Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, October to December 2023 (Quarter 2)

14 December 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 ensure 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.**

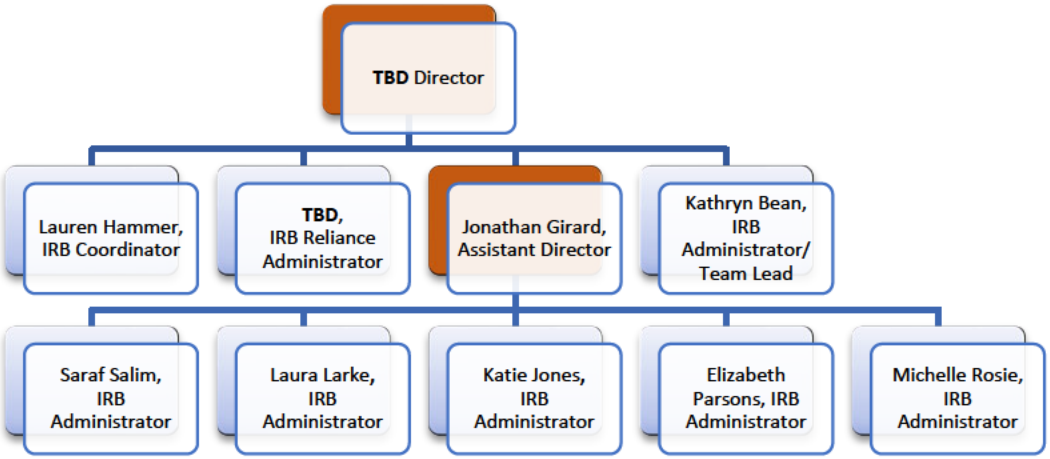
Who We Are

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.



Measures 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 November 2023). Table 2 and Graph 2 are the same comparison; however, they represent metrics for Calendar Year 2022 (January 2022 – November 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		Sep-23		Oct-23		Nov-23	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	18	59	16	52	20	64	17	50	14	41	15	39	20	68	12	32	11	18	11	24	10	15
Exempt	8	30	6	22	6	18	6	16	6	25	9	30	6	23	6	21	7	22	5	14	4	11
NHSR	3	9	3	7	5	16	4	6	4	14	5	8	3	5	5	14	4	8	5	10	3	5
Expedited	3	8	3	7	5	10	3	8	4	10	4	7	2	3	4	11	3	5	4	8	2	4

