Report on Operations

Quarterly Meeting of the
Harvard University Area Advisory Committee
(July – September 2021)

SEPTEMBER 9, 2021

Harvard University Area IRB

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

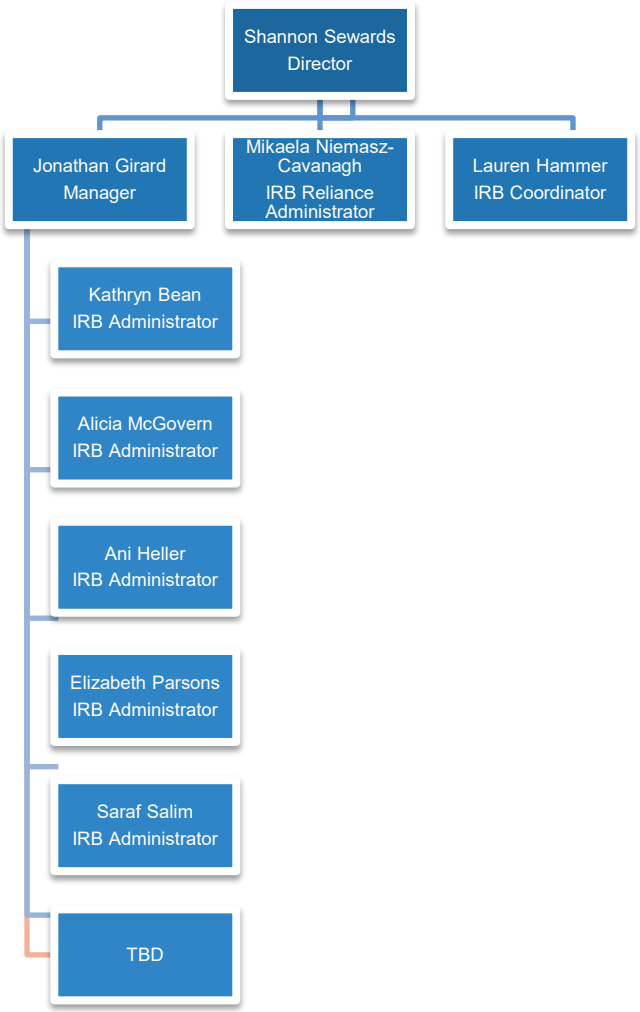
Ethical Principles

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 the time-to-completion (in calendar days) for studies (according to type of review) that were completed by the IRB staff. Please note that while the IRB provides many types of reviews and determinations, only the most common are included here.

The time-to-completion 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. 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 (Jan - Aug 2021)								
	Jan-21	**Feb-21**	**Mar-21**	**Apr-21**	**May-21**	**Jun-21**	**Jul-21**	**Aug-21**
Expedited	18.81	11.08	12.75	13.87	13.92	11.59	8.59	2.84
Exempt	8.43	7.85	8.18	9.66	8.19	6.27	5.86	1.85
NHSR	7.28	8.01	6.91	6.00	13.70	2.87	5.33	1.30
Expedited Modification	6.85	7.55	6.86	3.62	3.08	2.47	2.62	1.46

