Report on Operations

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

DECEMBER 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

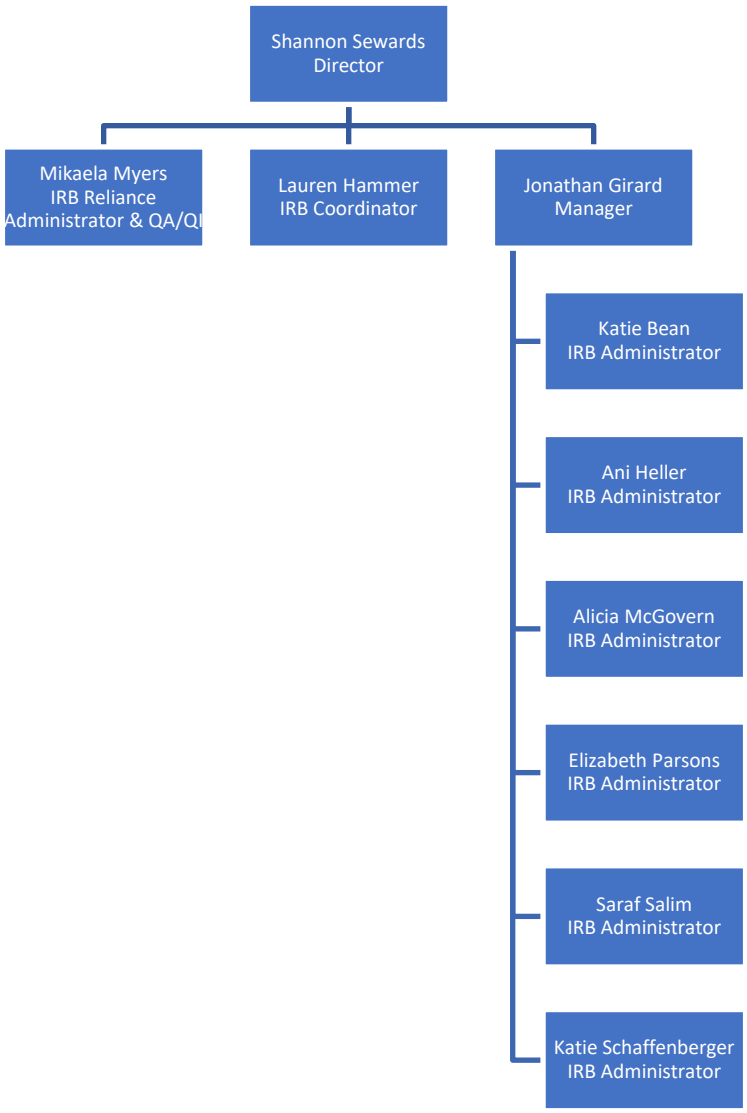
Ethical Principles

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 staff review time (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 staff 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). Note that this metric only represents the amount of time for the staff's review, not the review time for the study team.

Table 1

IRB Staff Review Time (CY 2021)											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov
Expedited	18.81	11.08	13.46	13.87	14.11	18.73	10.85	11.02	11.70	13.37	10.02
Exempt	8.43	7.85	8.18	9.66	8.90	6.38	7.39	7.67	4.17	3.36	5.27
NHSR	7.28	8.01	6.91	6.00	13.70	6.31	6.27	7.42	5.01	5.05	2.73
Expedited Modification	6.85	7.55	6.86	3.62	3.08	2.51	2.94	3.87	2.11	3.35	2.66

