Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, January to March 2024 (Quarter 3)

14 March 2024

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.**

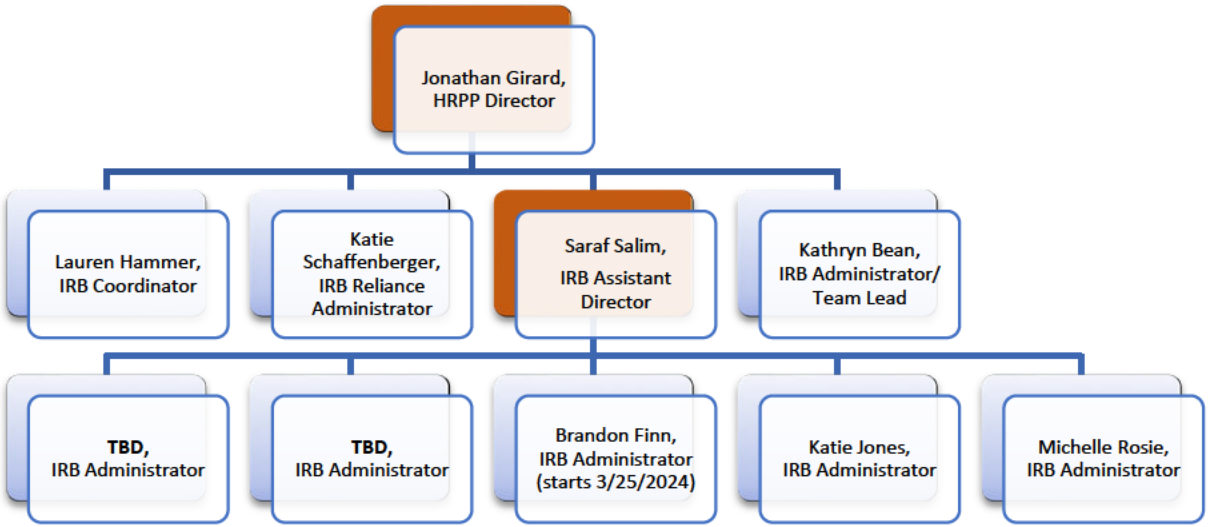
Who We Are

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 Fiscal Year 2024 to date (July 2023 to February 2024). Table 2 and Graph 2 are the same comparison; however, they represent metrics for Fiscal Year 2023 (July 2022 to February 2023).

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 FY24																
	Jul-23		Aug-23		Sep-23		Oct-23		Nov-23		Dec-23		Jan-24		Feb-24	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	20	82	12	38	11	40	14	54	17	40	27	47	9	21	8	9
Exempt	6	23	6	23	7	25	7	28	9	23	11	28	7	17	5	13
NHSR	3	5	5	14	4	8	6	13	6	19	8	19	4	9	3	3
Expedited Modification	2	3	4	11	3	7	4	11	3	7	5	12	2	6	3	4

