Report on Operations Quarterly Report

Harvard University Area Advisory Committee
Quarterly Meeting, April – June 2022
June 9, 2022

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."

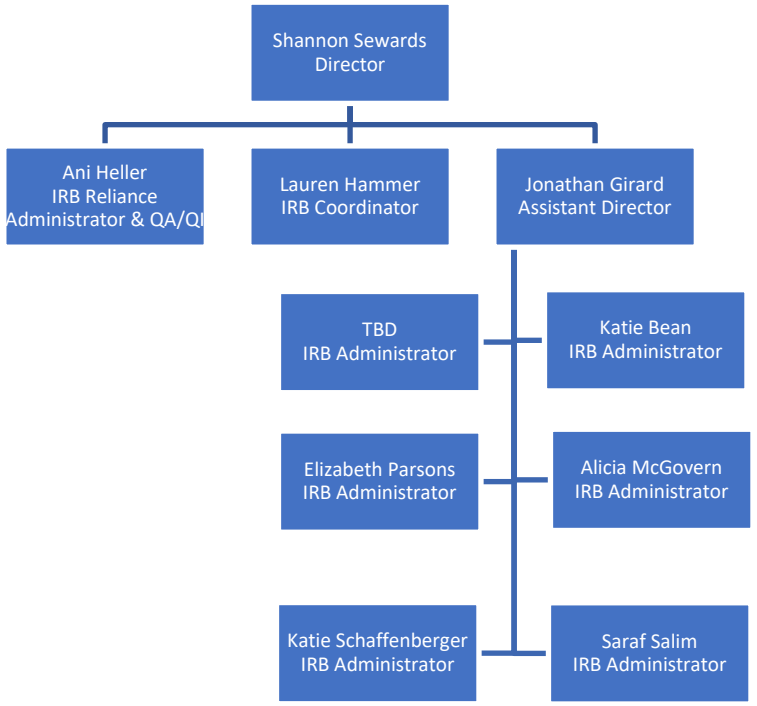
Who We Are

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 2022 to date (July 2021 – May 2022). Table 2 and Graph 2 are the same comparison however represent metrics for Fiscal Year 2021 (July 2020 – May 2021).

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).

Table 1

IRB Staff Review Time versus Total Review Time FY22																						
	Jul-21		Aug-21		Sep-21		Oct-21		Nov-21		Dec-21		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	11	31	17	53	26	78	24	68	18	60	15	59	16	57	6	30	14	33	9	23	4	12
Exempt	8	29	8	22	6	25	4	16	9	32	13	34	7	15	7	21	5	14	4	12	3	8
NHSR	6	13	7	16	9	16	7	11	12	14	24	36	9	21	10	27	6	9	4	8	3	5
Expedited Modification	3	6	4	8	4	9	4	8	4	9	5	14	4	10	3	6	2	5	2	6	3	4