Graph 1

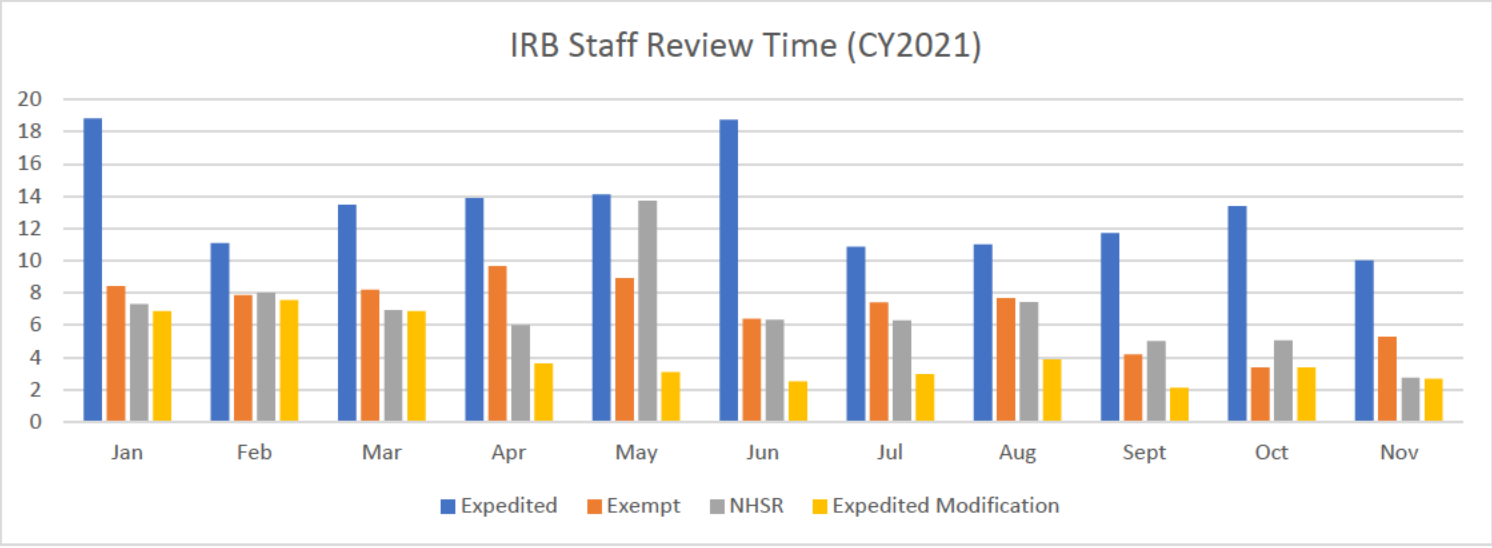


Table 2a (2021) and Table 2b (2020) represent a comparison of IRB staff review time as a demonstration of effectiveness, efficiency, and overall performance of the office.

Table 2a (2021)

IRB Staff Review Time (CY 2021)											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov
Expedited	18.81	11.08	13.46	13.87	14.11	18.73	10.85	11.02	11.70	13.37	10.02
Exempt	8.43	7.85	8.18	9.66	8.90	6.38	7.39	7.67	4.17	3.36	5.27
NHSR	7.28	8.01	6.91	6.00	13.70	6.31	6.27	7.42	5.01	5.05	2.73
Expedited Modification	6.85	7.55	6.86	3.62	3.08	2.51	2.94	3.87	2.11	3.35	2.66

Table 2b (2020)

IRB Staff Review Time (CY 2020)											
	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov
Expedited	19.00	16.03	15.50	21.74	17.64	25.16	14.85	22.75	30.23	25.86	35.14
Exempt	57.00	7.67	10.42	5.10	10.01	7.73	8.22	13.19	9.92	13.31	15.19
NHSR	11.00	16.04	7.10	2.35	6.18	7.59	6.97	9.01	7.99	8.44	20.06
Expedited Modification	86.00	6.60	6.58	4.52	6.00	8.98	7.17	6.38	6.64	8.51	13.44

Graph 3 and Table 3 represent the overall volume of incoming submissions received during a given month for calendar 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**	**Sept**	**Oct**	**Nov**
2019	279	299	276	281	378	347	339	270	329	255	251
2020	262	212	254	286	235	284	223	190	219	237	160
2021	185	201	232	221	225	231	196	191	210	190	208