Graph 1

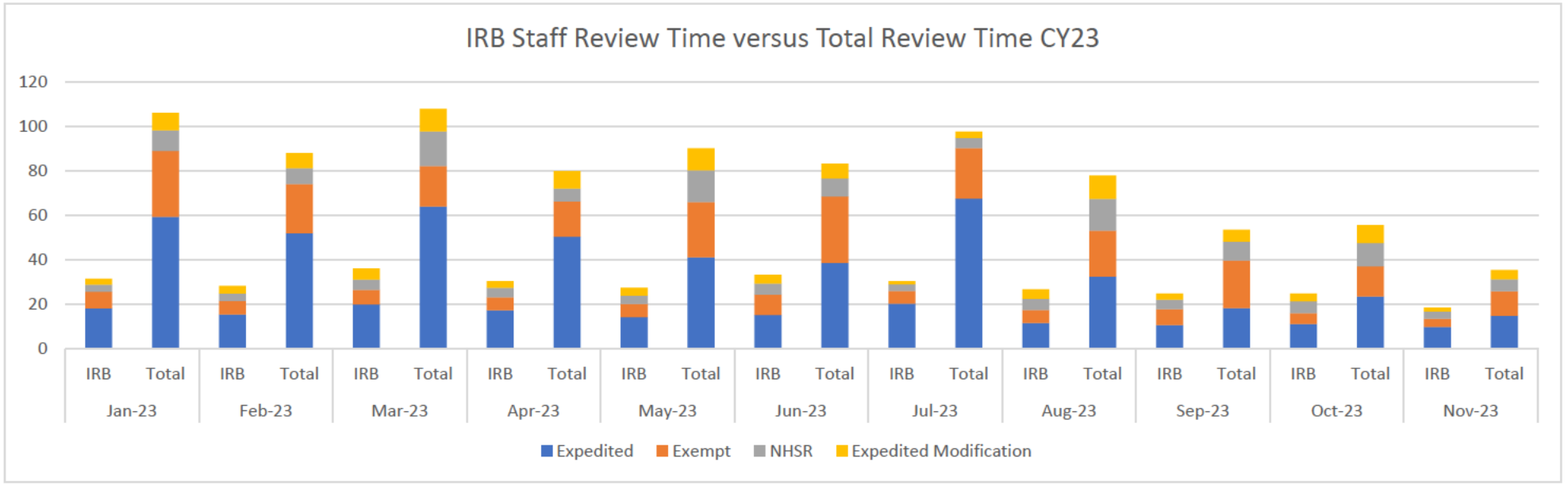


Table 2

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		Sep-22		Oct-22		Nov-22	
	IRB	Total	IRB	Total	IRB	Total	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	54	24	76	21	69	13	53	25	76
Exempt	7	21	9	25	6	18	4	19	4	19	9	28	8	24	9	36	14	38	10	29	10	26
NHSR	9	21	10	27	6	9	4	8	4	15	14	24	2	5	5	12	4	8	5	12	3	8
Expedited	4	10	3	7	2	6	2	9	3	12	2	5	3	7	4	8	4	9	5	15	4	9

Graph 2

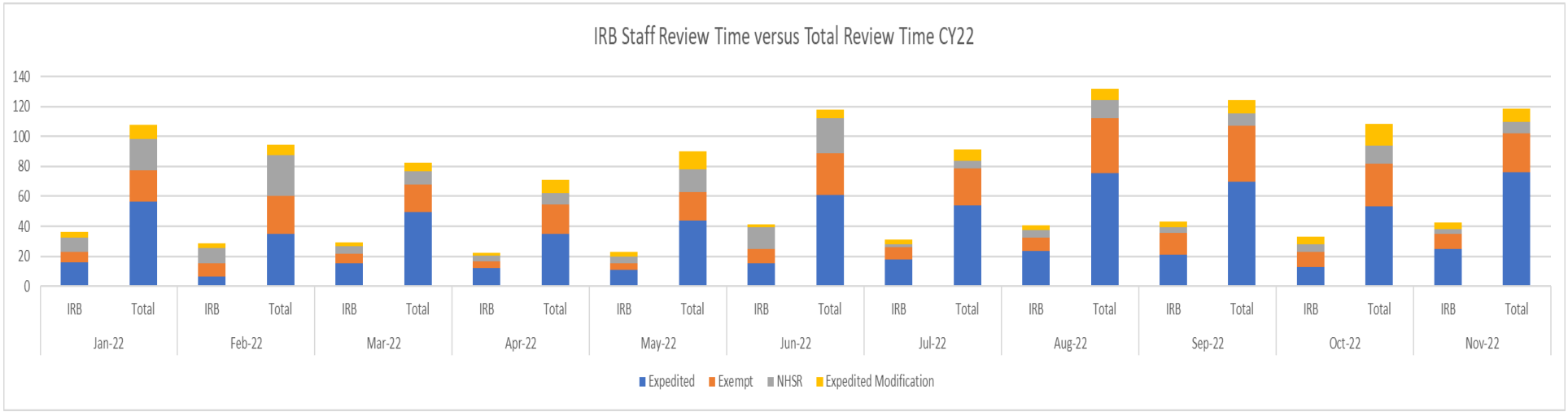


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for Calendar Years 2021, 2022, and 2023. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions that receive approval or a determination (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 - CY Comparison											
	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov
2021	180	195	227	215	219	223	193	182	205	178	183
2022	148	182	204	198	215	250	200	188	205	169	155
2023	167	170	149	153	213	248	185	226	221	187	210

