Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, April – June 2023 (Quarter 4)

June 8, 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 of respect for persons, beneficence, and justice, as 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."

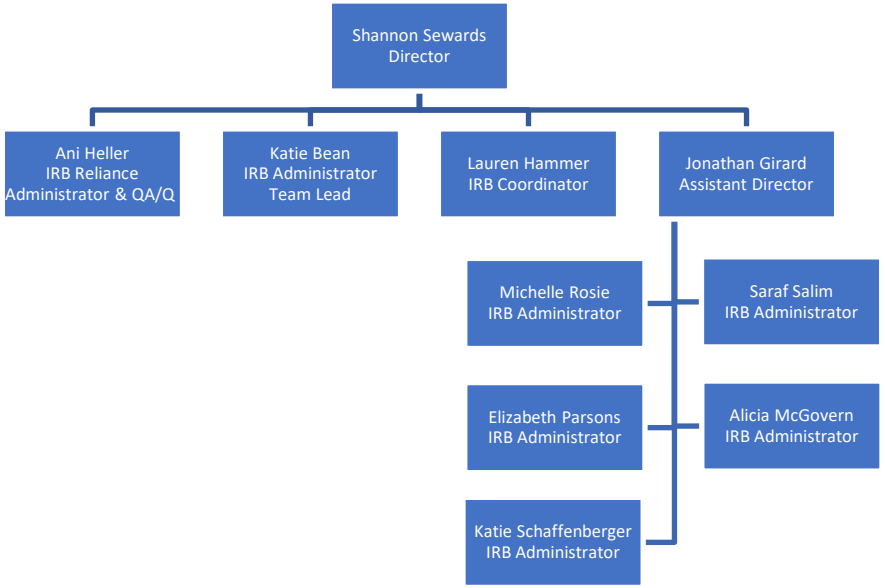
Who We Are

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 2023 to date (July 2022 to May 2023). Table 2 and Graph 2 are the same comparison however represent metrics for Fiscal Year 2022 (July 2021 – May 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 FY23																						
	Jul-22		Aug-22		Sep-22		Oct-22		Nov-22		Dec-23		Jan-23		Feb-23		Mar-23		Apr-23		May-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	53	21	76	21	69	13	53	25	61	25	84	17	40	17	45	14	36	14	32	7	18
Exempt	8	24	9	36	14	38	10	29	10	26	7	23	7	21	6	22	6	16	5	11	3	7
NHSR	2	5	5	12	4	8	5	12	3	8	6	11	3	9	3	7	5	16	4	6	3	4
Expedited Modification	3	7	4	8	4	9	5	11	4	9	5	8	2	5	3	5	4	8	3	5	2	3

