Report on Operations Quarterly Report

Harvard University Area Advisory Committee
Quarterly Meeting, July 2022 – September 2022
September 8, 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."

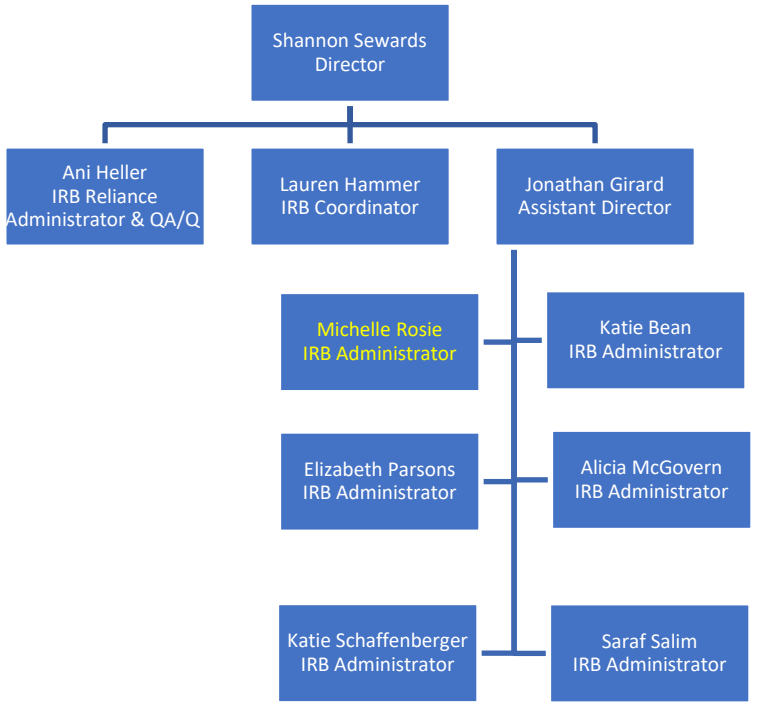
Who We Are

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 Calendar Year 2022 to date (January 2022 to August 2022). Table 2 and Graph 2 are the same comparison however represent metrics for Calendar Year 2021 (January 2021 – August 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 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	7	46	15	39	12	34	9	25	12	40	12	18	6	6
Exempt	7	20	8	23	6	18	4	19	4	14	8	19	6	11	6	18
NHSR	9	21	10	27	6	9	4	8	4	15	8	11	2	3	3	5
Expedited Modification	4	10	3	7	2	6	2	9	3	9	2	5	3	3	2	4

Graph 1

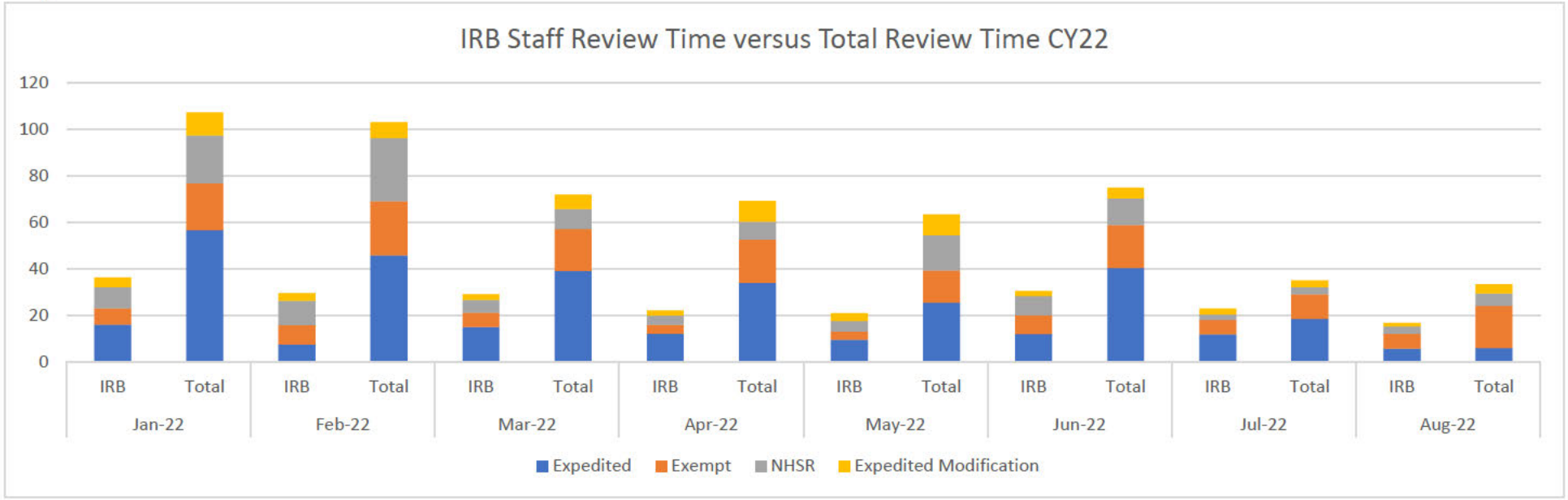


Table 2

IRB Staff Review Time versus Total Review Time CY21																
	Jan-21		Feb-21		Mar-21		Apr-21		May-21		Jun-21		Jul-21		Aug-21	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	19	52	11	36	13	43	16	43	14	39	19	43	14	52	17	53
Exempt	8	20	8	15	8	17	10	24	9	30	6	14	8	29	8	22
NHSR	7	14	8	11	7	16	6	13	14	26	6	13	6	13	7	16
Expedited Modification	7	12	8	13	7	14	4	9	3	5	3	7	3	6	4	8

