Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, July to September 2023 (Quarter 1)

14 September 2023

Mission

The Harvard University Area (HUA) IRB aims to promote a culture of compliance and to establish across the University the highest expectations for performance and oversight of research involving human subjects. The IRB is committed to the education of the Harvard research community and outreach to collaborating institutions.

The mission of the IRB is to assure that all participants are protected from any unnecessary risk when enrolled in a research study, that they can make an informed decision to participate, and when possible, that participant and/or society at large benefits from the knowledge gained from the research study. The goal of the IRB is to assist investigators in developing appropriate research protocols in accordance with federal and University policies, and within accepted ethical guidelines.

The IRB is guided by the ethical principles of respect for persons, beneficence, and justice.

Ethical Principles

All Human Subjects Research conducted by Harvard University investigators, regardless of source of funding or location of the research, is guided by the ethical principles set forth in the April 18, 1979, report of The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research entitled *Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, also known as "The Belmont Report"—**respect for persons, beneficence, and justice.**

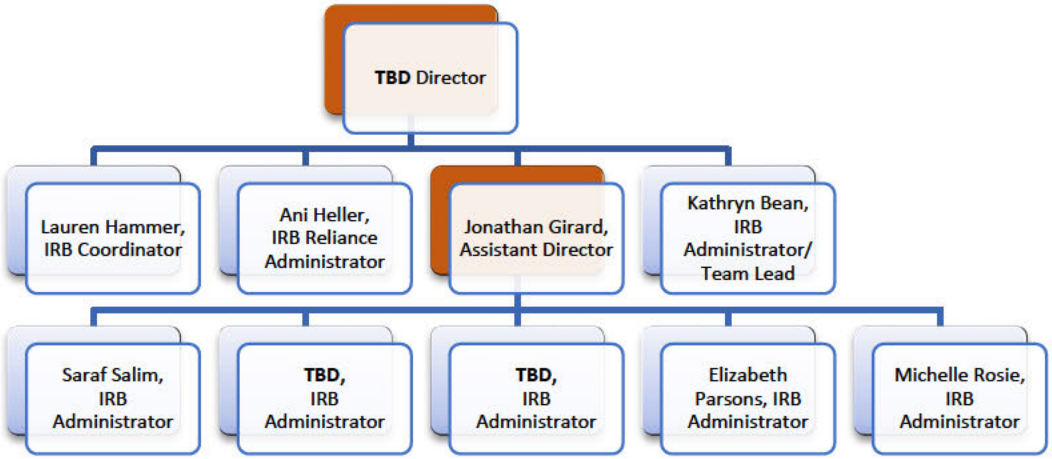
Who We Are

The IRB

The Harvard University Area includes the Faculty of Arts and Sciences, Harvard Graduate School of Education, Harvard Kennedy School, Harvard Divinity School, Harvard Business School, Harvard Law School, Harvard Graduate School of Design, the Harvard School of Engineering and Applied Sciences, Harvard University Health Services, and the Radcliffe Institute for Advanced Study. The IRB of record for the Harvard University Area is referred to as the Committee on the Use of Human Subjects (CUHS).

The IRB Office

The HUA IRB administrative office is responsible for managing the day-to-day operations and support of the IRB. The HUA IRB office staff perform a variety of functions in addition to supporting the IRB such as providing IRB determinations, reviewing studies on behalf of the IRB, assisting researchers with IRB related questions, and providing training and outreach.



Measure of Efficiency

Metrics Summary

Table 1 and Graph 1 represent staff review time (in calendar days) for studies (according to type of review) that were completed by the IRB staff as compared to overall review time for Calendar Year 2023 to date (January 2023 to August 2023). Table 2 and Graph 2 are the same comparison; however, they represent metrics for Calendar Year 2022 (January 2022 – August 2022).

Please note that while the IRB provides many types of reviews and determinations, only the most common are included here.

The review time for a submission is calculated as the time that a submission enters our e-submission system, ESTR (Electronic Submission, Tracking, and Reporting), until the time that a determination is made. Any study's time-to-completion may be affected by the time taken by the IRB, or the time taken by the study staff, by the type of review (e.g., convened IRB review takes longer as there is only one meeting per month), or by the difficulty of the submission (e.g., a modification that involves substantial changes to an IRB submission versus a modification to add a study team member).

