
Report on Operations



**Quarterly Meeting of the Harvard University
Area Advisory Committee (April – June 2021)
JUNE 10, 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

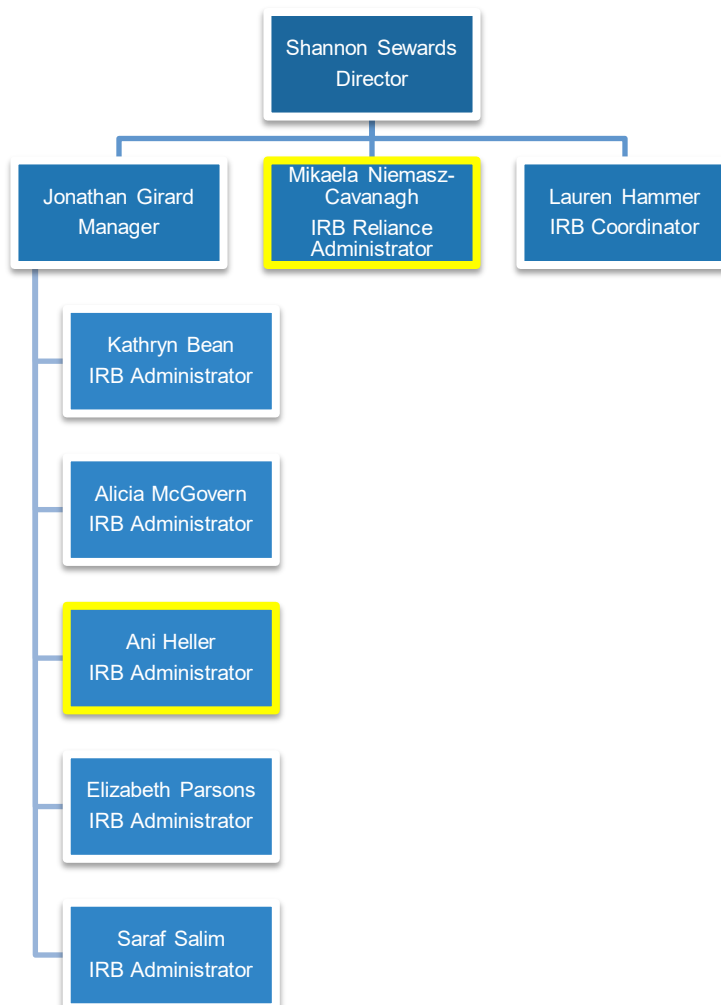
Ethical Principles

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 Time-to-Completion											
	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21
Expedited	14.85	21.46	29.01	26.58	35.14	22.41	18.81	11.08	12.72	12.42	3.17
Exempt	8.22	13.19	9.92	13.29	15.19	13.20	8.43	7.85	8.04	7.19	1.06
NHSR	6.97	9.01	7.99	8.44	20.06	8.28	7.28	8.01	6.91	5.51	3.49
Modification (Exp.)	7.17	6.38	6.64	8.51	13.44	14.55	6.85	7.55	6.93	3.55	1.37

