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Director’s Statement

On behalf of the Office of Human Research Administration (OHRA), I am pleased to share the FY18 annual report with the Harvard Longwood Medical Area (LMA) Schools research community.

Every year OHRA reviews its HRPP Toolkit. The HRPP Toolkit is a comprehensive system of interrelated worksheets, checklists, forms, templates, and SOPs designed to ensure compliance with human research regulation and institutional policy. Most materials are inward facing, offering direction and guidance to the IRB Review Team; however, the Investigator Manual continues to serve as the principal document available to assist faculty, staff, and student investigators. Our FY18 toolkit review provided an opportunity to address the following:

- **Changing regulatory landscape.** FY18 brought many changes to the regulatory landscape governing human research. In response, OHRA readied its toolkit to comply with the revised Common Rule, i.e., the Federal Policy for the Protection of Human Subjects; General Data Protection Regulations (GDPR), a broad-sweeping regulation that aims to protect individuals’ fundamental rights to data protection and the free flow of personal data, and NIH Policy for Issuing Certificates of Confidentiality, which outlines when and how a Certificate of Confidentiality is issued, and applies to research “in which identifiable, sensitive information is collected.”

- **Association for the Accreditation of Human Research Protection Programs (AAHRPP) Re-accreditation.** This effort marks the first re-accreditation as a consolidated Harvard LMA Schools Human Research Protection Program (HSPH, HMS, and HSDM). This process involved a tedious self-assessment requiring institutions to address gaps in policies, procedures, and practices. It culminated during the 2-day site visit in February 2018. During that time, site visitors noted three strengths, including the OHRA leadership and staff, competency of IRB members, and engagement of the LMA research community. During their exit interview, AAHRPP site visitors shared no findings nor noted any areas in need of improvement. AAHRPP council granted the Harvard LMA Schools HRPP full re-accreditation status in June 2018.
• **IRB harmonization at Harvard.** OHRA leveraged its collaboration with the Harvard University-Area (Cambridge-based) IRB to review and harmonize “shared” toolkit documents, i.e., those worksheets, checklists, forms, and templates maintained in the University’s eIRB system, ESTR. As a result, we now share over 50% of the toolkit with our Harvard University Area counterparts - a true reflection of “One Harvard” at work.

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 FY18 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, and oversee 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 FY18, Elizabeth Ehrlich (“Liz”) joined the IRB Operations unit as an IRB Review Specialist. Prior to her hire, Liz worked as a Human Research Coordinator and IRB Member for the Dana-Farber Cancer Institute IRB. She received her Bachelor’s degree from University of Virginia in 2012 and earned her Certification of IRB Professionals (CIP) designation in 2017. For a list of the departments that Liz manages, visit the OHRA website.
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 Specialist Team manages non-committee reviews, including not human subjects research determinations, exemption determinations, and expedited review.

**IRB Membership Highlights**

- **Membership Changes**
  - The HMS/HSDM IRB welcomed a new non-affiliated member with experience and expertise in FDA-regulated drugs and devices, and the Harvard Chan School IRB added a new non-affiliated member with experience and expertise in health economics and development of pharmaceuticals and vaccines for infectious diseases in developing countries.
  - Longstanding Harvard Chan School IRB member, Dr. Marie McCormick stepped down. The Chairs, membership, and staff at the Office of Human Research Administration express their thanks to Dr. McCormick for her service and dedication and wish her all the best in retirement.

- **Annual Member Evaluation.** The FY18 IRB Member Self Evaluation achieved a 95% response rate. The results demonstrate that IRB members felt that they were well equipped to fulfill their role as reviewers, that education sessions at each meeting were timely and helpful, that ESTR was useful and convenient, and that IRB staff adequately corresponds with PIs outside of the IRB meetings.
Meet the IRB Review Team

Kimberly Serpico, ME, CIP
Assistant Director of IRB Operations

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

Grace Ayers, BA, CIP
IRB Review Specialist

Alma Castro, MA, CIP
IRB Review Specialist

Elizabeth Ehrlich, BA, CIP
IRB Review Specialist

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, BA, CIP
QA/QI Specialist
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.

FY18 HIGHLIGHTS

Conducted 39+ Trainings

Trained 530+ faculty, staff, and students

Completed 20 First Time PI onsite reviews (i.e., not-for-cause audits)

Completed 108 IRB file audits

AAHRPP AREA OF DISTINCTION

The QIP Program, particularly its “first time Harvard PI audit initiative,” was noted as an AAHRPP “Area of Distinction”
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 for FY18, N=598**

The Harvard Chan School accounts for 63% of the total active protocols; Harvard Medical School, 30%, and Harvard School of Dental Medicine, 7%. The largest application volume continues to be submitted from the departments of Global Health and Population at the Harvard Chan School (25%), Health Care Policy at Harvard Medical School (26%), and Oral Health Policy and Epidemiology at the Harvard School of Dental Medicine (28%).