Please see next page →

Table 1

IRB Staff Review Time versus Total Review Time CY23																
	Jan-23		Feb-23		Mar-23		Apr-23		May-23		Jun-23		Jul-23		Aug-23	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	18	59	16	52	19	59	17	50	14	37	11	24	22	34	7	13
Exempt	8	30	6	22	6	18	6	16	6	21	8	23	5	13	5	14
NHSR	3	9	3	7	5	16	4	6	4	9	5	8	3	5	2	4
Expedited	3	8	3	7	5	10	3	8	4	10	4	7	2	3	2	4

Graph 1

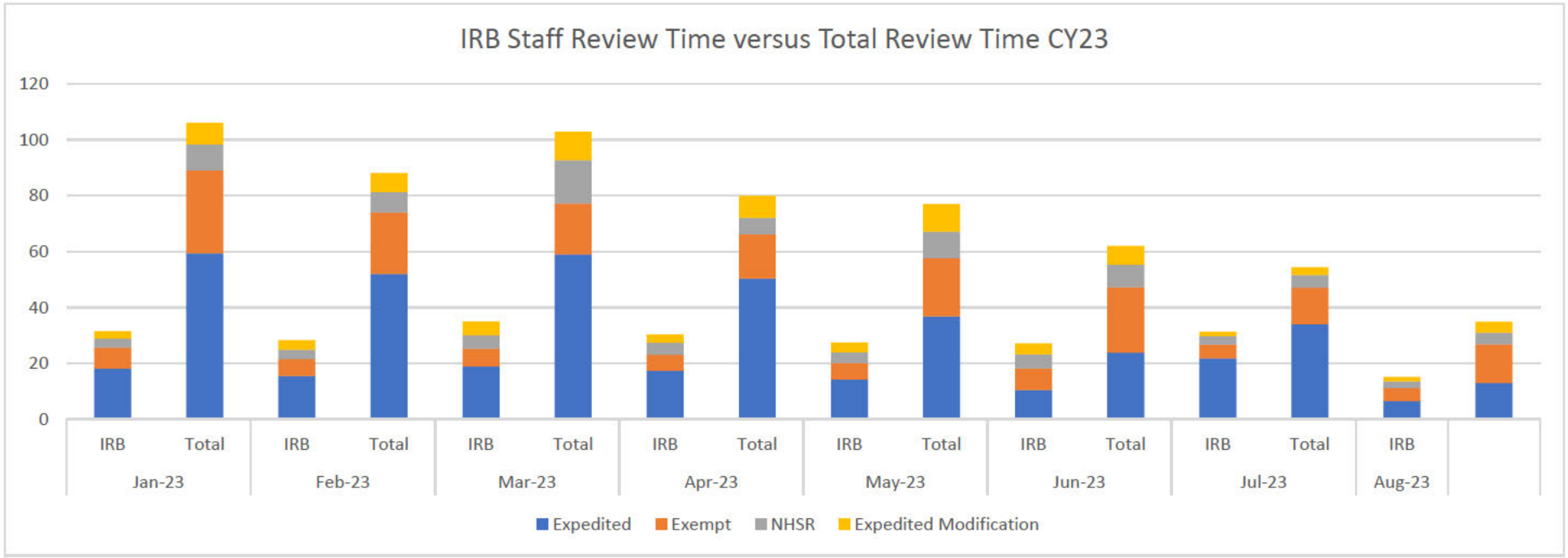


Table 2

IRB Staff Review Time versus Total Review Time CY22																
	Jan-22		Feb-22		Mar-22		Apr-22		May-22		Jun-22		Jul-22		Aug-22	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	16	57	6	35	15	49	12	35	11	44	16	61	18	53	24	76
Exempt	7	21	9	24	6	18	4	19	4	19	9	28	8	24	9	36
NHSR	9	21	10	27	6	9	4	8	4	15	14	24	2	5	5	12
Expedited	4	10	3	7	2	6	2	9	3	12	2	5	3	7	4	8

