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Director’s Statement

On behalf of the Office of Human Research Administration, I am pleased to share the FY16 annual report with the Harvard LMA research community.

This past fiscal year, OHRA had an opportunity to reorganize following the departure of IRB Review Specialist Paul Hryvniak and IRB Administrative Chair Julie Kaberry. This change allowed the IRB Review Team to further streamline its operations and reduce personnel costs. Kimberley Serpico assumed a leadership role as Assistant Director, and manages IRB operations and review team performance. At the national arena, there was also notable change:

- On September 8, 2015, the Department of Health and Human Services (DHHS) issued a Notice of Proposed Rulemaking (NPRM) for revisions to the Federal Policy for the Protection of Human Subjects, or "Common Rule." If adopted, the proposals in the NPRM will result in the most substantive revisions to the core regulation governing federally funded human subjects research in the United States since 1981. At the time of this Annual Report, DHHS had not adopted the proposed changes.
- On June 21, 2016, the National Institutes of Health (NIH) published their “Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research.” This policy established an expectation that a single IRB would be designated to “conduct ethical reviews for domestic sites of multi-site, non-exempt human subjects research protocols that are funded by NIH.” This policy goes into effect May 25, 2017.

In this report, please find an overview of our human research protection program, its mission and scope, unit-specific summaries, program highlights, and a glimpse at what’s ahead.

I owe many thanks to the OHRA leadership for their continued commitment to protecting human subjects and promoting our mission, including our Institutional Officials: Ms. Pamela Caudill, HMS Chief of Research and Administrative Operations and Dr. Delia Wolf, Associate Dean for Regulatory Affairs & Research Compliance; IRB Chairs: Dr. Julie Buring (Harvard Faculty of Medicine), Dr. David Christiani (Harvard Chan School), and Dr. Ichiro Kawachi (Harvard Chan School).

As always, I extend my appreciation to the entire OHRA staff, who worked tirelessly this past year through significant reorganization. A final thank-you to Lisa Gabel, Kimberley Serpico, and Alyssa Speier for their diligent work and support in compiling this report.
Our Organization

The Office of Human Research Administration (OHRA) is a comprehensive administrative office designed to review, approve, assist, and oversee all human research projects conducted by faculty, staff, and students across the Harvard Longwood Medical Area (LMA) Schools: including Harvard Medical School, Harvard School of Dental Medicine, and Harvard T.H. Chan School of Public Health. Our mission is to protect the rights and welfare of subjects involved in human research and to provide high-level education and human research support to our research community. OHRA is comprised of two units: the Institutional Review Board (IRB) and the Quality Improvement Program (QIP).

This past fiscal year, OHRA experienced some staffing mobility. The changes allowed duties formerly tasked to our IRB Administrative Chair and IRB Coordinator positions to be absorbed by the Managing Director and Review Team. Workload will be closely evaluated in FY17 to ensure sufficient staffing is in place. Additionally, staffing strategies for FY17 will focus on cultivating unit-specific leadership for the Quality Improvement Program.

The following OHRA staff members assumed new positions during FY16:

- Grace Bullock, IRB Review Specialist
- Kimberley Serpico, Assistant Director of IRB Operations
- Stanley Estime, Assistant Director of Lab and Biosafety (Mr. Estime’s position now falls outside the scope of Office of Human Research Administration; however, he will continue to support the Quality Improvement Program, as workload demands).
Institutional Review Board (IRB) Operations
The IRB Operations unit is responsible for managing and supporting the scientific and ethical review of research studies submitted by Harvard Medical School, Harvard School of Dental Medicine, and Harvard T.H. Chan School of Public Health faculty, staff, and students. There are two IRB panels, one serving the Harvard Chan School and one serving the Harvard Faculty of Medicine. In addition to the convened IRB panels, the IRB Review Specialist team each manage a review portfolio of assigned departments; granting not human subjects research and exemption determinations, and approving expedited research.

RMAS Audit of Harvard IRBs
In FY16 Harvard’s Risk Management & Audit Services initiated an audit of the Harvard IRBs. Preliminary findings revealed no compliance concerns. Recommendations are expected in order to enhance operations and ensure future compliance.