Graph 3

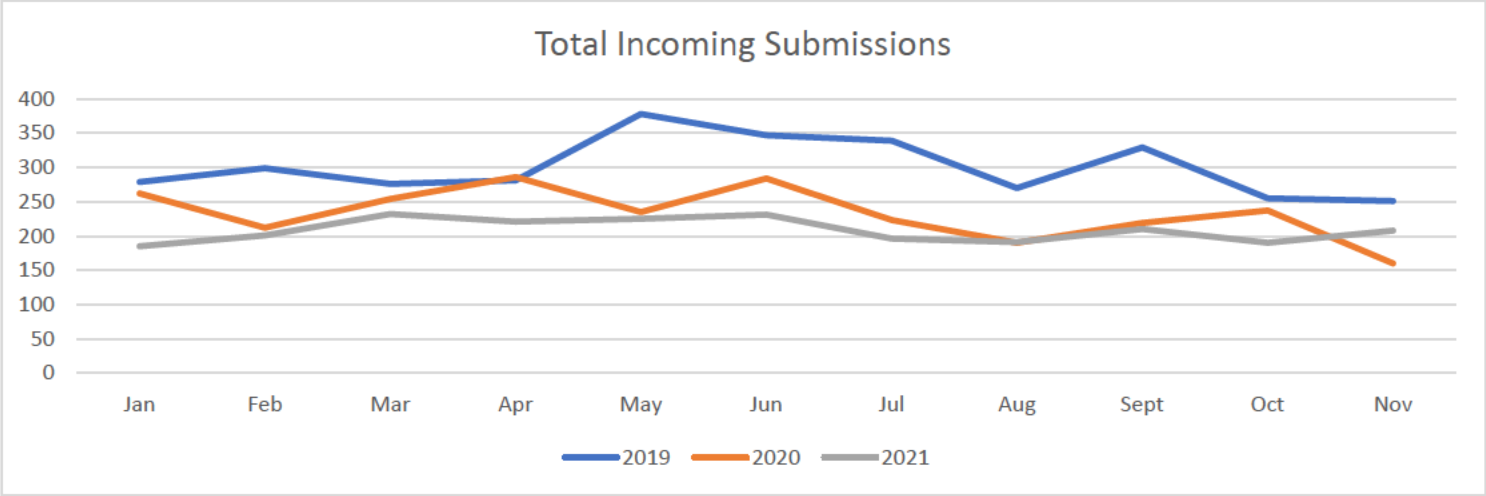


Table 4 represents the IRB's completion rate for calendar year 2021. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in March 2021, the IRB office received a total of 105 initial submissions. Of those 105 submissions, 52 received a determination or approval by month's end while 53 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)											
	Jan-21	*Feb-21*	*Mar-21*	*Apr-21*	*May-21*	*Jun-21*	*21-Jul*	*21-Aug*	*21-Sep*	*Oct-21*	*Nov-21*
Initial Study Total Received	**92**	**83**	**105**	**106**	**78**	**90**	**87**	**76**	**66**	**83**	**108**
Approved Full	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	5	4	4	6	6	9	4	5	2	2	3
Approved Exempt	29	26	35	30	15	30	25	24	20	21	21
Not Human Research	8	8	12	12	8	14	10	6	9	11	12
Human Research, Not Engaged	0	0	1	0	0	0	0	1	0	1	1
Disapproved	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**42**	**38**	**52**	**48**	**29**	**53**	**39**	**36**	**31**	**35**	**37**
Clarification Requested (Pre-Review & Designated Review)	27	30	33	25	26	22	28	26	19	33	45
Modifications Required	2	0	1	1	2	0	0	0	0	2	1
Pre-Review	21	15	19	28	21	15	20	14	16	13	25
In-Review	**50**	**45**	**53**	**54**	**49**	**37**	**48**	**40**	**35**	**48**	**71**
Percent Complete per Month	**46%**	**46%**	**50%**	**45%**	**37%**	**59%**	**45%**	**47%**	**47%**	**42%**	**34%**

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
October	[redacted]	[redacted]	[redacted]
November	[redacted]	[redacted]	[redacted]
November	[redacted]	[redacted]	[redacted]
December	[redacted]	[redacted]	[redacted]

We had one Principal Investigator who did not return the assessment for the month of November due to time constraints. The December assessment is pending. No issues of concern noted for those assessments that have been completed.