Graph 1

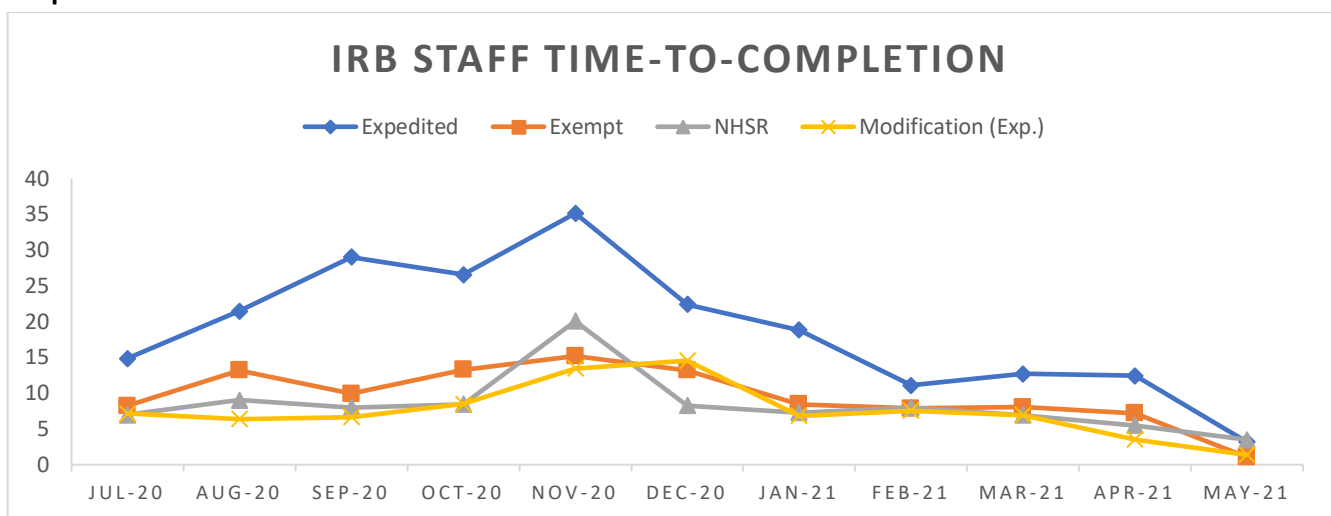


Table 2a (FY 2021) and Table 2b (FY2020) represent a fiscal year comparison (2021 and 2020) of IRB staff time-to-completion as a demonstration of effectiveness, efficiency, and overall performance of the office.

Table 2a (FY2021)

IRB Staff Time-to-Completion											
	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21
Expedited	14.85	21.46	29.01	26.58	35.14	22.41	18.81	11.08	12.72	12.42	3.17
Exempt	8.22	13.19	9.92	13.29	15.19	13.20	8.43	7.85	8.04	7.19	1.06
NHSR	6.97	9.01	7.99	8.44	20.06	8.28	7.28	8.01	6.91	5.51	3.49
Modification (Exp.)	7.17	6.38	6.64	8.51	13.44	14.55	6.85	7.55	6.93	3.55	1.37

Table 2b (FY 2020)

IRB Staff Time-to-Completion											
	Jul-19	Aug-19	Sep-19	Oct-19	Nov-19	Dec-19	Jan-20	Feb-20	Mar-20	Apr-20	May-20
Expedited	20.59	30.49	17.99	23.27	25.40	26.44	12.92	16.03	16.05	23.34	17.64
Exempt	9.32	9.15	11.04	16.34	14.09	14.81	9.99	7.67	10.21	5.10	10.01
NHSR	3.70	15.04	6.07	7.09	15.34	15.00	17.74	16.04	7.10	2.35	6.18
Modification (Exp.)	7.49	7.88	5.07	5.41	6.45	9.16	6.66	6.60	6.58	4.52	6.00

Graph 3 and Table 3 represent the overall volume of incoming submissions received during a given month for fiscal year 2020 and fiscal 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

IRB Incoming Submission Volume											
	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May
FY2021	224	192	220	237	161	146	185	203	236	232	239
FY2020	339	271	332	256	251	223	262	212	254	288	235