Meet the Review Team

Kimberley Serpico, MEd, CIP
Assistant Director of IRB Operations

Keren-Nicole Insalaco, MS, CIP, CIM
Senior IRB Review Specialist

Grace Bullock, BA, CIP
IRB Review Specialist

Jada Dixon, MJ, MPH, CIP
IRB Review Specialist

FY16 HIGHLIGHTS
IRB Operations further streamlined review such that department-assigned IRB Review Specialists facilitate the review of protocol-related conflict of interest disclosures and reportable new information.

* ESTR, the eIRB submission system, realigned with the vendor’s delivered product in order to provide robust, enduring, and cost effective development support. ESTR is the system used by Harvard’s two Human Research Protection Programs.

* The HMS/HSDM and HSPH IRB panels enhanced membership by adding new members with experience and expertise in international research, periodontic surgery and implants, academic research integrity, and data security.
Quality Improvement Program

The Quality Improvement Program (QIP) is a division within the Office of Human Research Administration (OHRA), independent of the IRB. QIP consists of three distinct units: Compliance, Education, and Human Research Support.

QIP’s Compliance and Education units are responsible for performing routine onsite review and/or directed audit of investigator and IRB records, and providing training and education to the research community. The Human Research Support unit provides a variety of support services designed to facilitate the IRB review and approval process and improve site performance, e.g., IRB submission/grant writing assistance; study management tools; routine onsite monitoring, and external audit preparation.

QIP Collaborates with PRIM&R

In FY16, QIP brought its QA/QI Boot Camp to the national stage offering it as a one-day pre-conference program in conjunction with Public Responsibility in Medicine and Research’s (PRIM&R) annual Advancing Ethical Research conference. QIP is expected to facilitate this pre-conference program alternate years going forward.

Meet the Quality Improvement Program Team

Stanley Estime, MSCI, CIP
Assistant Director, Lab & Biosafety

Lisa Gabel, BA, CIP
Senior QA/QI Specialist

Alyssa Speier, MS, CIP
Assistant Director, Regulatory Affairs & Research Compliance

FY16 HIGHLIGHTS

45+ Trainings conducted
525+ Faculty, staff, and students trained
58,500+ Hits to the OHRA webpages
As reported in the FY15 Annual Report, QIP implemented new triggers for not-for-cause audits, which are projected to result in 22 potential audits for FY17
Program Metrics
Evaluating and improving the quality of our program is a top priority. According to the Association for the Accreditation of Human Research Protection Programs (AAHRPP), effective and efficient systems of oversight provide better protections for research participants and produce higher quality research. The following metrics are collected from the University-wide electronic submission platform, Electronic Submission, Tracking, and Reporting (ESTR).

The Office of Human Research Administration oversees a small, but dynamic portfolio of human research.

Figure 1. Number of active protocols, i.e., exemption determinations; expedited initial and continuing reviews; convened IRB initial and continuing reviews across Harvard LMA Schools. Since FY15, there has been a 35% increase in active protocols. The largest application volume, by school, continues to be submitted from the departments of Global Health and Population at the Harvard Chan School (19%), Health Care Policy at Harvard Medical School (25%), and Oral Health Policy and Epidemiology at the Harvard School of Dental Medicine (38%).
Figure 2. Number of active protocols by research type. Note: categories are not mutually exclusive and protocols may include both biomedical and social behavioral components. ‘Other’ captures protocols where a Harvard LMA School is serving as a data coordinating center.

Figure 3. Number of active protocols by type of review. The majority of exemption determinations continue to include tests/surveys/interviews and the use of existing data/specimens, categories 45 CFR 46.101(b)(2) and (4) respectively (of note, exemption categories are not mutually exclusive, meaning that one or more than one category may apply to a single exemption determination). The majority of expedited protocols continue to involve identifiable data/specimen analysis and/or use of survey or interview procedures, categories 5 and 7 respectively.
Figure 4. Number of active protocols by risk level. Figure 3 illustrates that 71% of active protocols are reviewed using the expedited review procedure, which requires that the research procedures pose no more than minimal risk.