Graph 2

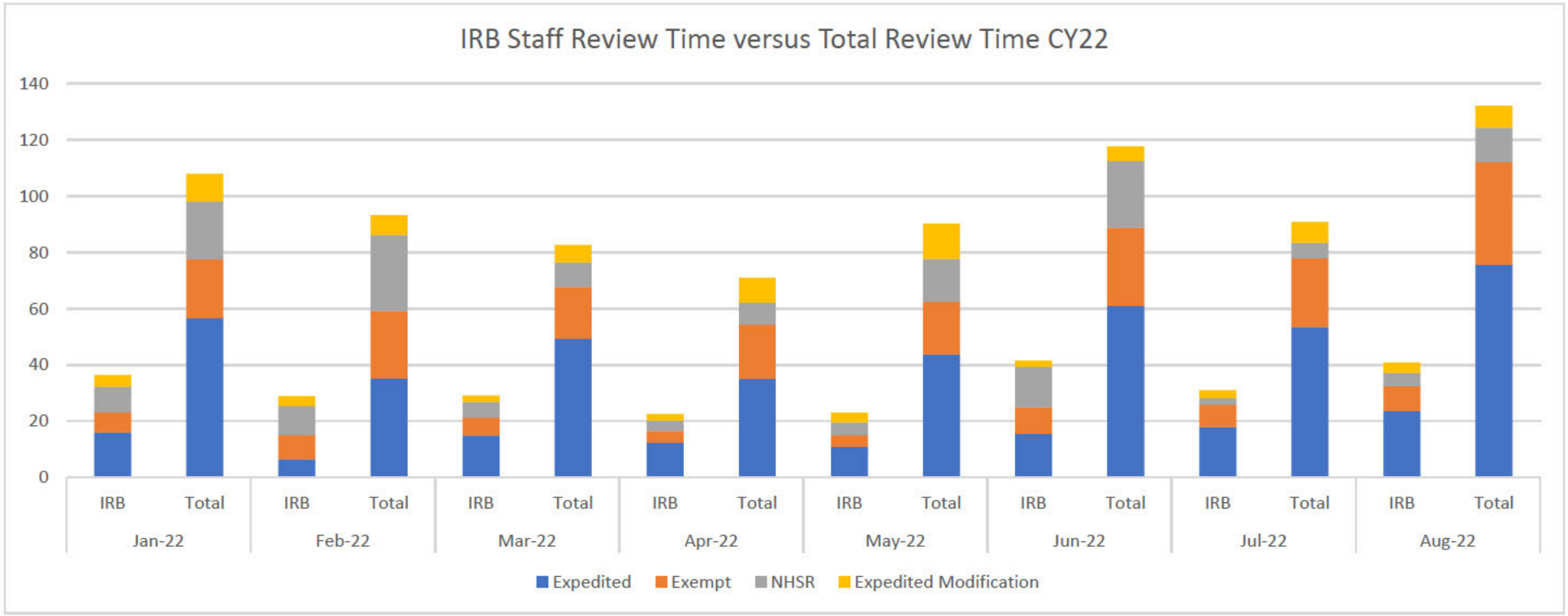


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for Fiscal Years 2021, 2022, and 2023. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions that receive an approval or determination (e.g., Convened IRB, Expedited, Exempt, Not Research, etc.). Follow-on submissions "follow" the initial submission and are comprised of modifications, continuing reviews, reports of new information ("RNI"), and the like.

Table 3

Total Incoming Submissions - CY Comparison								
	Jan	Feb	Mar	Apr	May	June	July	Aug
2021	180	195	228	216	219	223	193	182
2022	149	183	204	198	216	250	201	188
2023	168	170	149	152	216	249	191	237