Graph 1

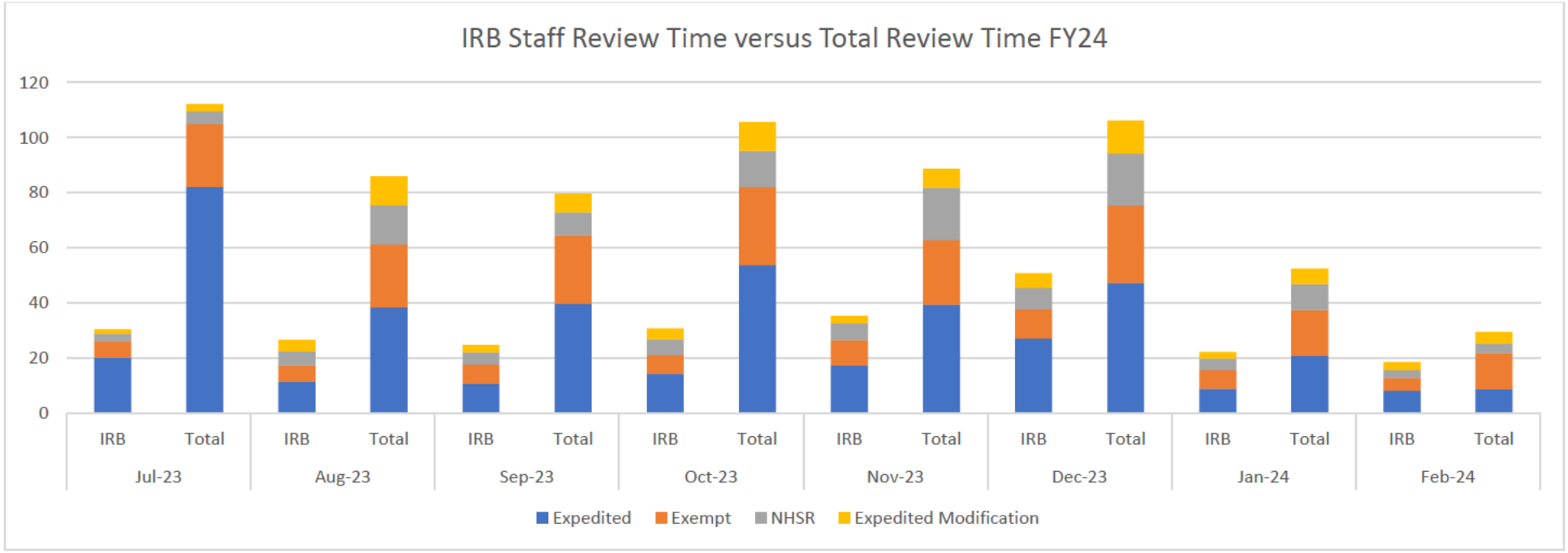


Table 2

IRB Staff Review Time versus Total Review Time FY23																
	Jul-22		Aug-22		Sep-22		Oct-22		Nov-22		Dec-22		Jan-23		Feb-23	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	18	54	25	83	21	69	13	53	25	76	20	113	17	55	16	52
Exempt	8	24	8	32	14	38	10	29	10	26	7	24	8	30	6	22
NHSR	2	5	5	12	4	8	5	12	3	8	6	11	3	9	3	7
Expedited Modification	3	7	4	8	4	9	5	15	4	9	5	8	3	8	3	7

Graph 2

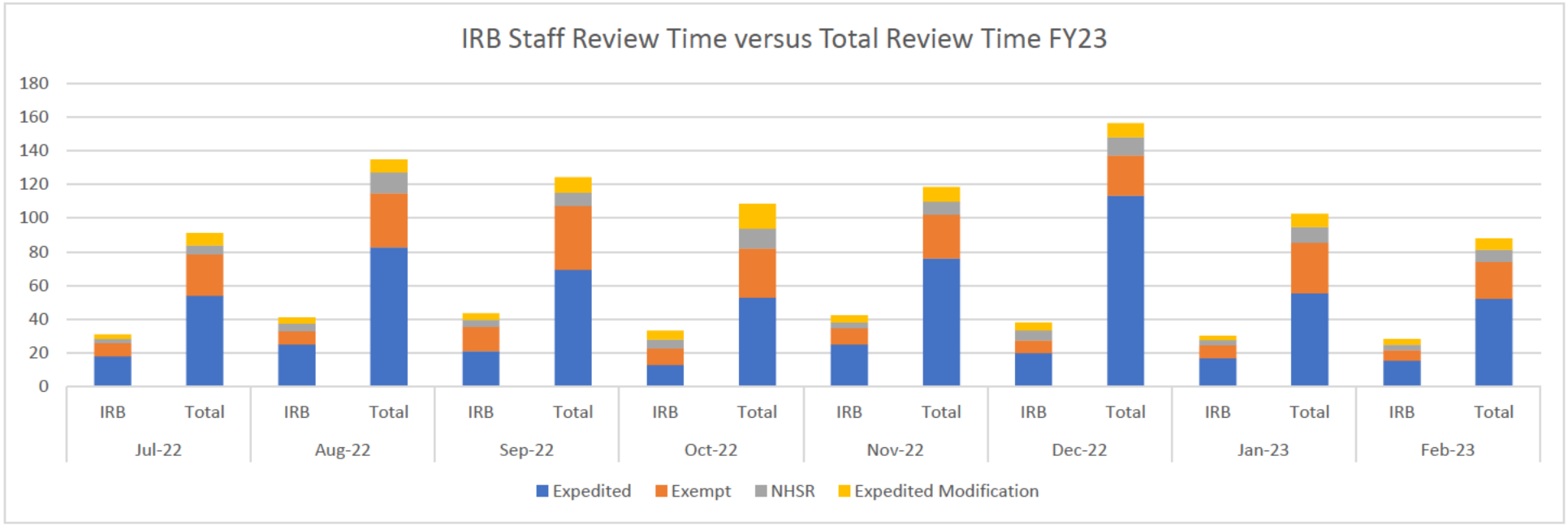


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for Fiscal Years 2022, 2023, and 2024. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions that receive approval or a determination (e.g., Convened IRB, Expedited, Exempt, Not Research, etc.). Follow-on submissions "follow" the initial submission and are comprised of modifications, continuing reviews, and reports of new information ("RNI").