Graph 1

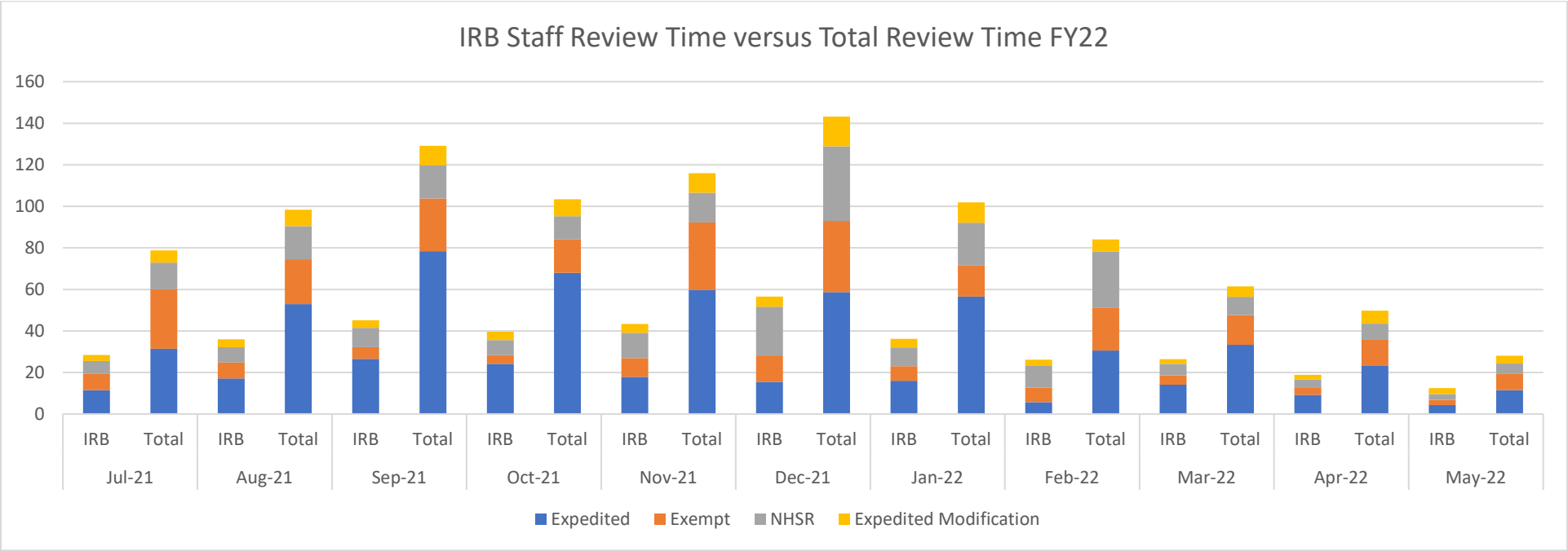
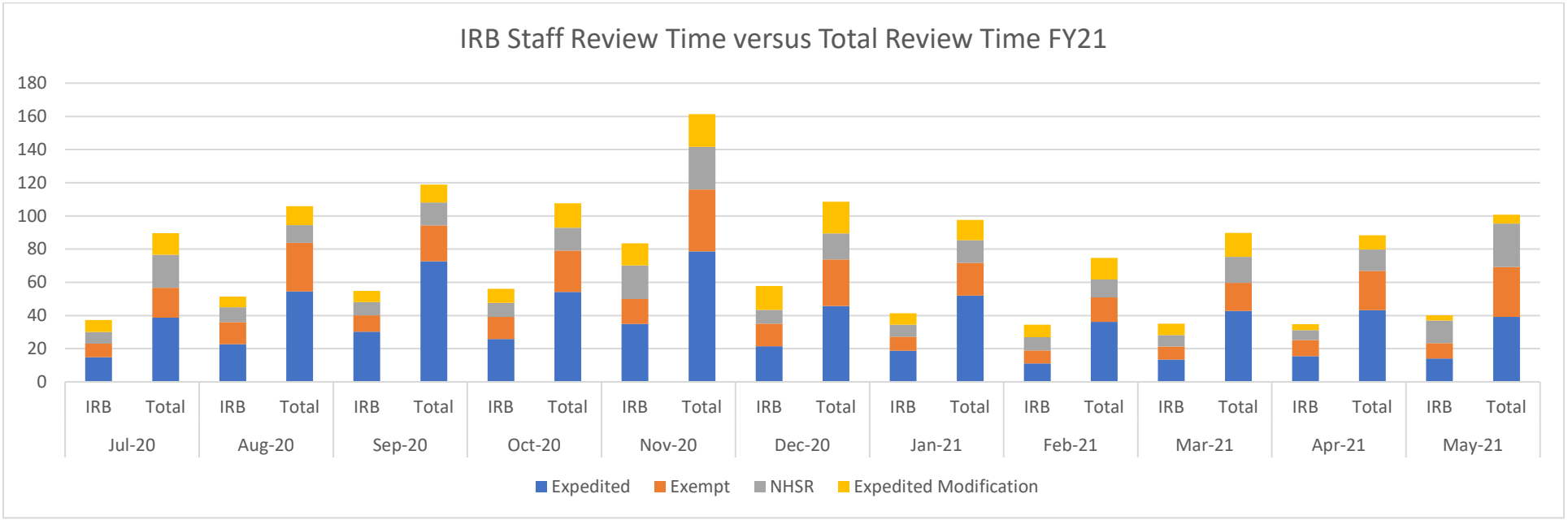


Table 2

IRB Staff Review Time versus Total Review Time FY21																						
	Jul-20		Aug-20		Sep-20		Oct-20		Nov-20		Dec-20		Jan-21		Feb-21		Mar-21		Apr-21		May-21	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	15	39	23	54	30	73	26	54	35	79	21	46	19	52	11	36	13	43	16	43	14	39
Exempt	8	18	13	29	10	22	13	25	15	37	14	28	8	20	8	15	8	17	10	24	9	30
NHSR	7	20	9	11	8	14	8	14	20	26	8	16	7	14	8	11	7	16	6	13	14	26
Expedited Modification	7	13	6	11	7	11	9	15	13	20	15	19	7	12	8	13	7	14	4	9	3	5