Graph 1

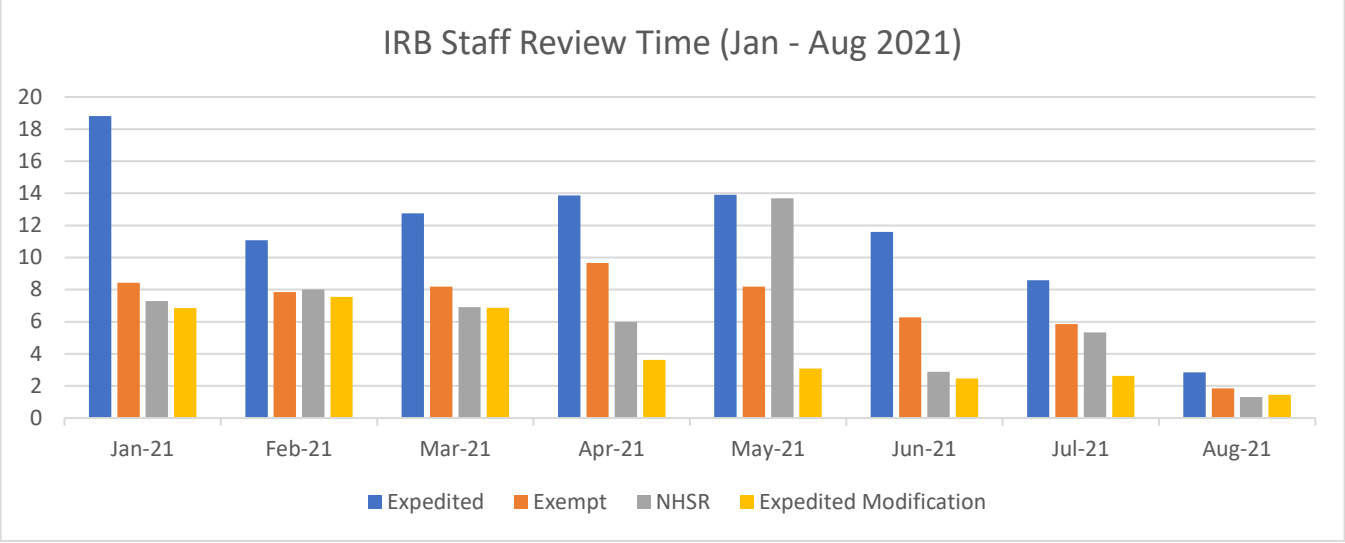


Table 2a (2021) and Table 2b (2020) represent a comparison of IRB staff time-to-completion as a demonstration of effectiveness, efficiency, and overall performance of the office.

Table 2a (2021)

IRB Staff Review Time (Jan - Aug 2021)								
	Jan-21	**Feb-21**	**Mar-21**	**Apr-21**	**May-21**	**Jun-21**	**Jul-21**	**Aug-21**
Expedited	18.81	11.08	12.75	13.87	13.92	11.59	8.59	2.84
Exempt	8.43	7.85	8.18	9.66	8.19	6.27	5.86	1.85
NHSR	7.28	8.01	6.91	6.00	13.70	2.87	5.33	1.30
Expedited Modification	6.85	7.55	6.86	3.62	3.08	2.47	2.62	1.46

Table 2b (2020)

IRB Staff Review Time (Jan - Aug 2020)								
	Jan-20	**Feb-20**	**Mar-20**	**Apr-20**	**May-20**	**Jun-20**	**Jul-20**	**Aug-20**
Expedited	12.92	16.03	16.05	21.74	17.64	25.16	14.85	22.75
Exempt	9.99	7.67	10.21	5.10	10.01	7.73	8.22	13.19
NHSR	17.74	16.04	7.10	2.35	6.18	7.59	6.97	9.01
Expedited Modification	6.66	6.60	6.58	4.52	6.00	8.98	7.17	6.38

Graph 3 and Table 3 represent the overall volume of incoming submissions received during a given month for year 2019, year 2020, and year 2021. 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								
	Jan	**Feb**	**Mar**	**Apr**	**May**	**Jun**	**Jul**	**Aug**
2019	279	300	276	281	380	347	339	271
2020	262	212	254	286	235	284	223	190
2021	185	201	233	226	229	232	204	197