Graph 1

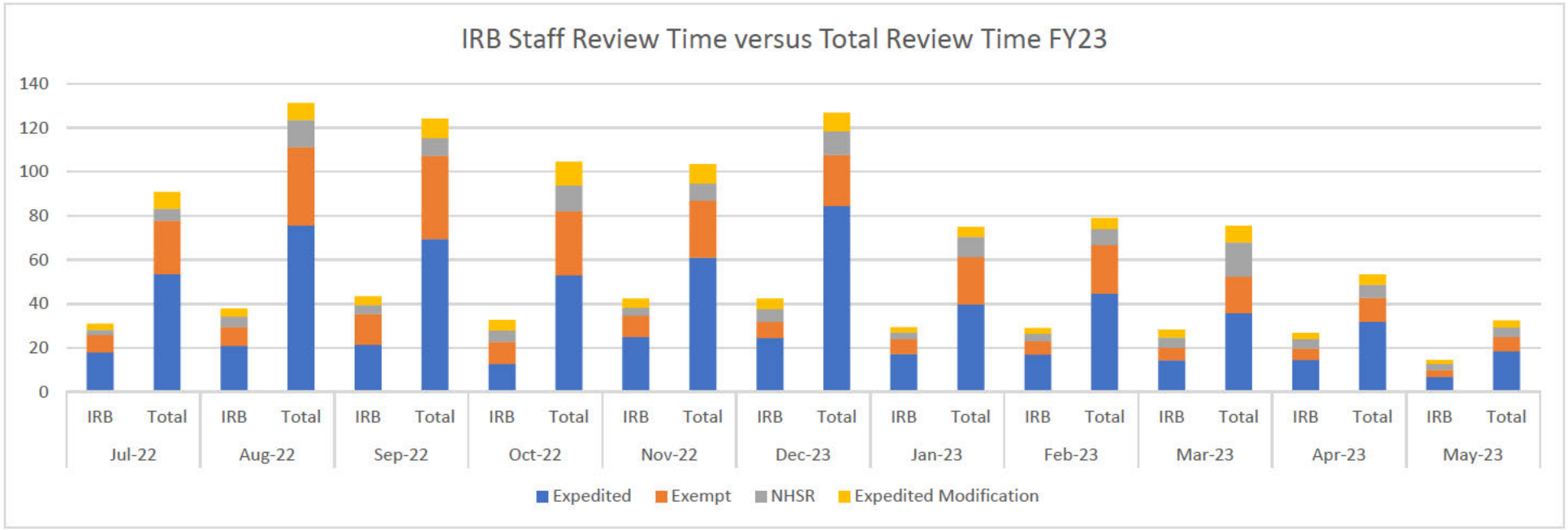


Table 2

IRB Staff Review Time versus Total Review Time FY22																						
	Jul-21		Aug-21		Sep-21		Oct-21		Nov-21		Dec-22		Jan-22		Feb-22		Mar-22		Apr-22		May-22	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	14	52	17	53	27	82	24	68	20	68	19	77	16	57	6	46	14	48	12	34	11	42
Exempt	8	29	8	22	6	25	4	16	9	32	15	41	7	20	8	23	6	18	4	19	4	19
NHSR	6	13	7	16	9	16	7	11	12	14	24	36	9	21	10	27	6	9	4	8	4	15
Expedited Modification	3	6	4	8	4	9	4	8	4	9	5	14	4	10	3	7	2	6	2	9	3	12

Graph 2

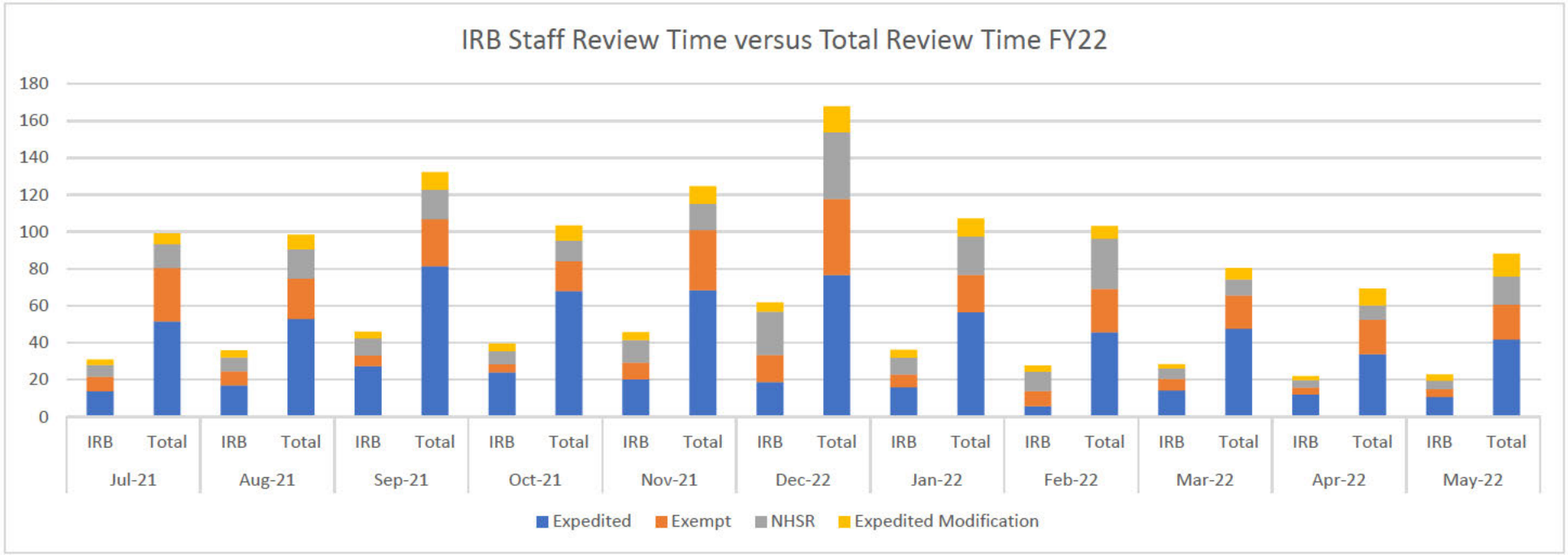


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for Fiscal Years 2021, 2022, and 2023. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions which following review, receive 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 - FY Comparison											
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
FY21	221	190	218	234	158	144	183	200	229	218	222
FY22	195	186	206	181	186	113	150	185	207	202	219
FY23	201	189	205	169	157	98	172	171	152	158	236

