## Contents

Director’s Statement .................................................. 3  
Our Organization ......................................................... 4  
Institutional Review Board Operations ......................... 5  
Quality Improvement Program ...................................... 6  
Program Metrics .......................................................... 7  
Highlights ................................................................. 14
On behalf of the Office of Human Research Administration, I am pleased to share the FY15 annual report with the Harvard LMA research community. Although we perform regular evaluation of our program, this annual report represents the first formal document collecting our observations from the year and expressing our future direction.

To follow, we have provided an overview of our program, its mission and scope; unit-specific summaries; program highlights, and a glimpse of what’s ahead.

I would like to thank OHRA leadership including our Institutional Officials Ms. Pamela Caudill, HMS Chief Research Operations Officer, and Dr. Delia Wolf, Associate Dean for Regulatory Affairs & Research Compliance and IRB Chairs Drs. Julie Buring (Harvard Faculty of Medicine), David Christiani (Harvard Chan School), and Ichiro Kawachi (Harvard Chan School) for their continued commitment to protecting human subjects and promoting our mission. Without your support, we would not be able to meet our collective objectives and goals.

In addition, I extend my admiration and gratitude to the entire OHRA staff, whom demonstrate to me every day their commitment and dedication. Lastly, a final thank-you to Stanley Estime, Lisa Gabel, and Kimberley Serpico for their diligent work and support in compiling the program metrics included in this report.

Leslie Howes
Director, Office of Human Research Administration
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).

Staffing strategies for FY15 focused on supporting the Office mission and building capacity at all levels to cultivate leadership and build a culture of inclusivity. IRB and QIP units meet bimonthly to discuss unit-specific objectives, and the larger OHRA staff meets monthly to facilitate Office-wide initiatives. For FY16, efforts will continue to be made to cultivate unit-specific leadership.

The following OHRA staff members assumed new positions during FY15:

- Keren-Nicole Insalaco, Sr. IRB Review Specialist
- Kimberley Serpico, Sr. IRB Review Specialist
- Alyssa Speier, Assistant Director of Regulatory Affairs & Research Compliance (Alyssa also continues her work within OHRA’s Quality Improvement Program)
Institutional Review Board Operations

The IRB Operations unit is responsible for managing and supporting the IRB’s 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. Each panel meets monthly to conduct Full Committee review. Non-committee review (i.e. human research/exemption determinations and expedited review) occur on a rolling basis.

What’s Ahead to Facilitate IRB Review

Harvard Faculty of Medicine and Harvard Chan School IRBs to conduct cross review of initial (new) applications for Full Committee review twice a month

Review Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Contact Information</th>
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<tr>
<td>Julie Kaberry, MHP, CIP</td>
<td>IRB Administrative Chair</td>
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<tr>
<td>Keren-Nicole Insalaco, MS, CIP</td>
<td>Sr. IRB Review Specialist</td>
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<td>Kimberley Serpico, MEd, CIP</td>
<td>Sr. IRB Review Specialist</td>
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<tr>
<td>Paul Hryvniak, MS, CIP</td>
<td>IRB Review Specialist</td>
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<tr>
<td>Keisha Turner, BA</td>
<td>IRB Review Specialist</td>
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<td>Grace Bullock, BA</td>
<td>IRB Coordinator</td>
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Changes to ESTR

Changes anticipated to the IRB’s electronic submission platform, Electronic Submission, Tracking, and Reporting (ESTR) in October 2015. The ESTR Product Path Project aims to revise previous customizations and update ESTR to the current version of Click® IRB, such that vendor designed and provided upgrades may be regularly applied in the future. Through this initiative, the Click® IRB product will continue to be customized to Harvard’s needs and will provide the benefit of sustainable long-term and robust support. Alignment will also ensure that the IRB remains compliant with accreditors and that all ESTR users benefit from a vendor-supported and hosted system.
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.

Highlights:

- New electronic regulatory binders are available via SharePoint and REDCap platforms
- Investigator Portal created within QIP’s web presence to compile resources and address FAQs
- QIP’s Investigator Self-Assessment tool streamlined to facilitate implementation

QIP Team

Stanley Estime, MSCI, CIP
Sr. QA/QI Specialist

Lisa Gabel, BA, CIP
QA/QI Specialist

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

40+
Trainings conducted

260+
Faculty, staff, and students trained

54,500+
Hits to the OHRA webpages
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.