Graph 3

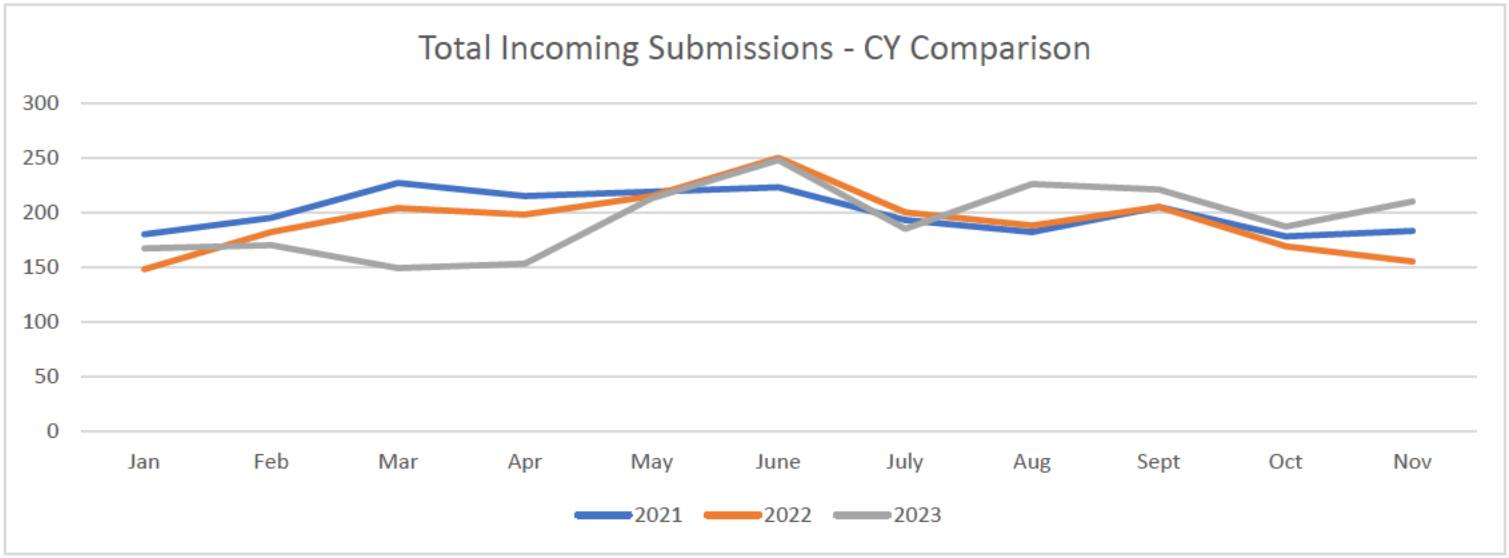


Table 4 represents the IRB's completion rate for Calendar Year 2023. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

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 →

[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)*

Table 4

Comp ete vs. n-Rev ew (for n t a subm ss ons on y)											
	23-Jan	*23-Feb*	*23-Mar*	*23-Apr*	*23-May*	*23-Jun*	*23-Jul*	*23-Aug*	*23-Sep*	*23-Oct*	*23-Nov*
n t a Study Tota Rece ved	**79**	**77**	**95**	**86**	**129**	**96**	**81**	**86**	**77**	**89**	**92**
Approved Fu	0	0	0	0	0	0	0	0	0	0	0
Approved Exped ted	3	0	3	3	9	9	3	3	4	5	2
Approved Exempt	11	21	22	25	26	21	26	27	17	18	15
Not uman Research	12	9	12	12	25	14	17	13	14	16	14
uman Research, Not Engaged	0	0	1	0	0	1	0	0	0	0	0
D sapproved	0	0	0	0	0	0	0	0	0	0	0
Rev ew Comp ete	**26**	**30**	**38**	**40**	**60**	**45**	**46**	**43**	**35**	**39**	**31**
C ar f cat on Requested (Pre-Rev ew & Des gnated Rev ew)	32	32	31	21	56	30	25	35	31	41	37
Mod f cat ons Requ red	0	0	0	1	0	1	0	1	0	0	3
Pre-Rev ew	20	14	25	24	13	18	10	7	9	9	21
n-Rev ew	**52**	**46**	**56**	**46**	**69**	**49**	**35**	**43**	**40**	**50**	**61**
Percent Comp ete per Month	**33%**	**39%**	**40%**	**47%**	**47%**	**47%**	**57%**	**50%**	**45%**	**44%**	**37%**

Measures of Quality and Compliance – Quarter 2

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
September 2023	[redacted]	[redacted]	[redacted]	[redacted]	*October 3, 2023*
October 2023	[redacted]	[redacted]	[redacted]	[redacted]	*January 9, 2024*
November 2023	[redacted]	[redacted]	[redacted]	[redacted]	*January 9, 2024*
December 2023	[redacted]	[redacted]	[redacted]	[redacted]	*January 9, 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
September 2023	*Yes*	*No issues noted*	*October 3, 2023*
October 2023	*No IRB meeting*		
November 2023	*Yes*	*No issues noted*	*January 9, 2024*

Training, Outreach, and Other Initiatives - Quarter 2

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from September 1 through November 30, 2023, our website had about 12,000 visitors with 23,000 page views. The most visited pages include: What DOES and DOES NOT require IRB Review and Approval?; Required Ethics Training Overview; and Everything You Wanted to Know about Documented Consent but were Afraid to Ask.