Graph 2



Graph 3 and Table 3 represent the overall volume of incoming submissions received during a given month for comparative Fiscal Years 2020, 2021, and 2022. 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
FY20	339	269	329	255	247	221	262	211	253	286	235
FY21	223	190	219	237	159	144	184	201	231	221	225
FY22	196	189	207	184	187	114	154	190	214	215	226

Graph 3

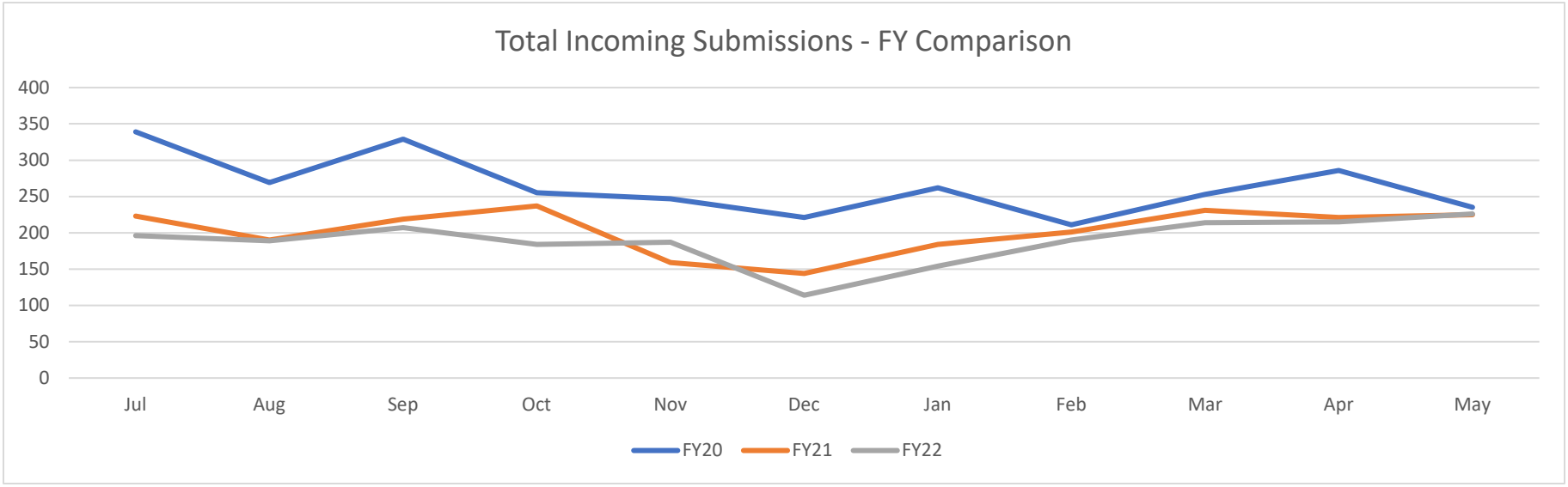


Table 4 represents the IRB's completion rate from July 2021 through May 2022. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in November 2021, the IRB office received a total of 108 initial submissions. Of those 108 submissions, 37 received a determination or approval by month's end while 71 submissions were at some point in the review process[1].

Table 4

Complete vs. in-Review (for initial submissions only)											
	21-Jul	*21-Aug*	*21-Sep*	*Oct-21*	*Nov-21*	*Dec-21*	*22-Jan*	*Feb-22*	*22-Mar*	*22-Apr*	*22-May*
Initial Study Total Received	**87**	**76**	**66**	**83**	**108**	**60**	**66**	**73**	**107**	**114**	**107**
Approved Full	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	4	5	2	2	3	1	1	3	3	2	5
Approved Exempt	25	24	20	21	21	16	16	20	30	4	26
Not Human Research	10	6	9	11	12	2	12	7	15	31	20
Human Research, Not Engaged	0	1	0	1	1	0	0	0	0	16	0
Disapproved	0	0	0	0	0	0	0	0	0	1	0
Review Complete	**39**	**36**	**31**	**35**	**37**	**19**	**29**	**30**	**48**	**54**	**51**
Clarification Requested (Pre-Review & Designated Review)	28	26	19	33	45	16	18	30	37	41	35
Modifications Required	0	0	0	2	1	1	0	0	1	1	3
Pre-Review	20	14	16	13	25	24	19	13	21	19	18
In-Review	**48**	**40**	**35**	**48**	**71**	**41**	**37**	**43**	**59**	**61**	**56**
Percent Complete per Month	**45%**	**47%**	**47%**	**42%**	**34%**	**32%**	**44%**	**41%**	**45%**	**47%**	**48%**