- **88% regulated by DHHS**
- **25% funded by U.S. Federal Government**
- **33% conducted internationally (80% from HSPH)**

![Active Protocols by School](image)

**Figure 1.** Number of active protocols, i.e., exemption determinations; expedited and full committee initial and continuing reviews, across Harvard LMA Schools. The largest volume of which is produced by the Departments of Global Health and Population at the Harvard Chan School (21%), Health Care Policy at the Harvard Medical School (26%), and Oral Health Policy and Epidemiology at the Harvard School of Dental Medicine (36%).
Figure 2. Number of active protocols by research type. Of the biomedical research, 8% (24 protocols) are registered through Harvard’s Clinicaltrials.gov accounts. 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. Ninety-four percent of exemption determinations include the use of survey or interview procedures and/or existing data/specimens, categories 45 CFR 46.101(b)(2) and (4) respectively. Fifty-eight percent of expedited protocols involve data/specimens and/or use of survey or interview procedures, categories 5 and 7 respectively.
Figure 4. Number of active protocols by risk level. This isn’t surprising as Figure 3 illustrates that approximately 70% 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 6. Number of active protocols by special populations, determinations, and/or waivers. Note: categories are not mutually exclusive and protocols may include more than one special population and/or waiver.
Figure 7. Map of active protocols conducted internationally. Seventy-one countries represented, including Angola, Australia, Bangladesh, Belgium, Botswana, Burundi, Cambodia, Canada, Central African Republic, Chile, China, Colombia, Congo, Cote d’Ivoire, Croatia, Cyprus, Denmark, El Salvador, Ethiopia, Faroe Islands, France, Germany, Ghana, Greece, Greenland, Guatemala, Haiti, Hungary, India, Indonesia, Ireland, Israel, Italy, Japan, Kenya, Kuwait, Lebanon, Madagascar, Malawi, Malaysia, Mexico, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nigeria, Norway, Peru, Philippines, Puerto Rico, Qatar, Russia, Rwanda, Senegal, Sierra Leone, South Africa, South Sudan, Spain, Sri Lanka, Sudan, Sweden, Switzerland, Tanzania, Thailand, The Gambia, Turkey, Uganda, Zambia.

Figure 8. Number of active protocols that include at least one international site by type of review.
Figure 9. Median time from submission to IRB determination (human research or exemption) or approval (expedited or full committee) in calendar days. Harvard LMA IRB FY14 and FY15 times compared to internal Office targets as well as AAHRPP 2014 Metrics on Human Research Protection Program Performance, which was updated May 15, 2015. Of note, AAHRPP combines expedited reviews, including initial and continuing 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, which lowers the median. Turnaround times have been consistent the past two years with the exception of full committee reviews where there’s been noticeable improvement.
QIP Services

Figure 10. Utilization of QIP Services across the Harvard LMA Schools. QIP’s most popular service continues to be Submission Assistance, 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. Investigator Self-Assessments have been completed for Q1 and Q2, and remain pending for Q3 and Q4. A total of 15 IRB File Audits were conducted: 11 not-for-cause and 4 for-cause. A total of 3 Investigator File Audits were conducted: 2 not-for-cause and 1 for-cause. No (potential) serious and/or continuing non-compliance was observed for either IRB or Investigator audits.

What’s Ahead to Increase Engagement

QIP continues to be a voluntary program; however, to increase the number of not-for-cause audits and better serve the Harvard Faculty of Medicine, new triggers have been implemented for FY16, e.g., requiring not-for-cause audit of new/exception/transfer PIs and revitalizing QIP’s “Onsite Review & Support Service” offered at the departmental level.
Highlights

The following are some FY15 highlights from the Office of Human Research Administration.

November 2014

The Harvard LMA IRB received the 2014 Health Improvement Institute’s Best Practice award for its One-Stop Shop Model of IRB review, in which investigators have a single point of contact for all protocols—regardless of submission type or mode of review.

August 2014

Harvard T.H. Chan School of Public Health Institutional Official Dr. Delia Wolf, Associate Dean for Regulatory Affairs & Research Compliance, conducted Responsible Conduct of Research (RCR) training in Gaborone, Botswana.
December 2014

QIP presented its “Impact of Submission Assistance on IRB Review Turnaround Time” poster at Public Responsibility in Medicine and Research’s (PRIM&R) annual conference in Baltimore, MD
April 2015

OHRA hosted its IRB Member Retreat at the Harvard Faculty Club, which included Institutional leadership and IRB members from both Harvard Faculty of Medicine and Harvard Chan School committees. Each IRB Chair led a team in a lively game of IRB Jeopardy (Team Kawachi prevailed; rematch planned for 2016)!

June 2015

QIP conducted a two-day international site visit in France, including a routine (not-for-cause) onsite review and observation of the consent process.