Graph 3

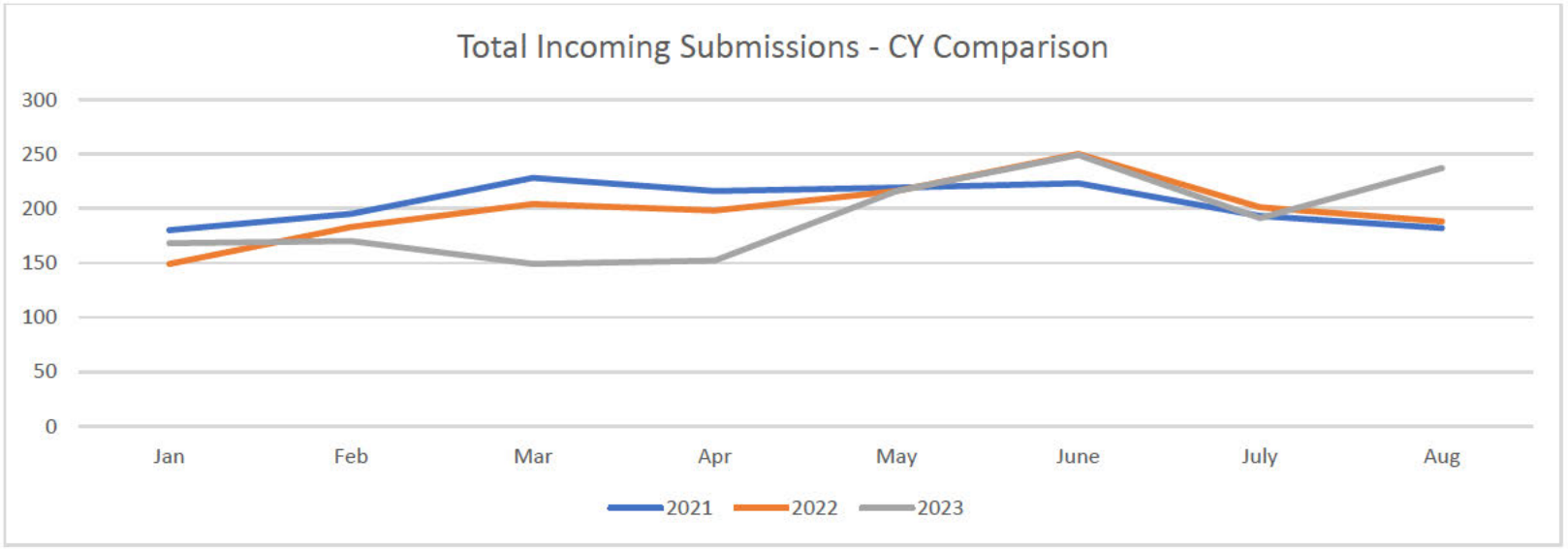


Table 4 represents the IRB's completion rate for Academic Year 2022-2023. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in July 2023, the IRB office received a total of 81 initial submissions. Of those 81 submissions, 46 received a determination or approval by month's end while 35 submissions were at some point in the review process[1].

Please see next page →

Table 4

[1] *Clarifications requested (the submission has received review and has been sent to the research team); Pre-review (the submission has either not started review or is back from the research team and is now under review by IRB staff); or Modifications required (the submission has been sent to the research team and is in a state where there are outstanding items that are needed such as a reliance agreement or data security review)*

Complete vs. in-Review (for initial submissions only)												
	22 Sep	*22 Oct*	*22 Nov*	*22 Dec*	*23 Jan*	*23 Feb*	*23 Mar*	*23 Apr*	*23 May*	*23 Jun*	*23 Jul*	*23 Aug*
Initial Study Total Received	**78**	**78**	**91**	**71**	**79**	**77**	**95**	**86**	**129**	**96**	**81**	86
Approved Fu	0	0	0	0	0	0	0	0	0	0	0	0
Approved Exped ted	1	2	0	0	3	0	3	3	9	9	3	3
Approved Exempt	17	14	20	22	11	21	22	25	26	21	26	27
Not Human Research	15	11	12	5	12	9	12	12	25	14	17	13
Human Research, Not Engaged	0	0	0	1	0	0	1	0	0	1	0	0
D sapproved	0	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**33**	**27**	**32**	**28**	**26**	**30**	**38**	**40**	**60**	**45**	**46**	43
C ar f cat on Requested (Pre Rev ew & Des gnated Rev ew)	29	40	46	21	32	32	31	21	56	30	25	35
Mod f cat ons Requ red	1	0	0	0	0	0	0	1	0	1	0	1
Pre Rev ew	15	11	13	22	20	14	25	24	13	18	10	7
In-Review	**45**	**51**	**59**	**43**	**52**	**46**	**56**	**46**	**69**	**49**	**35**	43
Percent Complete per Month	**42%**	**35%**	**35%**	**39%**	**33%**	**39%**	**40%**	**47%**	**47%**	**47%**	**57%**	**50%**

Measures of Quality and Compliance – Quarter 1

As outlined in HRP – 060 – HUA – Evaluations of the HRPP, we use the following processes monthly to measure compliance of the HRPP. These outcomes are reported to the Advisory Committee at our quarterly meetings, and an overall assessment including these and other required assessments takes place at the end of each calendar year.

