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Reflecting Back
It’s hard to believe, but back in 2011, the government first sought public input on an array of issues related to the ethics, safety, and oversight of human research in an advance notice of proposed rulemaking (ANPRM). At the time, the ANPRM sought comments on potential revisions to the Common Rule. Progress continued -albeit with revision and delay- through a notice of proposed rulemaking (NPRM) in 2015, final rule in 2017, and an interim final rule in 2018. So, on January 21, 2019, it was with great anticipation that the revised Common Rule (aka “2018 Requirements”) went into effect. One year later, we’re starting to see small, but impactful changes to our research portfolio suggesting that the revised Common Rule may -as originally intended- eased the administrative burden. For example, there are approximately 300 non-expiring protocols in ESTR, i.e., ongoing human research where the requirement for continuing review has been eliminated.

What to expect in 2020
- **New Website!** Be on the lookout for a refreshed website for the Office of Regulatory Affairs and Research Compliance (ORARC), which will signify the final step in sun-setting the Office of Human Research Administration name/website. These efforts aim to streamline the presentation of ORARC to include its broad scope of research compliance, inclusive of human research. The IRB Operations unit and the Quality Improvement Program will remain a shared-service across the Harvard Longwood Campus (HLC) Schools.
- **Staff Expansion!** We’re adding an **IRB Reliance & QA/QI Specialist** in response to new regulatory drivers, including the **NIH sIRB Policy** and **revised Common Rule** cooperative agreement clause, which require reliance on a single IRB for multisite, non-exempt human research. This new role will enable ORARC to provide greater reliance support to its research community while also ensuring regulatory compliance.

Thank You!
Thank you to the HRPP 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 Christiani (Harvard T.H. Chan School of Public Health); IRB Chairs: Dr. Julie Buring (Harvard Faculty of Medicine), Dr. David Christiani (Harvard Chan School) and Dr. Ichiro Kawachi (Harvard Chan School).

Finally, I am pleased to share this report with the HLC Schools research community. To follow, you’ll find an overview of our human research protection program (HRPP), its mission and scope, unit-specific summaries from the IRB Operations and Quality Improvement Program, program metrics, and highlights of our year. Many thanks to Lisa Gabel, Kim Serpico, and Alyssa Speier for your diligence in preparing the content, including the mining of tedious metrics. And, to Alma Castro, who indulged the many iterations and continues to improve upon the presentation of this material year after year. Thank you!
Our Organization

The Office of Human Research Administration (OHRA) is a comprehensive administrative office designed to review, approve, and oversee all human research conducted by faculty, staff, and students across the Harvard Longwood Campus Schools (Harvard Faculty of Medicine, comprised of Harvard Medical School and Harvard School of Dental Medicine, and Harvard T.H. Chan School of Public Health).

Our mission is to protect the rights and welfare of 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).

One Harvard @ OHRA

OHRA collaborates with OVPR, HUIT and HUA IRB to pilot a change to the Harvard Research Data Security Policy in which IT certification was required prior to final IRB approval. Feedback from this pilot will inform policy changes.

OHRA participates in the Harvard-wide Research Data Security Operations Committee (“ReDSOC”), whose charge is to standardize school-wide research data security controls, collection, storage, collaboration, and archiving.

OHRA continues close collaboration with HUIT and HUA IRB to identify and harmonize business practices, HRPP Toolkit materials, and eIRB system, ESTR usage.

OHRA connects with the Harvard Longwood Campus negotiating offices (Sponsored Programs Administration at HSPH & Office of Research Administration at HMS) to facilitate parallel review of grants/contracts and IRB applications.

OHRA continues to collaborate with Office of General Counsel, the HUA IRB, and OVPR, to develop resources and guidance for researchers who are impacted by the EU General Data Protection Regulation (GDPR). This includes standardizing data use agreement requirements for EU data procurement and consent form template language for EU data collection.
Meet the Staff

IRB Review Team

Kim Serpico, MEd, CIP  
Asst. Dir. of IRB Operations

Keren-Nicole Insalaco, MS, CIP, CIM  
Sr. IRB Review Specialist

Elizabeth Ehrlich, BA, CIP  
IRB Review Specialist

Grace Ayers, BA, CIP  
IRB Review Specialist

Alma Castro, MA, CIP  
Sr. IRB Review Specialist

Alyssa Speier, MS, CIP  
Assc. Dir. of Regulatory Affairs & Research Compliance

Lisa Gabel, BA, CIP  
Sr. QA/QI Specialist

Stanley Estime, MSCI, CIP  
Asst. Dir., Lab & Biosafety

Alexis Fagan, BA  
ORARC Coordinator

Quality Improvement Team
Institutional Review Board (IRB) Operations

The IRB Operations unit is responsible for managing and supporting the scientific and ethical review of human research conducted by faculty, staff, and students at the Harvard Longwood Campus (HLC) Schools. The unit provides administrative support to two IRB panels: Harvard Chan School and Harvard Faculty of Medicine.