Graph 2

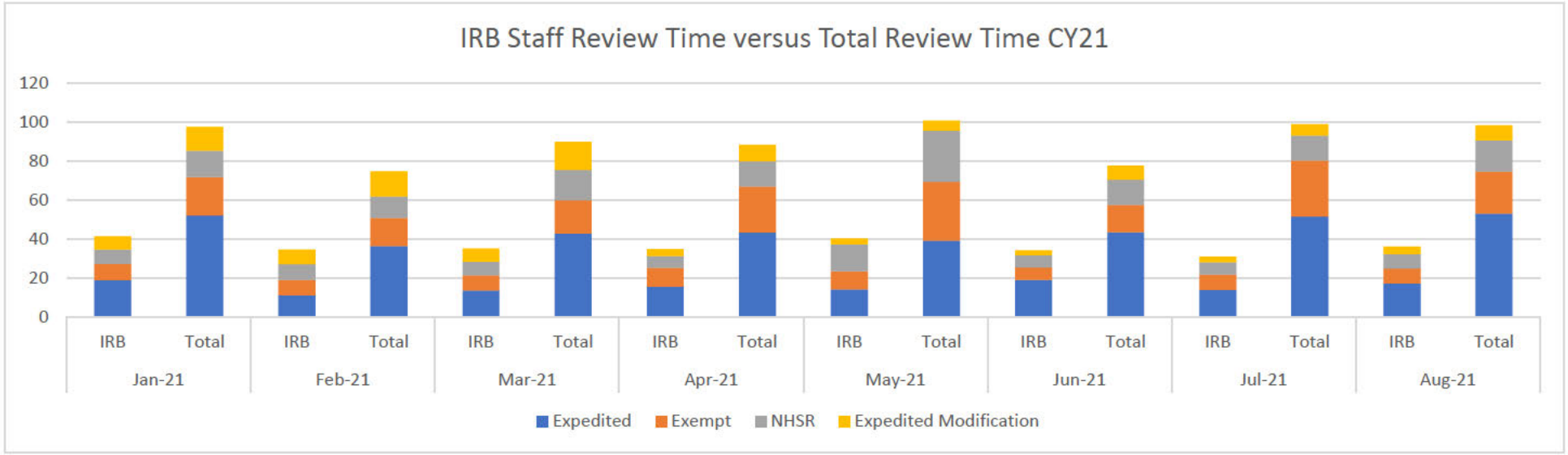


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for comparative Calendar Years 2020, 2021, and 2022. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions which following review, 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 - CY Comparison								
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug
CY20	262	211	252	284	233	282	222	190
CY21	184	201	230	220	225	230	196	188
CY22	150	186	208	206	220	257	208	205