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
October 21, 2021	10/28/21	Yes	None	Dec. 16, 2021
November 18, 2021 (meeting canceled)	N/A	N/A	N/A	N/A
December 9, 2021	Pending	Pending	Pending	Dec. 16, 2021

Training, Outreach, and Other Initiatives - September - December 2021

What's New on Our Website

Becoming an IRB Member

To expand the expertise and potential contribution of members from various areas of our academic community as well as those from outside Harvard, we have created a new webpage that provides an overview of what membership entails and outlines how to request becoming a member. Please see the Becoming an IRB Member webpage here.

For HUA IRB Members

We've created a one-stop shop for our IRB membership that includes resources, training, an overview of expectations, and other important items. See the HUA IRB Members page here.

Thank an IRB Staff Member

We created a quick and easy way that our research community can thank an IRB staff member. By clicking on the link "Thank an IRB Staff Member" on our website, we've created a brief Qualtrics form where the research community may send a note of appreciation. You can see the Thank an IRB Staff Member form here.

IRB Newsletter

Topics for our October, November, and December newsletters included the following:

- October 2021 - Who is an Agent of Harvard?, Personal Information Protection Law (PIPL), What it Means to Be a Faculty Sponsor, What's New on Our Website, and the Do You Speak IRB topic - Coercion and Undue Influence.
- November 2021 - PIPL - New Information Posted, URTP - What You Need to Know, URTP In-Person Training Dates, Recruiting from Harvard Guidelines, ESTR Not Available this Weekend, and the Do You Speak IRB topic - Principal Investigator Eligibility.
- December 2021 - Office Closed for Winter Recess, Tips for a successful IRB Review, and the Do You Speak IRB topic - HRPP & 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: Data security classification, international research reminders, and what is FDA regulated.

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: Secondary data, China's new data privacy regulation PIPL, U.S. data security laws, deception and incomplete disclosure, randomization, capacity to consent, and compensation for participation in research, among others.

Updates - September - December 2021

Return to the office

The IRB office has returned to the office beginning in November 2021. We have embraced a hybrid work model - three days in the office and two days working from home with our "anchor" day being Tuesday. Staff have transitioned well to this model – so far, so good. We continue to hold meetings with our research community via Zoom, including our IRB meetings as well as staff-led trainings.

FDA Inspection

The HUA IRB office was subject to a routine inspection as part of the FDA's Bioresearch Monitoring Program (BIMO). The objectives of the BIMO Program are: 1) To protect the rights, safety, and welfare of subjects involved in FDA-regulated clinical trials; 2) To verify the accuracy and reliability of clinical trial data submitted to FDA in support of research or marketing applications; and 3) To assess compliance with FDA's regulations governing the conduct of clinical trials.

The inspection lasted five business days. During this time, the entirety of our HRPP as well as the in-depth review of three FDA regulated studies were inspected. There were no observations, findings, or recommendations for our program.

AAHRPP Annual Progress Report

Can you believe it has been a year since our HRPP received full accreditation from the Association for the Accreditation of Human Research Programs (AAHRPP)? How time flies when you are accredited! As part of the requirements of our accreditation, we will be submitting an annual progress report to AAHRPP that details what we've been up to during the past year as well as our annual accreditation fee.

Community Member Outreach

We have been working with the Harvard Catalyst Community Engagement Program to seek new membership for the Community Member positions on our IRB panel. The role of the IRB Community Member is integral to the purpose and mission of the IRB as they are truly the "voice" of the community that they represent. The Community Engagement Program has been a true partner in this effort - we now have two potential Community Members.

Revision to School and Department Distribution

With the start of our new IRB Administrator, we will soon be shifting some of our established review portfolios among staff as well as reducing the review portfolios from our Manager and IRB Reliance Administrator.

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 Manger and IRB Reliance Administrator, for our Manager, 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.