The IRB Review Team, comprised of the Assistant Director of IRB Operations and IRB Review Specialists, are responsible for managing a portfolio of department assignments spanning across the HLC Schools. As appointed IRB members, the Review Team provides front-line review, regardless of mode of review or submission type. Reviewers have the authority to perform non-committee reviews, including not human subjects research determinations, exemption determinations and the expedited review procedure.

Below are some of the significant accomplishments completed in 2019.

1. ESTR, eIRB system Upgrades

- There were 3 system upgrades in 2019. Key changes included:
  - Revisions necessary to keep pace with regulatory changes required of the Revised Common Rule.
  - Creation of a unified Inbox for system users in preparation for the integration of new modules supported across Harvard University, e.g., Agreements, etc.
  - Enhancements highlighted by system users, including the research community, e.g., addition of departments, workflow changes to External IRB applications, enhanced reports, and ongoing streamlining of notification letters and system notices.

2. IRB Decision Tool

- The IRB Decision Tool went live October 2019.

- This HarvardKey-protected tool facilitates a user in determining whether proposed activities meet the regulatory definitions of human subjects research and identifying when an IRB application is required.

- Since go-live in October, this tool has experienced over 300 uses!

- The tool will benefit from continuous improvement through a separate Feedback Survey accompanying the tool.
HRPP Toolkit Update

- The Human Research Protection Program (HRPP) Toolkit expanded with the addition of two new documents: Repository Protocol (and accompanying guidance) and PI Departure Worksheet.

- The Research Protocol template now better reflects consent for secondary analysis, FERPA- and GDPR-regulated research, and includes clearer instruction for clinical trials.

- The Investigator Manual provides guidance on GDPR, serving as PI, human subjects training requirements, lapsed human research, IRB meeting deadlines, ESTR instructions, data confidentiality measures, and the reliance process.

IRB Membership

- HMS/HSDM IRB expanded membership with a pediatric pharmacist and a licensed psychologist/attorney.

- The 2018 IRB member self-evaluation enjoyed an 80% response rate across the two IRB panels. IRB members reported they are very equipped to fulfill their role, education sessions are timely and helpful, and that they can effectively utilize ESTR. In addition, IRB members shared high praise for the IRB Review Team.
Quality Improvement Program

The Quality Improvement Program (QIP), independent of the IRB, is a robust group consisting 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 both investigator 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 assistance; design and dissemination of template study management tools; routine onsite monitoring; and external audit preparation. Below are the major projects and initiatives completed in 2019.

Quick QIP Stats

- Conducted 37 Trainings, including 10 revised Common Rule sessions.
- Trained more than 375 Faculty, staff, and students, including 100 attendees present at the revised Common Rule sessions.
- Completed 21 routine Investigator audits; 18 complementary IRB file audits.

OHRA-PRIM&R Partnership

- OHRA continues to partner with Public Responsibility in Medicine & Research (PRIM&R) to facilitate the “QA/QI in Human Subjects Research” pre-conference.
- As part of the 2019 QA/QI pre-conference, Lisa Gabel developed a new Mock Audit tool, which received rave reviews from attendees, many citing it as the “most valuable” aspect of the workshop.
- 70+ attendees participated!
QIP International Site Visits

- QIP completed 4 international site visits (China, Ethiopia, Kenya, and South Africa), which affected 7 human research protocols.

- Site visits included auditing investigator files onsite, field observation, research staff training, meetings with local Ethical Review Committee leadership, and capacity building activities.
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).

**Initial Applications by School**

<table>
<thead>
<tr>
<th>School</th>
<th>NHSR</th>
<th>Exempt</th>
<th>Expedited</th>
<th>Convened IRB</th>
</tr>
</thead>
<tbody>
<tr>
<td>HSDM</td>
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<td>12</td>
<td>0</td>
<td>0</td>
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<td>HMS</td>
<td>70</td>
<td>58</td>
<td>31</td>
<td>12</td>
</tr>
<tr>
<td>HSPH</td>
<td>118</td>
<td>81</td>
<td>63</td>
<td>9</td>
</tr>
</tbody>
</table>

The total number of initial applications in 2019 (N = 480). Initial applications are comprised of not human subjects research determinations (44%); exemption determinations (31%); expedited review (20%), and convened IRB reviews (4%). The Harvard Chan School accounts for 56% of the total initial applications; Harvard Medical School, 36%, and Harvard School of Dental Medicine, 8%. 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.
Active Protocols by School

Active protocols in 2019 (N=728), inclusive of exempt determinations made during the year and active non-exempt human research protocols (expedited and convened IRB review). The Harvard Chan School accounts for 62% of the total active protocols; Harvard Medical School, 33%, and Harvard School of Dental Medicine, 5%. The largest application volume continues to be submitted from the departments of Global Health and Population at the Harvard Chan School, Health Care Policy at Harvard Medical School, and Restorative Dentistry at the Harvard School of Dental Medicine.

