# Table of Contents

Director’s Statement........................................................................................................ 3  
Our Organization................................................................................................................ 4  
Institutional Review Board (IRB) Operations .................................................................... 5  
Meet the Review Team......................................................................................................... 5  
Quality Improvement Program............................................................................................ 6  
Meet the Quality Improvement Program Team ................................................................. 6  
Program Metrics.................................................................................................................. 7  
FY17 Highlights.................................................................................................................... 12
Director’s Statement

On behalf of the Office of Human Research Administration, I am pleased to share the FY17 annual report with the Harvard Longwood Medical Area (LMA) Schools research community.

A few notable changes made during this fiscal year:

- **HMS Institutional Official.** In December 2016, Dr. Ara Tahmassian, Harvard University Chief Research Compliance Officer, assumed the role of Institutional Official for Harvard Faculty of Medicine, replacing Ms. Pamela Caudill, HMS Chief of Research and Administrative Operations.

- **Reliance/Cede Agreements.** In September 2016, Harvard Faculty of Medicine and Harvard T.H. Chan School of Public Health joined SMART IRB—a national platform designed to facilitate the implementation of the NIH Single IRB Review policy. Smart IRB is intended to replace the local Harvard Catalyst cede request system, which was decommissioned in September 2017.

- **AAHRPP Accreditation.** The Harvard LMA Schools Human Research Protection Program (HRPP) is pursuing re-accreditation through the Association for the Accreditation of Human Research Protection Programs (AAHRPP). AAHRPP is an independent, non-profit accrediting body that uses a voluntary, peer-driven, educational model to ensure that HRPPs meet rigorous standards for quality and protection. Harvard Chan School first received AAHRPP-accreditation in 2010 and re-accreditation in 2013. This is the first re-accreditation as a consolidated Harvard LMA Schools Human Research Protection Program (HSPH, HMS, and HSDM). A site visit is scheduled for February 26-27, 2018.

In this report, please find an overview of our human research protection program, its mission and scope, unit-specific summaries for the IRB Operations and Quality Improvement Program, program metrics, and FY17 highlights.

I owe many thanks to the OHRA leadership for their continued commitment to protecting human subjects and promoting our mission, including our Institutional Officials: Dr. Ara Tahmassian (Harvard Faculty of Medicine) and Dr. Delia Wolf (Harvard Chan School); IRB Chairs: Dr. Julie Buring (Harvard Faculty of Medicine), Dr. David Christiani (Harvard Chan School), and Dr. Ichiro Kawachi (Harvard Chan School). I wish to extend a final thank-you to Alma Castro, Lisa Gabel, Kimberley Serpico, and Alyssa Speier for working with me to compile this report.
Our Organization

The Office of Human Research Administration (OHRA) is a comprehensive administrative office designed to review, approve, oversee, and assist all human research projects conducted by faculty, staff, and students across the Harvard Longwood Medical Area (LMA) Schools, including the Faculty of Medicine and Harvard T.H. Chan School of Public Health. OHRA’s mission is to protect the rights and welfare of human participants involved in human research and to provide high-level education and human research support to our research community. The Office of Human Research Administration is comprised of two units: the Institutional Review Board (IRB) operations and the Quality Improvement Program (QIP).

Staff Changes

During the FY17, Alyssa Speier assumed a new position as Associate Director of Regulatory Affairs and Research Compliance. In this role, Ms. Speier is now responsible for managing the Quality Improvement Program. Scott Meyers joined the Quality Improvement Program as a QA/QI Specialist. Alma Castro joined the IRB Operations unit as an IRB Review Specialist. For a list of the departments that Ms. Castro manages, visit the OHRA website. This past fiscal year, Alma Castro and Scott Meyers obtained their Certified IRB Professional (CIP) designation, a credentialing initiative designed to ensure that IRB professionals have demonstrated an advanced level of knowledge, understanding, and experience.
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 Faculty of 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 Team manages non-committee reviews, including not human subjects research requests, exemption requests, and expedited human research.

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

Alma Castro, MA, CIP
IRB Review Specialist

Jada Dixon, MJ, MPH, CIP
IRB Review Specialist

FY17 HIGHLIGHTS

Enhanced HMS/HSDM IRB membership composition with the addition of a new prisoner representative

Updated/revised ESTR technical support, including the Investigator Study Submission Guide and ESTR Support Website

A new IRB member training program was pilot tested this year with great success. The Harvard LMA IRB now has a formal training module specific to OHRA and the Harvard LMA research community for onboarding new IRB members.
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 (not-for-cause) and/or directed (for-cause) audits of investigators and IRB records as well as 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.

Additional Clinical Trials Support

In response to Federal regulation and NIH policy updates regarding clinical trials, QIP has increased their support by providing additional training opportunities and consultation on these topics.