We recently updated and streamlined our page for 6 Tips for Speeding Up a Review!

IRB Outreach & Training

For the period from September 1 through November 30, 2023, the HUA IRB office held the following outreach and training sessions:

- 46 IRB office hour sessions (general meetings)
- 3 IRB office hour sessions with HKS affiliates
- 3 IRB office hour sessions with HLS affiliates
- 1 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 11 scheduled or invited trainings during Fall semester including 3 trainings through the Undergraduate Research Training Program as well as sessions for HKS SYPA students, HKS PAE advisors, HLS Winter Writing Project students, Health Policy and Sociology graduate students, among others.

IRB Newsletter

Topics for this quarter's newsletters included the following:

- The October edition of our monthly newsletter focused on training resources to help orient new researchers and members of the Harvard community. These included:
    - Human Subjects Protection Training—A summary of training requirements and options
    - URTP Training Dates for undergraduate researchers
    - Training Documentation in ESTR—An explanation of how training is tracked with IRB applications
    - University Administrator Resources by Role for our friends assisting with data safety, fCOI, and more
    - Do You Speak IRB?—Human Subjects Research, as the training requirements apply to those conducting such research

- The November edition of our monthly newsletter included:
    - Do You Speak IRB?: Ancillary Review
        - Faculty Sponsor Assurance,
        - Data Safety Reviews, and
        - Provostial Review

- The December edition of our monthly newsletter included:
    - Winter Recess Reminders
    - 6 Tips for Speeding Up a Review
    - Do You Speak IRB?: Identifiability

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 orienting IRB members to changes made in response to our August 2023 AAHRPP site visit and subsequent report. IRB members reviewed revisions to the SOPs related to IRB meeting preparation and minutes while also refreshing on existing SOPs for quorum and member expertise.

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 orienting IRB staff to changes made in response to our August 2023 AAHRPP site visit and subsequent report. IRB staff reviewed revisions to the SOPs related to IRB meeting preparation and minutes, financial conflicts of interest, and institutional conflicts of interest. Other topics included case studies of education research, the regulatory criteria for approval and electronic consent, and AI in human subjects research.

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 September 1 through November 30, 2023, our "For Participants" website had about 222 visitors with 328 page views. The Bill of Rights did not appear in our top 25 visited pages.

Other Initiatives

As outlined in the September 2023 Report of Operations, our HRPP has established participant outreach as a guiding goal for this academic year. At that time committee members were offered the opportunity to speak to their School's concerns to this effect, and were reminded to contact the IRB with any community outreach opportunities.

Beginning with this Report, we have expanded the training and outreach section to include a dedicated space for Research Participant Community Outreach. Here the IRB can report on the "For Participants" page as well as any outreach activities that have occurred. These revisions allow for a more regular, ongoing evaluation and discussion of the HRPP's participant outreach activities to supplement the annual evaluation that occurs at the end of every calendar year.

IRB staff have begun discussing participant outreach activities during staff meetings. Staff highlighted how the Bill of Rights may be require revision or an alternative version so that information is more geared toward non-clinical research. Staff also discussed partnering with campus study pools, like the Psychology Study Pool, to offer participant rights information as new members join the pool or during annual re-screening.

Updates – Quarter 2

Re-Accreditation Report (September and October 2023)

As summarized at the September meeting, 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.

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 was sent to IRB staff at the end of September and included all site visitor observations they shared at the end of the visit.

IRB staff prepared a response to AAHRPP in October to address the areas of concern. This explained how our HRPP intended to address the observations in three areas: policy/procedures changes, training/education, and monitoring. Our existing processes did not require substantial revision in result of AAHRPP's report, and no new SOPs were created. Education of IRB staff and members is complete. AAHRPP has confirmed receipt of the response and has not followed up with any questions. We await the determination of the AAHRPP Council on Accreditation.