Investigator QI Assessment

- *A randomly selected Investigator is sent a checklist to complete and return to the HUA IRB within a specified timeframe.*
- *The checklist that was sent out the previous month has the results tracked and examined for significant trends.*

Month	PI Name	ESTR #	Study Title	Department/School	Quarterly Check-In Date
July 2023	[redacted]				

Conduct assessment of minutes with regulatory compliance

- *The minutes from the previous month are analyzed to ensure regulatory compliance as well as the days required to complete the minutes.*
- *Significant trends in adherence to the regulations and days to complete the minutes are tracked and examined.*

Meeting Date	Minutes to Chair & Director within 7 calendar days?	General Minutes Requirements Notes	Quarterly Check-In Date
June 2023	*Yes*	*No issues noted*	*October 3, 2023*
July 2023	*Yes*	*No issues noted*	*October 3, 2023*
August 2023	*Yes*	*No issues noted*	*October 3, 2023*

Training, Outreach, and Other Initiatives - Quarter 1

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from June 1, 2023, through August 31, 2023, our website had about 4,000 visitors with 8,000 page views. The most visited pages include *what does and does not require IRB review* (as part of our IRB Lifecycle series), *required ethics training,* and *everything you wanted to know about documented consent but were afraid to ask*.

IRB Outreach & Training

For the period from June 1, 2023, through August 31, 2023, the HUA IRB office held the following outreach and training sessions:

- 26 IRB office hour sessions (general meetings)
- 4 IRB office hour sessions with HKS affiliates
- 0 IRB office hour sessions with HLS affiliates
- 0 IRB office hour session with affiliates from the Psychology Department

The above reflects those investigator meetings scheduled through the Bookings system. IRB staff often meet with researchers outside these office hours as well depending on urgency and researcher availability. The IRB did not offer any scheduled or invited trainings over the summer; however, there are several scheduled already for Fall 2023.

IRB Newsletter

Topics for our July newsletter included the following:

- **July 2023**:
    - DRAFT Limited IRB Review guidance from OHRP
    - Tips for a smooth summertime submission
    - Notes from Harvard Catalyst on clinical trials reporting and effective writing
    - Do You Speak IRB?: Payments to participants and the Human Subjects Payments Policy

The IRB newsletter was paused for August 2023 owing to the transition in IRB leadership and AAHRPP site visit. IRB staff intend to resume the newsletter this month. You can find our newsletters here.

IRB Member Continuing Education

To keep IRB members abreast of regulatory changes, institutional practice, and common regulatory concerns, a portion of each IRB meeting is devoted to a continuing education topic. Recent topics focused on preparing IRB Members for the AAHRPP site visit and included refreshers on: the HUA Human Research Protection Program and its key players, defining Research and Human Subjects, levels of IRB review, and the Criteria for Approval.

IRB Staff Continuing Education

As regulations change over time, it is important to not only cover regulatory items on a regular basis but also to check in to ensure that everyone is on the same page in their approach. As part of our weekly staff meeting, a regulatory/continuing education topic is covered. Recent topics focused on preparing IRB Staff for the AAHRPP site visit with weekly presentations of SOPs from our Toolkit. Other topics included Limited IRB Review & Exemptions - New OHRP Guidance and discussions of agency and institutional engagement.

Updates – Quarter 1

Re-Accreditation Site Visit (August 2023)

Initial AAHRPP accreditation is active for three years; re-accreditation is valid for five years. Our Step 1 and Step 2 applications for re-accreditation were approved, and our re-accreditation site visit was held August 29-30th. Before the AAHRPP site visit, we held various training sessions focused on key areas of our research community: IRB staff, IRB members, researchers/research staff, and representatives from offices that fulfill a research compliance function. IRB staff developed role-specific training materials, which will remain on our website for future use.

Prior to the site visit, the Interim Director coordinated with AAHRPP to identify records and studies for review (a re-accreditation SharePoint was created), as well as to finalize an interview schedule that included three dozen interviewees, each corresponding to particular AAHRPP elements for accreditation.

The AAHRPP site visitors noted several strengths of our human research protection program: department-based distribution, which allows for relationships between IRB staff, researchers, and the kind of research they do; the rigor of our training program for IRB staff, IRB members, and the research community; institutional safeguards like Provostial and Data Safety reviews; and an overall appreciation from researchers for how the IRB approaches its review of social and behavioral research, emphasizing how our process and documents fit for their research.

Importantly, they noted our sense of collegiality, and how well the IRB and other offices, partners, and researchers work to meet our shared mission. In particular, they were struck by how often interviewees referred not just to “the IRB,” but specific staff who they see as trusted sources

for consultation and guidance. This is a testament to the community we have built together, and how we at the IRB and OVPR see this as a shared process.