Figure 5. Number of active protocols by research data security level. As per the Harvard Research Data Security Policy, the IRB assigns a research data security level, 1-5, where “1” includes public information and “5” includes information that would cause severe harm to individuals, or the University, if disclosed.
Figure 7. Map of active protocols conducted internationally. Ninety-five countries represented, including Angola, Argentina, Armenia, Australia, Bangladesh, Belgium, Benin, Bolivia, Botswana, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Central African Republic, Chile, China, Colombia, Congo, Cote d'Ivoire, Croatia, Cyprus, Democratic Republic of Congo, Denmark, El Salvador, Ethiopia, Faroe Islands, France, The Gambia, Georgia, Germany, Ghana, Greece, Greenland, Guatemala, Guinea, Haiti, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Jordan, Kenya, Kuwait, Kyrgyz Republic, Lebanon, Lesotho, Liberia, Madagascar, Malawi, Malaysia, Mexico, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nigeria, Norway, Pakistan, Peru, Philippines, Portugal, Puerto Rico, Qatar, Russia, Rwanda, Senegal, Sierra Leone, Singapore, South Africa, South Sudan, Spain, Sri Lanka, Sudan, Swaziland, Sweden, Switzerland, Tanzania, Thailand, Turkey, Uganda, United Arab Emirates, United Kingdom, Vietnam, Zambia, Zimbabwe.

Figure 8. Number of active protocols that include at least one international site by type of review. (HSDM has no active protocols with international sites).
Figure 9. Median time from submission to IRB determination (human research or exemption) or approval (expedited or convened IRB) in calendar days. Harvard LMA IRB FY14, FY15, and FY16 times compared to internal OHRA targets as well as AAHRPP 2015 Metrics on Human Research Protection Program Performance. Of note, AAHRPP combines expedited reviews, including initial and continuing review applications, and modifications into a single data point. Harvard LMA IRB turnaround times are parsed out to better capture review of expedited continuings and modifications. Turnaround times have been consistent the past two years with the exception of full committee reviews where there’s been noticeable improvement.
Figure 10. Utilization of QIP Services across the Harvard LMA Schools. QIP’s most popular service continues to be Investigator Submission Support, which provides faculty with custom support drafting and/or editing study documents, and/or submitting through ESTR. On a quarterly basis, protocols are randomly selected from all schools and investigators are asked to voluntarily complete an Investigator Self-Assessment Checklist. The goal is to ensure that regulatory documents are properly maintained, participant files are complete and accurate, and the overall conduct of the study is compliant with the IRB-approved protocol, applicable policies, and regulations. A total of 49 Investigator Self-Assessments were completed in FY16. A total of 7 IRB File Audits were conducted: 6 not-for-cause and 1 for-cause. A total of 5 Investigator File Audits were conducted: 5 not-for-cause. No (potential) serious and/or continuing non-compliance was observed for either IRB or Investigator audits.
The following are some FY16 highlights from the Office of Human Research Administration.

**The Impact of Student-Specific Workshops on IRB Applications**

Kimberly Serpico, Grace Bullock, Lisa Gabel, Leslie Howes, Julie Kuberny, Jada Dixon, Paul Hrynivask, Keren-Nicole Insalaco, Katisha Turner, Della Wolf

Harvard Medical School, Harvard T.H. Chan School of Public Health, Harvard School of Dental Medicine

**Introduction**

Each year the Harvard Medical School Scholars in Medicine and Biological Sciences (SIBM) medical and dental students conduct a research project as part of the curriculum. To facilitate their academic success, each student is assigned a mentor. The Office of Human Research Administration (OHRA) developed and offered a series of workshops to assist students and faculty in navigating the IRB review and approval process.

**Approach**

**Who?**

First-year medical and dental students who develop research projects involving human subjects (IRB19).

**What?**

Optional one-hour workshop held weekly from February through April 2015 (8 weeks).

**Why?**

To educate new IRB students about the role of the IRB, to guide them through the application process, and to cultivate a positive application experience.

**Format**

Combination of 10-minute presentation followed by a 30-minute question and answer session. The seminar included basic IRB knowledge for researchers, including the roles of IRB review, de-identified data collection, and working with vulnerable populations.