Meet the Quality Improvement Program Team

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

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

Lisa Gabel, BA, CIP
Senior QA/QI Specialist

Scott Meyers, MS, CIP
QA/QI Specialist

FY17 HIGHLIGHTS

Conducted 45+ Trainings
Trained 520+ Faculty, staff, and students
Hosted the 5th Annual QA/QI Boot Camp in October 2016
Now supports reliance/cede agreements by providing a single point of contact for all reliance/cede requests (Scott Meyers)
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).

Figure 1. Number of active protocols (N=795), i.e., exemption determinations; expedited initial and continuing reviews; convened IRB initial and continuing reviews, across Harvard LMA Schools. The Harvard Chan School accounts for 67% of the total active protocols; Harvard Medical School, 27%, and Harvard School of Dental Medicine, 6%. The largest application volume continues to be submitted from the departments of Global Health and Population at the Harvard Chan School (23%), Health Care Policy at Harvard Medical School (32%), 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 educational tests, surveys, interviews and/or the use of existing data/specimens, categories 45 CFR 46.101(b)(2) and (4) respectively. The majority of expedited protocols continue to involve identifiable data/specimen analysis and/or the use of survey or interview procedures, expedited categories 5 and 7 respectively. Note: exemption and expedited review categories are not mutually exclusive meaning that more than one category may apply to a single exemption determination or expedited review.

Figure 4. Number of active protocols by research data security level (DSL). 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.” A DSL of “0” would be assigned where the Harvard Research Data Security Policy doesn’t apply, i.e., when the IRB determines that the proposed activities are not research as per 45 CFR 46.102(d).
Figure 5. Map of active international sites. One hundred and five countries are represented including Angola, Argentina, Armenia, Australia, Bangladesh, Belgium, Benin, Bolivia, Bosnia and Herzegovina, Botswana, Brazil, Burkina Faso, Burundi, Cambodia, Cameroon, Canada, Chile, China, Colombia, Costa Rica, Croatia, Denmark, Democratic Republic of the Congo, Ecuador, Egypt, El Salvador, England, Estonia, Ethiopia, Faroe Islands, Fiji, France, Georgia, Germany, Ghana, Greece, Guatemala, Guinea, Haiti, Honduras, Hong Kong, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kiribati, Kuwait, Kyrgyz Republic, Lebanon, Lesotho, Liberia, Madagascar, Malawi, Malaysia, Mexico, Mongolia, Mozambique, Myanmar, Namibia, Nepal, Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Portugal, Puerto Rico, Qatar, Rwanda, Saudi Arabia, Senegal, Sierra Leone, Singapore, Solomon Islands, South Africa, South Sudan, Spain, Sri Lanka, St Lucia, Sudan, Swaziland, Sweden, Switzerland, Tanzania, Thailand, The Gambia, Turkey, Tuvalu, Uganda, United Arab Emirates, United Kingdom, Vanuatu, Vietnam, Zambia, and Zimbabwe.
**Figure 6.** Active protocols with at least one international site by type of review, i.e., exempt, expedited, or convened IRB.

**Figure 7.** Utilization of QIP Services across the Harvard LMA Schools. QIP’s most popular service continues to be Investigator Submission Support, which provides faculty and students with custom support drafting and/or editing study documents, and/or submitting through the eIRB system, ESTR.
Figure 8. Median time from submission to IRB determination (not human research or exemption) or approval (expedited or convened IRB) in calendar days. Harvard LMA IRB FY17 times are compared to internal OHRA targets as well as AAHRPP 2016 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 continuing reviews and modifications. Turnaround times have been consistent the past year with the exception of convened IRB reviews, which increased in FY17. This increase is the result of multiple deferrals. For FY18, the IRB Operations unit plans to focus efforts on reducing convened IRB turnaround times.
FY17 Highlights

The following are some FY17 highlights from the Office of Human Research Administration.

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**Changes to Human Subjects Training**

In collaboration with the Office of the Vice Provost for Research and the University-Area IRB, the Office of Human Research Administration worked to streamline Harvard University’s online human subjects training (CITI curriculum). Basic training now includes 7 required modules and 3 electives.

In addition the Office of Human Research Administration now accepts NIH Protecting Human Research Participants online training as an acceptable equivalent training to CITI.

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**Regulatory Binder Updated**

The Quality Improvement Program revised its Regulatory Binder Template to facilitate implementation.
HRPP Toolkit Updated

As part of its annual evaluation, the Office of Human Research revised its toolkit, namely, its forms, checklists, worksheets, etc. The review resulted in significant changes: (a) decommissioning of the Exemption Request Form and Translation Attestation Form; (b) creation of a full suite of documents to ensure compliance with Massachusetts General Law ch. 112 §12J (Use of Fresh Human Fetal Tissue in Research); (c) addition of the PI Exception Form (allowing for non-faculty PIs to petition to serve as PI); (d) addition of an Exempt Human Research Consent Script Template.

Additionally, the Investigator Manual underwent significant updates to sections describing on what and how to report financial interests to the IRB; preparing the Research Protocol; consent considerations (specifically with regard to disclosing financial conflicts of interest); resources for data management, and additional general resources in the appendices.