Site visitors also shared areas for improvement. These include how institutional and financial conflicts of interest are reported to the IRB, how the division of responsibilities are noted in reliance agreements, and some specific regulatory decisions made by the Convened IRB. A final report prepared by AAHRPP will be sent to IRB staff by the end of September and may or may not include all site visitor observations. None of the observations, though, should substantially alter existing processes or result in new SOPs, etc.

Human Research Protection Program Goal Setting

AAHRPP site visitors highlighted that strategic goal setting is an essential process for a well-functioning HRPP, and that there should be some forum where these are reported and discussed. In September 2022, IRB staff and the Advisory Committee set goals for the coming academic year. Those are recreated and evaluated below. Guiding goals for the 2023-2024 academic year are included as well.

AY22-23 Goals

Last September the Advisory Committee established the following goals for the 2022-2023 academic year:

- **Community outreach to share information about the HUA IRB, educate those that wish to take part in research about their rights as research subjects and to empower those that wish to take part.**
  Those that take part in research are often only aware of their rights as a research subject during the consent process and as such, those that take part are only marginally aware of their rights as well as the role of an Institutional Review Board. The goal of this effort is to take a proactive approach in educating our local community as well as those communities where Harvard research takes place about research subject rights, afforded protections, and the role of the IRB.

  The HUA IRB maintains a For Participants page on its website that offers resources like a participant's Bill of Rights as well as links to OHRP resources. We maintain a relationship with Harvard Catalyst, which includes access to their Community Engagement Program and Community Coalition for Equity in Research. One member of the Community Coalition serves as an unaffiliated, non-scientist member of the HUA IRB. Even still, the IRB can take a more proactive approach in reaching out to community members who may participate in the studies led by our researchers. AAHRPP site visitors noted this, and this may appear in the final report. As such, this goal will carry over to the next academic year. Advisory Committee members are encouraged to share any ideas for how the IRB may reach the participants their researchers serve, or whether there are any specific requests for trainings or training materials.

- **Build positive and efficient relationships with other Harvard research administration and compliance offices to ensure a comprehensive approach to human subjects research at Harvard University.**
  The work of the IRB and the IRB office intersects many other research compliance offices across campus. Each office is interconnected and in fact, final IRB approval is often contingent upon the review by other university units. Given the interdependent nature of this compliance framework, it is important for the IRB office to understand the processes of each compliance office, policies, as well as to recognize pain points to ensure a comprehensive, efficient, and compliant human research protection program.

  The HUA IRB is part of a larger safety net of groups across campus with a research compliance function. Together these groups, along with researchers themselves, create a community of awareness of human subjects regulations and ethics. Our AAHRPP site visitors highlighted how well-connected the research community is to the IRB, as well as how well interconnected some processes are at Harvard. They particularly praised the Manage Related Projects function in our research compliance suite that allows IRB, Safety, and Agreements submissions to "talk" to each other.

  In the last year, IRB staff and members have received continuing education on a variety of Harvard policies from these groups—Provostial review, ancillary input from the Offices of General Counsel and Undergraduate Education, policies like Participant Payment, and more. Continuing Education was presented at IRB meetings through a policies tour, is maintained in our Harvard Policies Worksheet for internal use, and was elaborated upon each month in updates to the IRB membership (which includes staff).

  This goal is intentionally broad; it is also one to set in perpetuity. The IRB will always strive to build and maintain strong partnerships with our colleagues and to keep a general awareness of their roles so we can collectively best-serve researchers and participants.

AY23-24 Goals

- **Community outreach to share information about the HUA IRB, educate those that wish to take part in research about their rights as research subjects and to empower those that wish to take part.**
  Those that take part in research are often only aware of their rights as a research subject during the consent process and as such, those that take part are only marginally aware of their rights as well as the role of an Institutional Review Board. The goal of this effort is to take a proactive approach in educating our local community as well as those communities where Harvard research takes place about research subject rights, afforded protections, and the role of the IRB.

- **Expand of our Quality Assurance/Quality Improvement Program to develop and monitor measures of effectiveness and compliance for both researchers and internal practices.**

The HUA HRPP has several processes in place for measuring the effectiveness and compliance of our program, outlined in our SOPs for Annual Evaluation and QA/QI Program. These include assessments of investigators and IRB meeting minutes, as well as annual activities undertaken by the Advisory Committee each December. While these measures fulfill our basic obligations for AAHRPP accreditation, there is room for more proactive monitoring and richer engagement with the research community and our own processes.