Graph 3

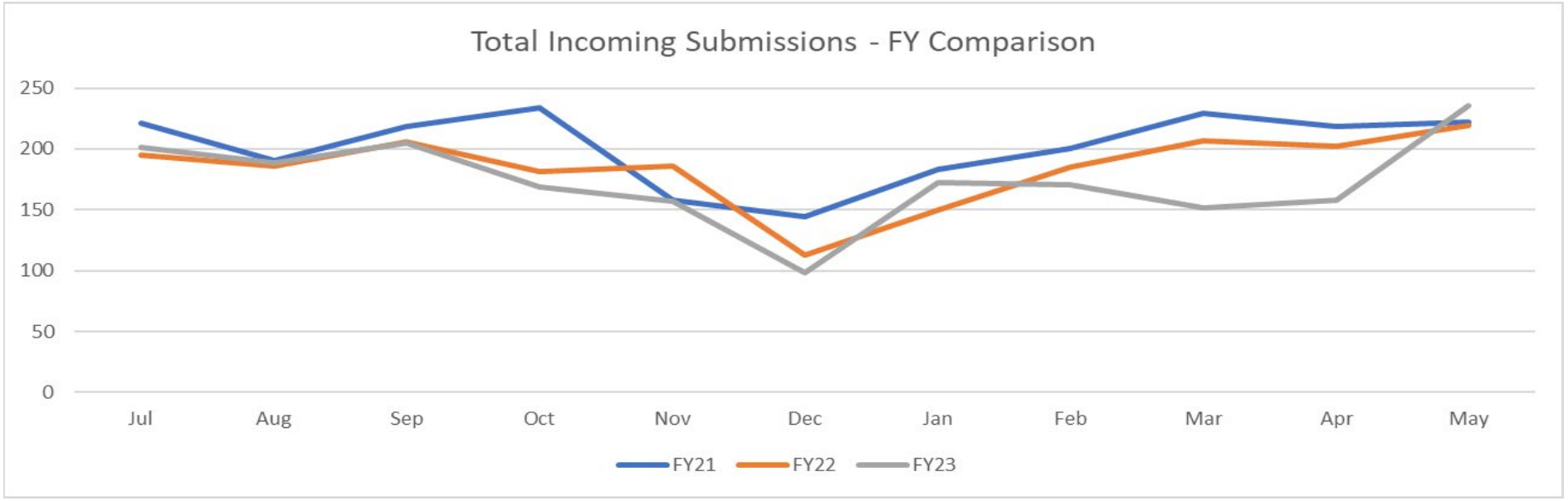


Table 4 represents the IRB's completion rate for Fiscal Year 2023 (July 2022 through May 2023). Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in September 2022, the IRB office received a total of 78 initial submissions. Of those 78 submissions, 33 received a determination or approval by month's end while 45 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

Complete vs. in-Review (for initial submissions only)											
	22-Jul	*22-Aug*	*22-Sep*	*22-Oct*	*22-Nov*	*22-Dec*	*23-Jan*	*23-Feb*	*23-Mar*	*23-Apr*	*23-May*
Initial Study Total Received	**86**	**85**	**78**	**78**	**91**	**71**	**79**	**77**	**95**	**86**	**129**
Approved Full	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	3	1	1	2	0	0	3	0	3	3	9
Approved Exempt	21	22	17	14	20	22	11	21	22	25	26
Not Human Research	8	10	15	11	12	5	12	9	12	12	25
Human Research, Not Engaged	1	0	0	0	0	1	0	0	1	0	0
Disapproved	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**33**	**33**	**33**	**27**	**32**	**28**	**26**	**30**	**38**	**40**	**60**
Clarification Requested (Pre-Review & Designated Review)	32	38	29	40	46	21	32	32	31	21	56
Modifications Required	2	0	1	0	0	0	0	0	0	1	0
Pre-Review	19	14	15	11	13	22	20	14	25	24	13
In-Review	**33**	**52**	**45**	**51**	**59**	**43**	**52**	**46**	**56**	**46**	**69**
Percent Complete per Month	**38%**	**39%**	**42%**	**35%**	**35%**	**39%**	**33%**	**39%**	**40%**	**47%**	**47%**

Measures of Quality and Compliance – Quarter 4

As outlined in HRP – 061 – HUA – Monthly HRPP Evaluations, 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 as well as other required yearly 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
March	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
April	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
May	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
June	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
June	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