Graph 3

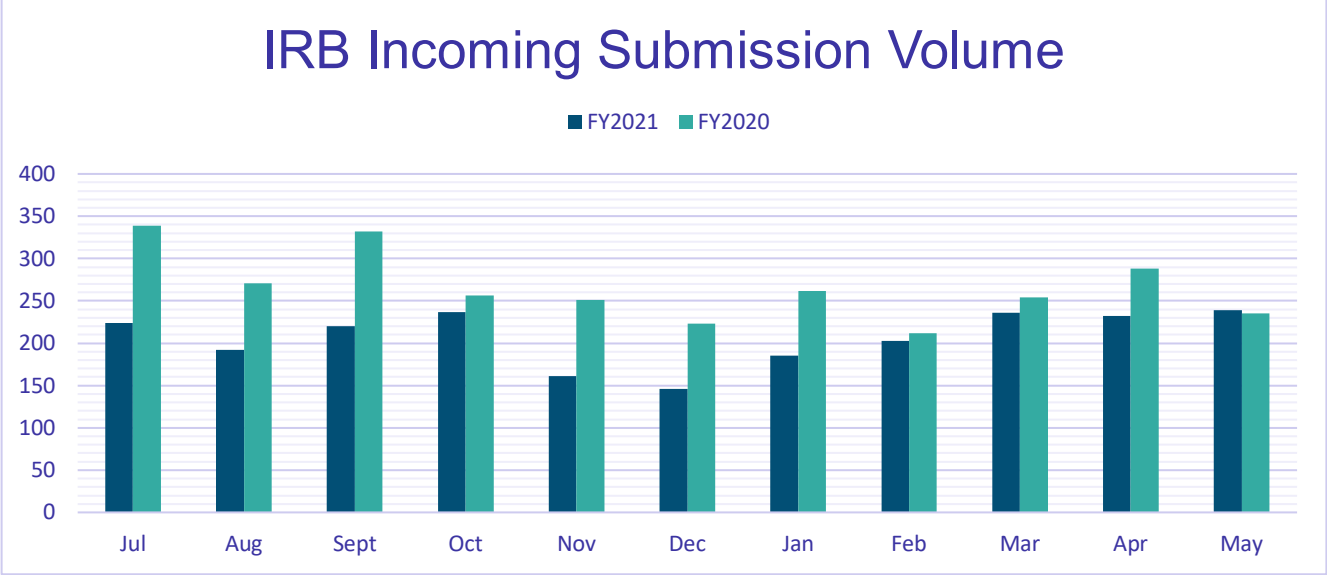


Table 4 represents the IRB’s completion rate for fiscal year 2021. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

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); 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
Initial Study Total Received	101	83	84	109	92	86	92	83	105	106	78
Approved Full	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	7	5	4	3	2	3	5	4	4	6	6
Approved Exempt	26	27	20	35	21	18	29	26	35	30	15
Not Human Research	12	4	11	11	4	4	8	8	12	12	8
Human Research, Not Engaged	0	1	0	0	0	0	0	0	1	0	0
Disapproved	0	0	0	0	0	0	0	0	0	0	0
Review Complete	45	37	35	49	27	25	42	38	52	48	29
Clarification Requested (Pre-Review & Designated Review)	28	25	29	24	34	19	27	30	33	25	26
Modifications Required	1	1	0	0	0	0	2	0	1	1	2
Pre-Review	27	20	17	36	31	42	21	15	19	28	21
In-Review	56	46	46	60	65	61	50	45	53	54	49
Percent Complete per Month	45%	45%	42%	45%	29%	29%	46%	46%	50%	45%	37%

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.*

Purpose: Review the quarter's Investigator Quality Improvement Assessments and look for trends and areas for improvement			
Description: Randomly select Investigator on a monthly basis to complete the HRP-430 for a specific study			
Q4 Investigator Assessment			
Date	QA Project	Findings/Trends	Potential Causes/Notes
March	<i>CONFIDENTIAL CONTENT REMOVED</i>		
April			
May			
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.*

Purpose: Review the quarter's IRB Meeting Minutes and look for trends and areas for improvement			
Description: Complete HRP-431 on a montly basis			
Date	Findings/Trends	Potential Causes/Notes	Action Plan
Q-4			
March	Should "Do the minutes describe the Report of New Information?" be removed from form? When might this information be included, such that "yes" would be checked? HRP-043 does not include information about whether a description of the RNI should be included in the meeting minutes.	Information *is* included about the RNI through the letter/meeting minutes overview.	No action plan is needed
April	No meeting		Not applicable
May	No issues noted		No issues noted

Training, Outreach, and Other Initiatives - FY2021 Overview

AAHRPP Accreditation

We did it! We're fully accredited. It truly took a village – from ensuring that all policies, procedures, and documents met regulatory and AAHRPP standard, to preparing and educating our community, planning the logistics of a fully remote site visit, as well as all the other tiny and not so tiny details that it took to receive full accreditation - we have reached the gold standard.

Undergraduate Research Training Program

The URTP, a comprehensive platform to create better prepared undergraduate researchers, continues to grow and flourish. The URTP is comprised of research ethics training sessions, a student-focused curriculum, and an online decision form that will assist students in determining whether their project requires IRB review. For this fiscal year, we have had over 200 students complete the URTP Decision Form and over 100 of these students took part in our in-person (now Zoom) research ethics training sessions.

Training by Request

For this fiscal year, there have been 18 presentations to various Schools and Departments across the University including the Davis Center, History of Science (FAS), Office of Institutional Research, Graduate School of Design/School of Engineering and Applied Science joint program, Anthropology (FAS), Harvard School of Continuing Education, Harvard Global Health Institute, and the Harvard Graduate School of Education. While most trainings focus on IRB regulatory basics, we receive specific topic requests from programs, such as how to submit an IRB submission and common questions from Doctoral students.

IRB Office Hours

The Harvard Law School, Harvard Kennedy School, the Harvard Psychology Department, and the Harvard Graduate School of Education take part in our monthly IRB office hours program. For this fiscal year, we have held over 30 IRB Office Hours sessions.

IRB Lifecycle Guide

As IRB review is an often misunderstood or unknown process and a source of frustration to many researchers, during this fiscal year we unveiled the mystery of this process on our website, the IRB Lifecycle Guide. We simplified the process according to the different “life” stages of the review – before submission, during submission, after submission, and the afterlife (closing a study). Each stage provides an overview of the rationale, what a researcher needs to know, IRB tips, as well as links to helpful resources and documents. The IRB Lifecycle Guide may be found on the main IRB webpage [here](#).