Graph 3

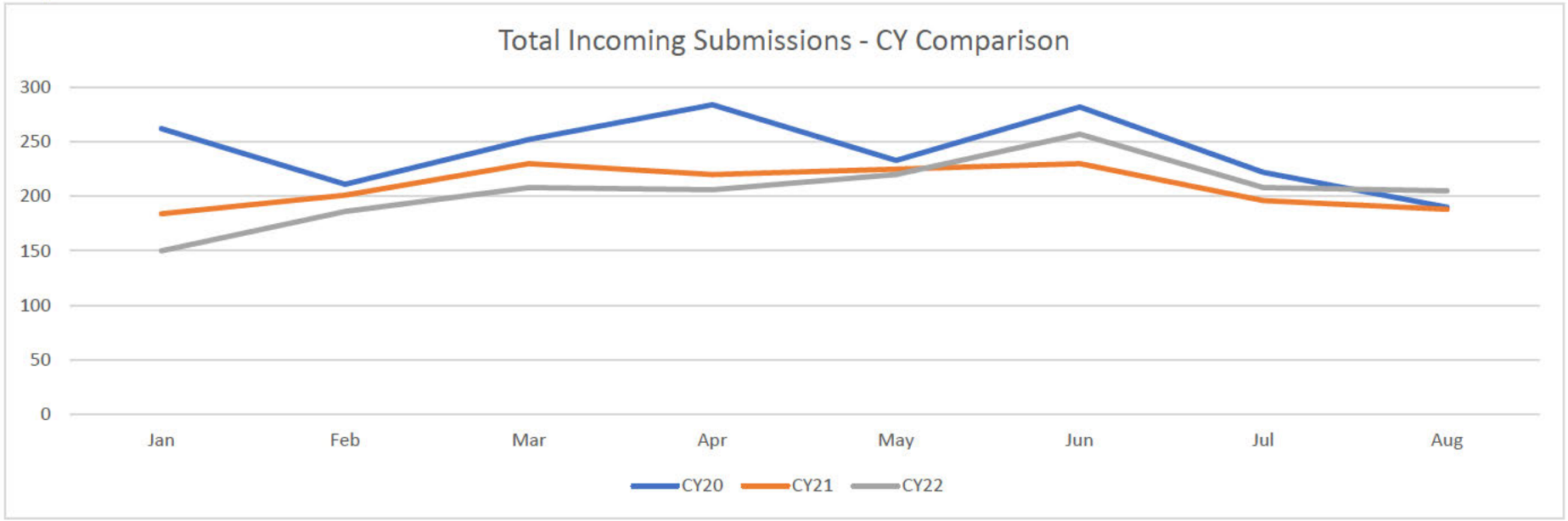


Table 4 represents the IRB's completion rate from January 2022 through August 2022. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in February 2022, the IRB office received a total of 73 initial submissions. Of those 73 submissions, 30 received a determination or approval by month's end while 43 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-Jan	*Feb-22*	*22-Mar*	*22-Apr*	*22-May*	*22-Jun*	*22-Jul*	*22-Aug*
n t a Study Tota Rece ved	**66**	**73**	**107**	**114**	**107**	**96**	**86**	**85**
Approved Fu	0	0	0	0	0	0	0	
Approved Exped ted	1	3	3	2	5	0	3	1
Approved Exempt	16	20	30	4	26	28	21	22
Not uman Research	12	7	15	31	20	6	8	10
uman Research, Not Engaged	0	0	0	16	0	2	1	0
D sapproved	0	0	0	1	0	0	0	0
Rev ew Comp ete	**29**	**30**	**48**	**54**	**51**	**36**	**33**	**33**
C ar f cat on Requested (Pre-Rev ew & Des gnated Rev ew)	18	30	37	41	34	33	32	38
Mod f cat ons Requ red	0	0	1	1	3	1	2	0
Pre-Rev ew	19	13	21	19	18	22	19	14
n-Rev ew	**37**	**43**	**59**	**61**	**55**	**56**	**53**	**52**
Percent Comp ete per Month	**44%**	**41%**	**45%**	**47%**	**44%**	**38%**	**38%**	**39%**

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
July	[redacted]	[redacted]	[redacted]	[redacted]
August	[redacted]	[redacted]	[redacted]	[redacted]
August (alternate)	[redacted]	[redacted]	[redacted]	[redacted]
September	[redacted]	[redacted]	[redacted]	[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 for significant trends.*

Meeting Date	Minutes to Chair & Director within 7 calendar days?	General Minutes Requirements Notes	Quarterly Check-In Date
June	*Yes*	*When reviewing the checklist, decided it was unnecessary to have the IRB number in the header as we only have one IRB.*	*July 5, 2022*
July	*Yes*	*None*	*September 21, 2022*
August	*Yes*	*None*	*September 21, 2022*

Training, Outreach, and Other Initiatives: July - September 2022

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from June 1, 2022, through August 31, 2022, our website had over 12,000 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 June 1, 2022, through August 31, 2022, the HUA IRB office has held the following outreach and training sessions:

- 51 IRB office hour sessions (general meetings)
- 1 IRB office hour sessions with HKS affiliates
- 0 IRB office hour sessions with HLS affiliates
- 1 IRB office hour session with affiliates from the Psychology Department
- 6 requested trainings for specific courses, departments, or programs

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

IRB Newsletter

Topics for our July, August, and September newsletters included the following:

- **July 2022**: Leaving Harvard?, Who Owns Research Data?, and Do you Speak IRB? Agency and Engagement of Visiting Scholars (Fellows and Faculty).
- **August 2022**: NIH DSMP Training Now Available, Are You an Undergraduate Planning to Conduct Research with People?, and Do You Speak IRB? What it Means to be a Faculty Sponsor.
- **September 2022**: Welcome to Harvard – an Introduction to the Harvard University Area IRB, IRB Lifecycle – Your Lifeline for All Things IRB, What Type of Data is This?, and Do You Speak IRB? Debriefing.

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: PI Eligibility and Faculty Sponsor Assurance and IRB Members Webpage Tour.

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: future use of data, data safety, ESTR pre-review versus designated review, PRIM&R FDA webinar, mandatory reporting laws, AAHRPP DEI webinar, financial conflicts of interest, IRB member recruitment update, toolkit revisions, FOIA requests, and public versus private, among others.

Updates: July - September 2022

New IRB Members

As we continue to seek new membership, we are pleased to report that a new IRB member from the Harvard Graduate School of Education, [redacted], will be joining us beginning with the September 2022 meeting. We are also recruiting a new community member for our IRB.

Moving Again?

Although we received notice that the IRB office will be moving to a new location, we are uncertain where that location will be. More information coming!

Goals for the Upcoming Year

As the HUA IRB office continues to grow and develop, we reflect on goals that we would like to achieve for the coming year. Here are two such 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.

- **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.