* *As [redacted] is on sabbatical, an additional Investigator was selected for the month of June.*

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 for significant trends.*

Meeting Date	Minutes to Chair & Director within 7 calendar days?	General Minutes Requirements Notes	Quarterly Check-In Date
March	*No meeting in March 2023*	*N/A*	*July 11, 2023*
April	*Yes*	- *The other attendees and guests table is missing* [redacted] - *"Do minutes document the level of risk determined by the convened IRB as either minimal risk or more than minimal risk?" Minutes say n/a for studies that have been deferred. However, the answer is a simple yes/no*	*July 11, 2023*
May	*Yes*	*No issues noted*	*July 11, 2023*

Training, Outreach, and Other Initiatives - Quarter 4

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from March 1, 2023, through June 1, 2023, our website had over 16,000 visitors with over 19,000 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 March 1, 2023, through June 1, 2023, the HUA IRB office has held the following outreach and training sessions:

- 64 IRB office hour sessions (general meetings)
- 4 IRB office hour sessions with HKS affiliates
- 0 IRB office hour sessions with HLS affiliates
- 2 IRB office hour session with affiliates from the Psychology Department
- 4 Undergraduate Research Training Program (URTP) sessions.
- 2 requested trainings for specific courses, departments, or programs including the Davis Center and the Harvard Law School.

Note that the lower rate of IRB office hours with specific departments is most likely due to an increase in the number of office hours with individual staff.

IRB Newsletter

Topics for our April, May, and June newsletters included the following:

- **April 2023**: Oh, We've Got Ethics Training!; Last Chance for Harvard Undergraduate In-Person Training for Spring 2023; Exempt Research - Everything You Wanted to Know; and the Do you Speak IRB? topic, Exculpatory.
- **May 2023**: Reminder about Closure Requests on Exempt Studies; A (very) Brief Overview of Faculty Sponsor and PI Eligibility; and the Do You Speak IRB? topic, Primary Contact or PI Proxy - what's the difference?.
- **June 2023**: AAHRPP Re-Accreditation Site Visit Coming Soon; Leaving Harvard? Plan and Take Action Prior to Your Departure; Helpful Reminders: Data Use Agreements, Current Version of the HUA IRB Protocol Template, Paying Participants, Use of the Harvard Name and Insignias; and the Do You Speak IRB? topic, Individual Investigator Agreements.

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 have included: Harvard Policies Tour--The Reboot: COMS and Radiation, Give me an O! OVPR, OUE, and OGC: an in-depth overview of institutional ancillary reviews.

IRB Staff Continuing Education

As regulations change over time as well as one's interpretation, 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 have included: OHRP education on "risks", HIPAA, HRPP toolkit updates, URTP feedback revisions, article discussion on the ethics of ancient DNA, DoD regulatory requirements, fCOI – institutional versus IRB process, decisional capacity and informed consent, ChatGPT and research, and SACHRP guidance on waivers of informed consent, among others.

Updates – Quarter 4

Clarity on Agency - PENDING

Which IRB is the correct IRB to go to when you are a student working in several institutions for your dissertation research? What if you are a faculty member with multiple appointments? The answer rests in the regulatory concept of "agency". Given the many facets of Harvard and the relationship between Harvard and affiliated hospitals, determining agency becomes quite complicated. The HUA IRB office has partnered with the HLC IRB office to work with OGC on establishing a clearer definition of agency. The definition will also include thinking points to create more transparency with how agency and which IRB one should report to is determined.

Re-Accreditation Effort – Next Steps

Initial AAHRPP accreditation is active for three years with the re-accreditation application due one year prior. This means that we are currently working on our re-accreditation application. This process requires that we review every document that is part of our toolkit and to re-examine our processes to ensure that we are following AAHRPP requirements and recommendations. This entails a great deal of work but fully worth the effort.

Our Step 1 and Step 2 application are approved, and our re-accreditation site visit has been scheduled for Tuesday, August 29th through Wednesday, August 30th. Before the AAHRPP site visit, we will be holding various training sessions. Training sessions will be focused on key areas of our research community - IRB staff, IRB members, and other "Key Personnel" such as representatives from the Office of Sponsored Programs, Office of the Vice Provost for Research, Office of General Counsel, other offices that fulfill a research compliance function, and researchers and their staff.

We are conducting these training sessions to re-familiarize and harmonize each of our roles in the oversight and responsibilities that comprise our Harvard Human Research Protection Program (HRPP). We will be utilizing the role-based training materials that were used for our initial accreditation and can be found on our website here.