IRB Website

Our website contained a lot of information and it was often difficult to find what you needed. We have made substantial improvements to our website during this fiscal year to not only include the IRB Lifecycle Guide (as described above) but we also revised the following:

- “For Participants” section to make information easier to find, clearer, as well as using various formats to display content (e.g., pictures and videos).
- “Training” section has been expanded to include information on frequently asked questions.
- Overall format has been changed to be more visually pleasing.
- And, most importantly, we have also undertaken an “accessibility test” of our website to ensure that people with disabilities are able to easily navigate our website and find the information that is needed.

Handouts

In our continued effort to educate the research community about human subject regulations, we added new handouts to our arsenal of trifold’s. Our handout library include popular topics such as: What is the IRB?, Do I need IRB review?, NIH Basics I: Requirements that apply to all NIH funded research, NIH Basics II: Requirements for research that meets the NIH definition of a clinical trial, An Introduction to the URTP, An Overview of the Human Subject Regulation Changes, and FDA Basics.

IRB Newsletter

Our subscription rate continues to grow, and we now have over 6,000 subscribers. The newsletter has proven invaluable in informing our research community of upcoming regulatory changes, AAHRPP news and education, as well as teaching researchers “how to speak IRB”. Check out our newsletter archive [here](#).

COVID-19 Research

To date, the IRB office has reviewed and approved close to 200 initial studies, over 250 modifications to existing studies, and 15 IRB reliance agreements that pertained to research focusing on COVID or study procedure changes because of COVID. We also provided priority review for these studies due to the time-sensitive nature of this research – a big win with the research community.

COVID-19 Information for the Research Community

The COVID-19 pandemic defined fiscal year 2021 and continually required the research compliance community to be nimble and to provide support and guidance, even if we were not certain what that support and guidance would be the next day. Working in tandem with the University’s research resumption group, we continued to develop guidance, templates, as well as standard operating procedures to assist researchers and their Schools to get in-person human subjects research up and running.

Working Remotely

The COVID pandemic upended routines, changed the way that the office works together, and introduced us to a new phenomenon, Zoom fatigue. To make this remote working environment a little bit more comfortable and a little bit more normal, mid-pandemic we developed a “Working Remotely Re-launch” to figure out what our working needs were, re-assess resources, and re-

establish norms by creating a routine for our office. The Re-Launch included creating a shared working schedule that includes “quiet times” so that we are aware of how and when we work, creating a Microsoft Teams group to stay in touch in real time, establishing norms for how we communicate, and creating spaces where we can just ‘hang-out’.

During this time, we also successfully hired two new staff members and trained three staff members in their new roles, all remotely.

ReDSOC

The Research Data Security Operations Committee (“ReDSOC”) is a monthly meeting comprised of representatives from Harvard Information Security, Harvard School Security Officers (SSO’s), and the Harvard IRB’s. The group has been successful at streamlining processes for data security review, including the revision of the process by which Harvard IRB’s categorize research data, how the IRB notifies the SSO of the need for review of sensitive research data, as well as gaining a better understanding of how we work together.

Study Staff Modification Review and Approval

The addition or removal of study staff is the most common, high volume, and time sensitive modification that the IRB office receives. This is also the submission that receives the most complaints when a review takes too long. During this fiscal year, we have revised our process for the review of these modifications. Our ready, able, and responsible IRB Coordinator is now in charge of the review and approval of all Harvard study staff modifications. As our IRB Coordinator is not part of our review staff and does not carry a portfolio of existing studies, she is able to nimbly attend to these incoming modifications.

Looking Forward – Goals for FY2022

- IRB 101 Sessions – Create drop-in sessions that will cover topics such as *Regulatory Basics*, *What Forms to Use When*, and *Tricks of the Trade*, among others. The sessions will be scheduled at various times during the year and will utilize a drop-in attendance approach.
- Expansion of our burgeoning QA/QI Program – As a requirement of AAHRPP accreditation, we need an expansion of our current program. The goal is to develop a structured approach to target areas of non-compliance, create a post-approval monitoring program, and grow a continuous process improvement evaluation of the IRB review process to identify areas where quality or efficiency could be improved.
- Work Better Together – To work more closely with other University offices to streamline processes and identify pain points for administrators and researchers.
- Continue to Grow and Develop IRB Staff – Create a learning environment for staff to aid in retention, assist in professional development, and create a healthy workplace where all feel valued.