Graph 3

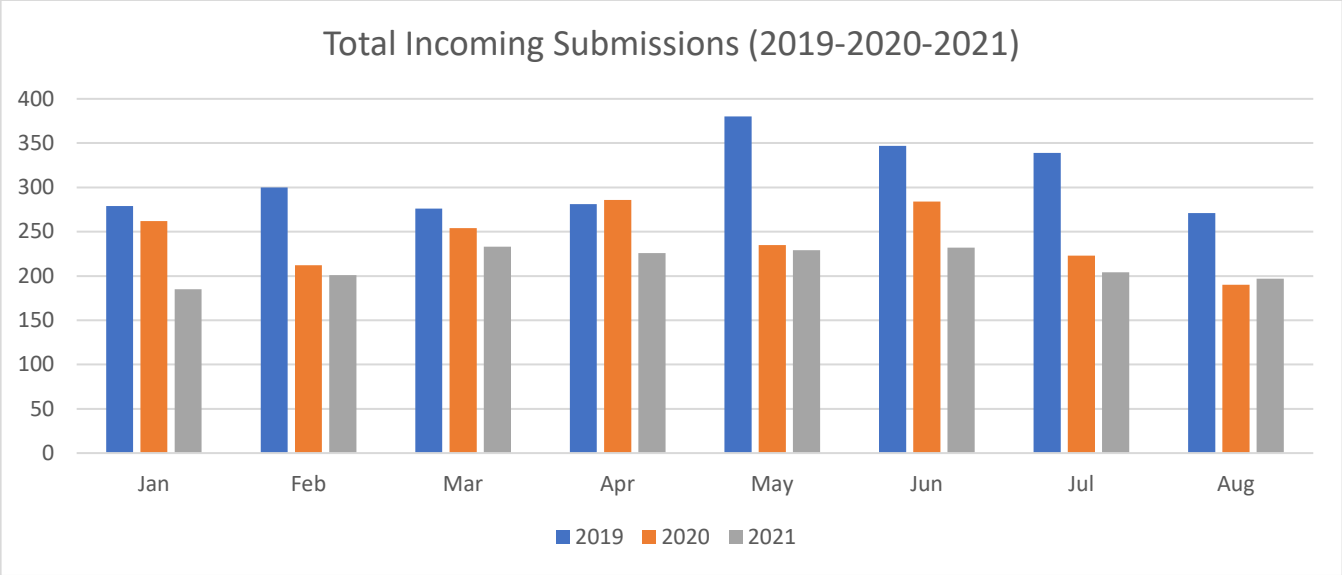


Table 4 represents the IRB's completion rate for partial year 2020 and year 2021. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in September 2020, the IRB office received a total of 84 initial submissions. Of those 84 submissions, 35 received a determination or approval by month's end while 46 submissions were at some point in the review process (i.e., 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)														
	Jul-20	*Aug-20*	*Sep-20*	*Oct-20*	*Nov-20*	*Dec-20*	*Jan-21*	*Feb-21*	*Mar-21*	*Apr-21*	*May-21*	*Jun-21*	*21-Jul*	*21-Aug*
Initial Study Total Received	**101**	**83**	**84**	**109**	**92**	**86**	**92**	**83**	**105**	**106**	**78**	**90**	**87**	**76**
Approved Full	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	7	5	4	3	2	3	5	4	4	6	6	9	4	5
Approved Exempt	26	27	20	35	21	18	29	26	35	30	15	30	25	24
Not Human Research	12	4	11	11	4	4	8	8	12	12	8	14	10	6
Human Research, Not Engaged	0	1	0	0	0	0	0	0	1	0	0	0	0	1
Disapproved	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**45**	**37**	**35**	**49**	**27**	**25**	**42**	**38**	**52**	**48**	**29**	**53**	**39**	**36**
Clarification Requested (Pre-Review & Designated Review)	28	25	29	24	34	19	27	30	33	25	26	22	28	26
Modifications Required	1	1	0	0	0	0	2	0	1	1	2	0	0	0
Pre-Review	27	20	17	36	31	42	21	15	19	28	21	15	20	14
In-Review	**56**	**46**	**46**	**60**	**65**	**61**	**50**	**45**	**53**	**54**	**49**	**37**	**48**	**40**
Percent Complete per Month	**45%**	**45%**	**42%**	**45%**	**29%**	**29%**	**46%**	**46%**	**50%**	**45%**	**37%**	**59%**	**45%**	**47%**

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	Principal Investigator	ESTR #	Study Title
July	[redacted]	[redacted]	[redacted]
August	[redacted]	[redacted]	[redacted]
September	[redacted]	[redacted]	[redacted]

No substantial findings were found for any of the above studies.

Note. PI names, ESTR #, and Study Title redacted for confidentiality.

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	Assessment Completion Date	Minutes to Chair & Director within 7 calendar days?	General Minutes Requirements Notes	Quarterly Check-In Date
June 17, 2021	8/23/21	Yes	None	Sept. 17, 2021
July 15, 2021	8/23/2021	Yes	None	Sept. 17, 2021
August 19, 2021	9/8/2021	No	Due to an unexpected health issue, one administrator was OOO, and the meeting minutes were delayed going out.	Sept. 17, 2021

Training, Outreach, and Other Initiatives - July – September 2021

What's New on Our Website

Quarterly Report

As part of our reporting requirements to the Harvard Human Research Protection Program, we are now providing our quarterly metrics, operational updates, and outreach efforts on our website. This information is also helpful for research teams to better plan when to submit their proposal to the IRB for review and approval. You can find the report on our website here.

Online Scheduling for IRB Office Hours

We have created a new online scheduling tool to schedule meetings with IRB staff as well as reserve a space for upcoming IRB Office Hours for Harvard Schools. By doing so, we have created a central location for all meeting scheduling. This also helps us to better track outreach to our research community. You can find our new scheduling tool here – and click on the link in the section "BOOK YOUR OFFICE HOURS APPOINTMENT". Or you can access the direct link to our scheduling tool here.

IRB Newsletter

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

- July: Resumption of Research - COVID-19 Update, CITI Training Now Available in Spanish, Just Arriving at Harvard? Or are You Departing Harvard? Tips for a successful transition, Do You Speak IRB? - Prompt Reporting Requirements
- August: Keep Your IRB Submission Up to Date, Harvard Catalyst Community Engagement Program, Do You Speak IRB? - External IRB Submissions
- September: New GDPR Guidance Document Just Released, What's New on Our Website - Quarterly Report and Online Scheduling Tool, Things to Known When Your Harvard Research Study Will Involve MGB, Do You Speak IRB? - DoD Research Regulation

You can find our newsletters here.

IRB Refresher Training / Continuing Education

IRB members recently received a special refresher training to provide an overview of best review practices, common regulatory issues, and other items that are pertinent to IRB members. This is a new training that has been implemented to compliment the introductory training that each member receives.

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: What is a Report of New Information (RNI), the concept of private versus public settings and information, a regulatory overview of prompt reporting requirements, and before and after IRB meeting SOPs.