**Figure 2: Percentage of clinical trials in the Harvard LMA research portfolio**

Areas of research in our portfolio include biomedical research, clinical trials, international research, social/behavioral research etc. Of all active protocols for FY 2018 (N = 598), about 28 are clinical trials.
The number of active protocols (N = 598) per school includes Exempt, Expedited, and Convened IRB reviews. 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.

As part of the review process, the IRB assigns a research data security level (DSL) per the Harvard Research Data Security Policy. The DSL levels range from 1-5, where DSL 1 includes “public information” and DSL 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).
Harvard Longwood Medical Area investigators conduct research globally and their reach spans over 90 countries. Currently active research locations are represented in the map above and the sites include such locations as Angola, Botswana, Columbia, Denmark, El Salvador, Faeroe Islands, Georgia, Hong Kong, Kiribati Republic, Lesotho, Mongolia, Nigeria, Philippines, Qatar, Rwanda, Singapore, Waiwan, UAE, Vanuatu.

A breakdown of protocols with international location sites by review category, i.e., exempt, expedited, or convened IRB across LMA schools.
Figure 7 details some of the QIP services provided across the 3 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. QIP conducted over seven hundred times more IRB File Reviews compared to FY17, which was largely in response to AAHRPP re-accreditation preparation.
The IRB and QIP work diligently and in collaboration to ensure that the investigator IRB experience is seamless. In Figure 8 median turnaround times (in calendar days) for ESTR submissions is presented. These include Not Human Subjects Research requests, Exemption determinations, Expedited review and Convened IRB reviews. Harvard LMA IRB FY17 and FY18 times are compared to internal OHRA targets as well as AAHRPP 2017 Metrics. Of note, AAHRPP combines expedited reviews (initial and continuing review applications, and modifications) into a single data point. Measures implemented during FY18 appear to have been effective as reducing turnaround time since FY17. These measures included thorough pre-committee review; pre-agenda check for IRB Staff to discuss pending submissions; IRB Chair consultation to determine convened IRB review-readiness; regular data monitoring; QIP IRB submission referrals.
Reliance, cede, or IRB authorization agreement are synonymous terms used to denote an instance where a single institution or IRB is designed as the IRB record.

Figures 9 & 10 show the amount of cede agreements processed within the Harvard Faculty of Medicine and Harvard T.H. Chan School of Public Health respectively.
FY18 Highlights

The following are some FY18 highlights from the Office of Human Research Administration.

IRB Member Retreat

OHRA hosted its biannual IRB Member Retreat in December 2017. The program included a discussion of the upcoming AAHRPP Accreditation site visit from the Institutional Officials, spotlight presentation on the Final Rule, a presentation of the annual member self-evaluation results, IRB membership attendance awards, and a fun game for members to refresh their knowledge of the regulations and ethical principles governing human subjects research.
ESTR, Enhanced

ESTR, the eIRB submission system used by both Human Research Protection Programs at Harvard University, was upgraded with four releases during FY18. These releases and configurations focused primarily on receiving vendor-provided updates and fixing bugs. The most notable change was the distinction between Research Locations and Collaborating Sites. Research Locations (formerly External Sites in the ESTR SmartForm) denote “places where the research will take place” where Collaborating Sites refer to institutions or study staff that are also taking part in the research study (e.g. via a reliance agreement). Of note, to support this distinction, Collaborating Sites are now maintained separately under Sites in ESTR.

Additional ESTR enhancements requested by the research community were also made including the addition of several departments, process changes to External IRB applications, enhancement of Ancillary Review processes and policy requirements, enrichment of ESTR Reports, and ongoing streamlining of notification letters and system notices. As part of ongoing ESTR technical support, the Investigator Study Submission Guide and ESTR Support Website were revised in real-time to support the above changes.
Conference Posters


New Hire Onboarding: A Team Effort with Results You Can Replicate!

Onboarding and training of new employees can be inconsistent and inefficient without a strategic plan in place to guide the process. The IRB Operations unit within the Harvard Longwood Medical Area (LMA) Office of Human Research Administration (OHRA) created the New Hire Process and Onboarding Manual to mitigate this challenge when onboarding new staff. The poster describes this process in detail.
Avoid a Deferral with a Referral: An Innovative Collaboration between the IRB & QIP

The most popular QIP support service is IRB application submission assistance and the outcome is a higher quality submission. Submission assistance is often referred directly from the IRB reviewer for new investigators or when a submission is in need of substantial revisions. When initially implemented, the QIP referral process brought challenges that impeded efficiency and confused investigators. IRB and QIP Staff implemented a new process to streamline communication and increase efficiency. The poster describes this collaboration in detail.