[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)*

Measures of Quality and Compliance

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	Quarterly Check-In Date
April	[redacted]	[redacted]	[redacted]	*May 18, 2022*
May	[redacted]	[redacted]	[redacted]	*May 18, 2022*
June	[redacted]	[redacted]	[redacted]	*August 18, 2022*

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	*Meeting Canceled*	*N/A*	*N/A*
April	*Yes*	*1) Consultant report & Scientific Merit checklist were not included with the Designated Review; 2) MRTSA included non-direct requests; 3) last statement in Section 2 of the form should include "Disapproved"*	*June 15, 2022*
May	*Yes*	*RNI N/A button not clickable on form*	*June 15, 2022*

Training, Outreach, and Other Initiatives: April - June 2022

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from April 1, 2022, through May 31, 2022, our website had 4,200 visitors. 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 April 1, 2022, through May 31, 2022, the HUA IRB office has held the following outreach and training sessions:

- 25 IRB office hour sessions (general meetings)
- 4 IRB office hour sessions with HKS affiliates
- 6 IRB office hour sessions with HLS affiliates
- 1 IRB office hour session with affiliates from the Psychology Department

IRB Newsletter

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

- **April 2022**: New NIAAA Data Sharing Policy -- Effective Immediately, Revision to Department/School Distribution Coming Soon, Removing Study Team Members, Collaborating with Another Institution? Check out our updated website page, Know the Submit Button, and Do you Speak IRB? Deception and Incomplete Disclosure.
- **May 2022**: Lotteries and Raffles as a Form of Subject Compensation, We Love to Hear from You, but We Don't Need To, Modifications on Exempt Determinations and Continuing Review on studies that follow the 2018 Requirements, and Do You Speak IRB? Multi-Site/Collaborative vs. Single-Site vs. Location - What Is the Difference?
- **June 2022**: ESTR Etiquette (Do not email irb@harvard.edu - it's not the IRB Office, Don’t Upload pdf’s, Revising Some Submission Documents - Choose “Update” Instead, Don’t Upload Revised Forms as a Comment – Upload Them in the ESTR SmartForm Instead, But ESTR Told Me to Upload Training Certificates to Item 2, Don’t Forget to Select “IRB Coordinator” when Sending a Comment, Include the Text for “Future Use of Data” in the Informed Consent Form Template – It’s a Requirement, Are You Using the Most Current Form), and Do You Speak IRB? HRPP and HRPP Plan.

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 "FDA Regulated Devices" and "Harvard Human Subjects Payment Policy".

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: not human subjects determination documentation, closing a study with a 5-digit number, data brokers, Harvard subject payment policy, delayed IRB meeting minutes, difficult studies, and a viewing of the PRIM&R webinar "Complex Conflict of Interest (COI)", among others.

Updates: April - June 2022

Moving Again?

We received notice that the IRB office will be moving to a new location during Fall 2022. As the University is seeking ways to best strategize many offices moving to remote work and to be more fiscally responsible, offices that are leasing space that is not Harvard owned are being asked to relocate to Harvard owned space. More information coming!

Revision to School and Department Distribution Implemented

On May 2, 2022, the IRB office shifted our established review portfolios among staff as well as reducing the review portfolios from our Assistant Director and IRB Reliance Administrator.

As a reminder, the goal of the revision was to create a more balanced review portfolio for each of the review staff as well as to minimize the number of schools and departments that were split among staff. By doing so, we can better track incoming distribution in real time as well as provide schools and departments with one point of contact.

Regarding the reduction of the review portfolios of our Assistant Director and IRB Reliance Administrator:

- For our Assistant Director, this will result in an increased focus on training opportunities including additional research community outreach, additional development, and attention to the training of IRB staff, increased oversight of completed reviews and spot auditing, and increased role in the management and operations of the IRB panel.
- For our IRB Reliance Administrator, we will now be able to create a more comprehensive quality assurance and quality improvement program, including the establishment of a post-approval monitoring program, as well as to expand the resources and support of our IRB reliance program.

AAHRPP Annual Progress Report

As an Association for the Accreditation of Human Research Protection Programs (AAHRPP) accreditation requirement, we are to submit an annual progress report to update our accrediting agency with any changes to our Human Research Protection Program (HRPP), number of studies reviewed and approved, as well as other metrics. The Harvard University HRPP passed with flying colors, and we were commended on our "continued commitment to the most comprehensive protections for research participants and the highest quality research." Go Harvard HRPP!