Active Protocols by Data Security Level

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.” There were no DSL 5 determinations in 2019.

Of the active protocols, 34% (245) include at least one international location where a Harvard Longwood Campus school is conducting or overseeing research activities. The graph above provides a breakdown of protocols with an international location by review category, i.e., exempt, expedited, or convened IRB across HLC schools.
Harvard Longwood Campus investigators conduct or oversee research activities in 78 international locations around the globe. Currently active research locations are represented in blue in the map above. The countries hosting the greatest number of human research protocols include India (22), Tanzania (21), Botswana (17), South Africa (14), China (12), Uganda (9), Ethiopia, Haiti, Nigeria, and Peru (each with 8 protocols), Faroe Islands, Kenya, and Mexico (7 protocols each), Ghana and Indonesia (6 protocols each) and Burundi, Guatemala, and Malawi (5 protocols each).
**Turnaround Time**

The median turnaround times (in calendar days). FY17, FY18, and FY19 times are compared to internal turnaround targets as well as AAHRPP 2018 Metrics. In FY19, the median turnaround time for not human subjects research determinations was 2.1 days, for exemption determinations it was 9.2 days, and for expedited initial submissions it was 24 days. These times all demonstrate a decrease in time from FY18. Median time for convened IRB initial submissions increased slightly to 58 days since FY18.

**Reliance Agreements**

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. The graph to the left shows the number of external IRB submissions where the HLC IRB is the relying IRB. In FY19 we embarked on an external IRB clean-up project that resulted in the closure of over 400 ceded protocols.
Utilization of QIP Services

The Quality Improvement Program’s (QIP) most popular service continues to be investigator submission support, which provides faculty and students with custom support drafting and editing study documents, and/or submitting through the eIRB system, ESTR.
Highlights of the Year

QIP International Site Visits

South Africa - February 2019
Lisa Gabel reviewing regulatory documents with a local Project Manager at the Red Cross War Memorial Children’s Hospital in Cape Town, South Africa.

Kenya - July 2019
Lisa Gabel and former QA/QI Specialist, Scott Meyers, reviewing consent documentation below at in Kilifi County Hospital, Kenya.

China - October 2019
Leslie Howes, Alyssa Speier, and Delia Wolf and the local study team at the Wuxi Mental Health Center in Wuxi, China.
2019 Ethical Issues in Global Health Research (EIGHR) Workshop

The Harvard T.H. Chan School of Public Health’s Office of Regulatory Affairs and Research Compliance (ORARC) offered its annual Ethical Issues in Global Health Research workshop in September 2019. The workshop provides a multi-disciplinary and comprehensive perspective into the various aspects affecting human research and supplies participants with the knowledge, resources, and peer network to help address the unique ethical challenges in this field. Participants attend EIGHR from around the world; this year attendees came from China, Egypt, Haiti, India, Rwanda, Saudi Arabia, and Ukraine.

Annual Mission Hill Health & Wellness Fair

The 9th annual Mission Hill Health & Wellness Fair will took place in September 2019. As part of this annual event, our Office provides information on research participant rights, the role of the IRB in research, and types of research conducted at the Harvard Longwood Campus Schools. Stanley Estime and Keren-Nicole Insalaco represented the Office at the event, greeting attendees, imparting valuable information, and providing some Office swag.
Accomplishments

Alma Castro, IRB Review Specialist, was selected as a Resident Fellow for the Harvard Administrative Fellowship Program. The Program provides participants with opportunities to enhance their professional experiences by both working within an academic environment as a mid-level administrator and working in an area that broadens and deepens previous opportunities. The Program also seeks to enrich and diversify the Harvard communities by bringing innovative talented professionals to and from a variety of geographical and institutional locales.

Lisa Gabel, Senior QA/QI Specialist, was nominated for the Sarah K. Wood Award for Outstanding Staff Performance, which recognizes a staff member who demonstrates the qualities of dedication, competence, positive attitude, initiative, and ability to mentor, encourage, and inspire others, in addition to a demonstrated commitment to the School and its mission.


Keren-Nicole Insalaco, Senior IRB Review Specialist, was recognized for her 20 years of service at the School.

Alyssa Speier, Associate Director, was nominated for the Ace (Acknowledging Commitment and Excellence) Award, which recognizes administrative staff who go “that extra mile” in a number of ways.

Several members of the Office joined the faculty of Public Responsibility in Medicine & Research’s Advancing Ethical Issues conference in Boston, November 2019: Alma Castro, Leslie Howes, Kim Serpico, Alyssa Speier, and Delia Wolf.