Table 3

Total Incoming Submissions - FY Comparison								
	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb
2022	192	182	205	177	183	113	148	181
2023	200	188	205	169	155	97	166	170
2024	184	221	217	178	198	148	183	205

Graph 3

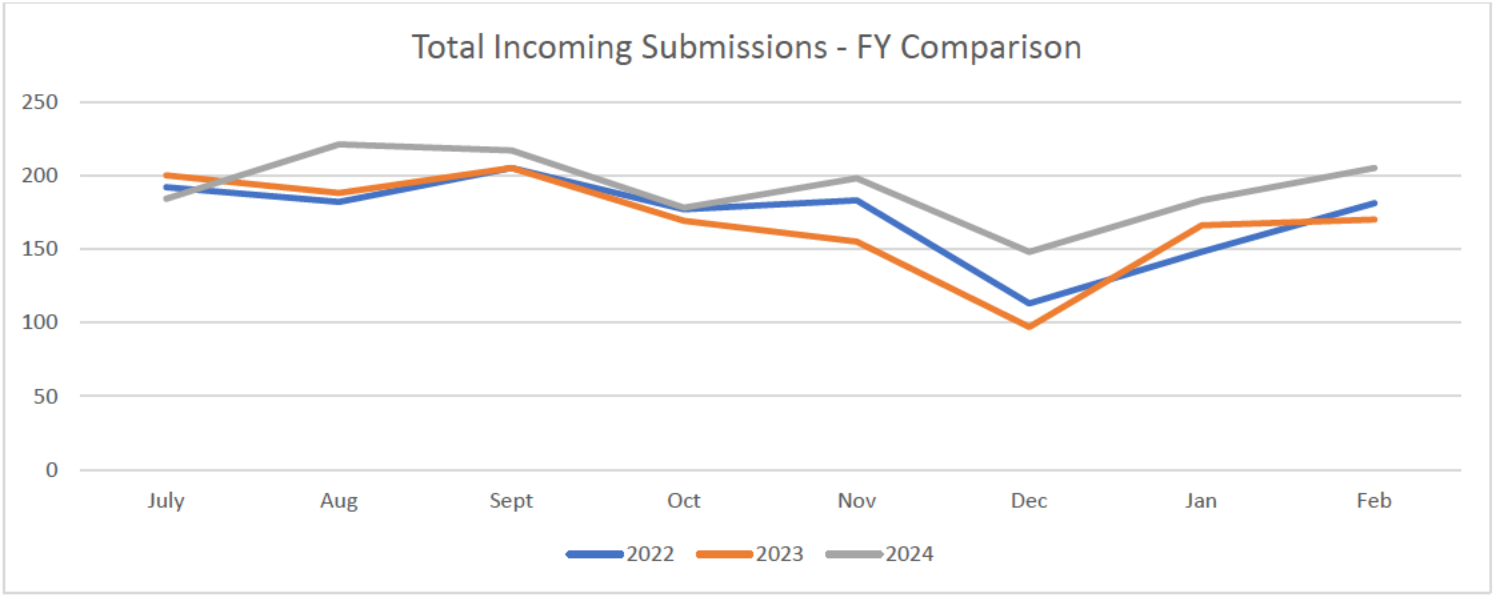


Table 4 represents the IRB's completion rate for the last 12 months. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

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 →

[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)													
	23-Feb	*23-Mar*	*23-Apr*	*23-May*	*23-Jun*	*23-Jul*	*23-Aug*	*23-Sep*	*23-Oct*	*23-Nov*	*23-Dec*	*24-Jan*	*24-Feb*
Initial Study Total Received	**77**	**95**	**86**	**129**	**96**	**81**	**86**	**77**	**89**	**92**	**87**	**76**	**103**
Approved Full	0	0	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	0	3	3	9	9	3	3	4	5	2	1	4	2
Approved Exempt	21	22	25	26	21	26	27	17	18	15	12	12	16
Not Human Research	9	12	12	25	14	17	13	14	16	14	14	12	9
Human Research, Not Engaged	0	1	0	0	1	0	0	0	0	0	0	1	0
Disapproved	0	0	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**30**	**38**	**40**	**60**	**45**	**46**	**43**	**35**	**39**	**31**	**27**	**29**	**27**
Clarification Requested (Pre-Review & Designated Review)	32	31	21	56	30	25	35	31	41	37	34	30	42
Modifications Required	0	0	1	0	1	0	1	0	0	3	0	1	2
Pre-Review	14	25	24	13	18	10	7	9	9	21	26	16	32
In-Review	**46**	**56**	**46**	**69**	**49**	**35**	**43**	**40**	**50**	**61**	**60**	**47**	**76**
Percent Complete per Month	**39%**	**40%**	**47%**	**47%**	**47%**	**57%**	**50%**	**45%**	**44%**	**34%**	**31%**	**38%**	**36%**