The workshops were designed to be interactive and hands-on, as the target audience was expected to have minimal experience with the IRB review process. The workshops were conducted by IRB staff and faculty mentors.

**Assessment**

Evaluation was performed in two stages. Workshop attendees were surveyed to assess the pre- and post-workshop knowledge (IRB19). Two months later, IRB19 students who submitted an IRB application were surveyed to assess their overall IRB application experience, regardless of workshops attended.

**Results**

- **20%** of attendees reported being more prepared to submit their application.
- **100%** of the attendees reported that they would recommend the workshop to their peers.

**Trend Toward Time Impact**

Turnaround time between submission and approval decreased from 22 days in 2014 to 13 days in 2015 (January 1 – April 15).

**Overall Workshop Findings**

- **40%** of respondents were satisfied with the turnaround time of their project review and approval.
- **74%** of respondents were satisfied with the communications provided and support from the IRB while the application was in process.
- **60%** rated the impact of student preparedness, understanding of the application process, and submission completeness and accuracy, which resulted in reduced turnaround time.

**Conclusion**

Based on the results from the 2015 application season and the success of our program implementation, student IRB workshops are something OHRA will continue to offer annually. As a result of student feedback and our experience, we intend to offer more frequent workshops prior to the application deadline and add office hours with one-on-one time slots. Additionally, we will make workshops mandatory so that all students benefit from this educational opportunity. We also plan to further develop the process by training the workshops into a webinar and enhance the application guidance included to students in the OHRA website. We would recommend that other institutions adopt student workshops as a way to facilitate and improve student submission experience.

**Further Information**

https://www.bwh.harvard.edu/ohra/SSS-primer-poster/

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**November 2015**

Grace Bullock and Kimberley Serpico presented “The Impact of Student-Specific Workshops on IRB Applications” poster at Public Responsibility in Medicine and Research’s (PRIM&R) annual Advancing Ethical Research conference in Boston, MA. Results were favorable, revealing that turnaround time from submission to approval decreased from 22 days in 2014 to 13 days in 2015; students reported benefit from Q&A sessions and focused one-on-one attention; and the workshops appeared to have a positive effect on student preparedness, understanding of the application process, and submission completeness and accuracy.
May 2016

Stanley Estime presented “Innovative Approach to Study Management: Ensuring Regulatory Compliance in a Paperless Environment” poster at the Association for the Accreditation of Human Research Protection Program’s (AAHRPP) 2016 Annual Conference in Long Beach, CA. The poster highlighted challenges in implementing electronic monitoring systems. The Quality Improvement Program tackled these challenges through consecutive customization and implementation of three off-the-shelf, freely available, data management products, including Sharepoint, REDCap, and Box.com
2016 Convened IRB Review Summary

The HMS/HSDM IRB panel reviewed 28 submissions, which included research studying medical devices, dental implants, and genetic sequencing. The Harvard Chan School IRB panel reviewed 69 submissions, which included social-behavioral interventions all over the world, clinical trials, and HIV/AIDS treatment research. Cross-panel review was implemented, allowing OHRA to leverage the IRB panels’ respective expertise while maximizing review efficiency for investigators.

June 2016

OHRA conducted a three-day international site visit to Mongolia, which included co-presenting “Capacity Building of Ethical Review, Compliance and Monitoring for Bio-Medical Research” workshop with the Mongolian Ministry of Health and Sports and Dr. Ganmaa Davaasambuu’s Mongolia-based research team.
What’s Ahead

Below are some of the initiatives planned for the Office of Human Research Administration for FY17:

- Review and streamline Harvard’s human subjects training curriculum, including baseline and refresher requirements, offered through the Collaborative Institutional Training Initiative (CITI) Program.
- Develop additional training modules and tools designed to facilitate IRB review for student researchers.
- Submit re-accreditation application to the Association for the Accreditation of Human Research Protection Program (AAHRPP) and develop a training plan to prepare the Harvard LMA research community for the AAHRPP site visit planned for Spring 2018.
- Continue to enhance the IRB’s e-submission system, ESTR, with bi-annual upgrades that combine periodic improvements developed by the software vendor with customized enhancements recommended by OHRA and the HLMA research community.