in Boston, MA. (Analysts Colleen Kohashi and Adrienne Tanner, OPHS, prepared and presented a workshop at this conference). Jason Silva attended PRIM&R's IRB Administrator 101 in Portland, Oregon in February 2014. OPHS staff viewed the Office for Human Research Protections' webinar "Conducting Internet Research: Challenges and Strategies for IRBs" in May 2014.

### General issues under discussion in the IRB world:

- Possible expansion of exempt categories for non-federal research.
- Use of "big data" in social science research as well for genetic/genomic biomedical research.
- Research use of social media.
- Massive open online courses (MOOCs) and the data that results being used for learning analytics in education research.