Measures of Quality and Compliance – Quarter 3

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
January 2024	[redacted]	[redacted]	[redacted]	[redacted]	*April 16, 2024*
February 2024	[redacted]	[redacted]	[redacted]	[redacted]	*April 16, 2024*
March 2024	[redacted]	[redacted]	[redacted]	[redacted]	*April 16, 2024*

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
December 2023	*Yes*	*No issues noted; Minutes QI Assessment question revised to better capture non-*	*January 9, 2024*

		compliance determinations for Reports of New Information, aligning with minutes	
January 2024	*Yes*	*No issues noted*	*April 16, 2024*
February 2024	*Yes*	*No issues noted; proposed revision to Minutes QI Assessment to better capture determinations on Not Human Subjects Research determinations*	*April 16, 2024*

Training, Outreach, and Other Initiatives - Quarter 3

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from **December 1, 2023** through **February 29, 2024**, our website had about **11,700** visitors with **23,600** page views. The most visited pages include: What DOES and DOES NOT require IRB Review and Approval; Required Ethics Training Overview; and Do You Need IRB Review and Why.

IRB Outreach & Training

For the period from **December 1, 2023 through February 29, 2024,** the HUA IRB office held the following outreach and training sessions:

- 37 IRB office hour sessions (general meetings)
- 1 IRB office hour sessions with HKS affiliates (HKS portfolio currently in rotation)
- 0 IRB office hour sessions with HLS affiliates (HLS portfolio currently in rotation)
- 3 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 participated in 7 scheduled or invited trainings during 2024 thus far including 2 trainings through the Undergraduate Research Training Program as well as sessions for Sociology and Government undergraduates, Sociology graduate students, and Psychology business office staff. Three additional sessions are scheduled in the coming month with student researchers.

IRB Newsletter

The February edition of our monthly newsletter focused on interview and survey research and included:

- Risk assessment and flexibility in reviewing interview and survey documents
- Key tips for document placement in ESTR and a reminder to close survey links
- Do You Speak IRB?: Expert Interviews

The March edition of our monthly newsletter included:

- IRB staff changes
- OHRP Informed Consent training
- Harvard's International Travel Loaner Devices program
- Do You Speak IRB?: OUE Review

The IRB newsletter archive may be found 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 the use of fetal tissue in research and the first of a multi-part program on informed consent. This first session addressed Respect for Persons, from the Belmont Report, and the elements of informed consent from the Common Rule's 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 regular staff meeting, a regulatory/continuing education topic is covered. Recent topics focused on use of study pools in research, umbrella protocols, ethnographic research, research including undocumented persons, and a refresher on letter preparation in ESTR.

Research Participant Community Outreach

HUA IRB Website

The HUA IRB offers materials for the research participant community, including a Participants Bill of Rights. For the period from **December 1, 2023** through **February 29, 2024**, our "For Participants" website had about **230** visitors with **300** page views. The most viewed section is the dropdown

for “Should I Take Part in a Research Study,” which had about **150** visitors with **170** page views. This section did not appear in our top 25 sections of our overall website last quarter.

Other Initiatives

There are no other specific initiatives at this time. IRB staff continue to discuss participant outreach activities during staff meetings. The Director of the HRPP discussed participant outreach activities at the Office of the Vice Provost of Research staff meeting and will liaise with the Associate Provost for Research, Willy Lensch, who took interest in this work given their background in participant outreach at another institution.

Updates – Quarter 3

HUA HRPP Full Accreditation

Our organization was reviewed by the Council on Accreditation of the Association for the Accreditation of Human Research Protection Programs (AAHRPP) at its December 2023 meeting. In that meeting, we were awarded Full Reaccreditation for five years. The Council on Accreditation requires that we submit a Status Report on our Site Visit observations by May 1, 2024, for review at the June 2024 Council meeting. We will then file annual progress reports. Thank you to all who participated in our visit and for serving as such important partners and leaders in our human research protection program!