Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, January – March 2023

March 9, 2023

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."

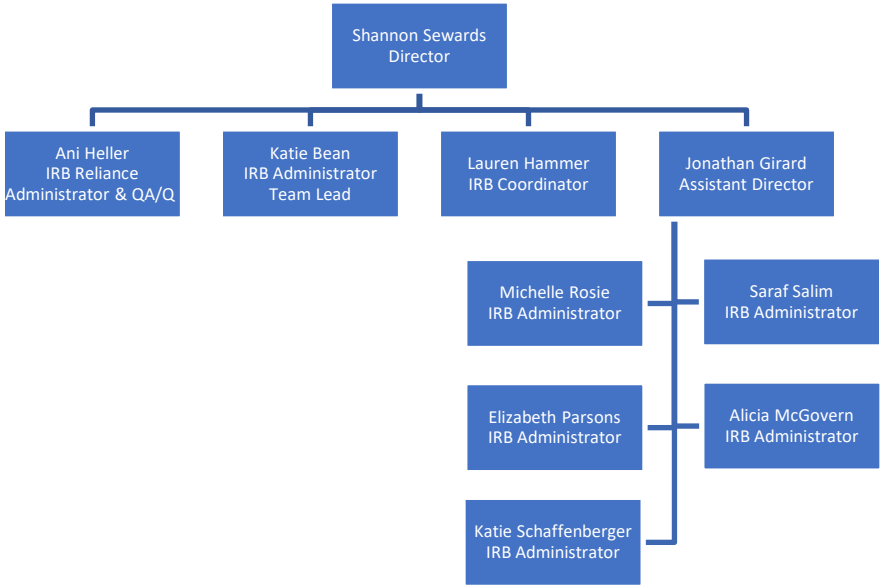
Who We Are

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 2023 to date (July 2022 to February 2023). Table 2 and Graph 2 are the same comparison however represent metrics for Fiscal Year 2022 (July 2021 – February 2022).

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).

Please see next page →

Table 1

IRB Staff Review Time versus Total Review Time FY23																
	Jul-22		Aug-22		Sep-22		Oct-22		Nov-22		Dec-23		Jan-23		Feb-23	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	18	53	21	55	21	50	13	40	22	48	17	81	11	24	0	0
Exempt	8	24	9	31	13	34	9	24	10	26	8	19	7	19	4	11
NHSR	2	5	5	12	4	8	5	12	3	8	6	11	3	7	2	2
Expedited Modification	3	7	4	8	4	9	5	11	4	9	5	8	2	4	1	2

Graph 1

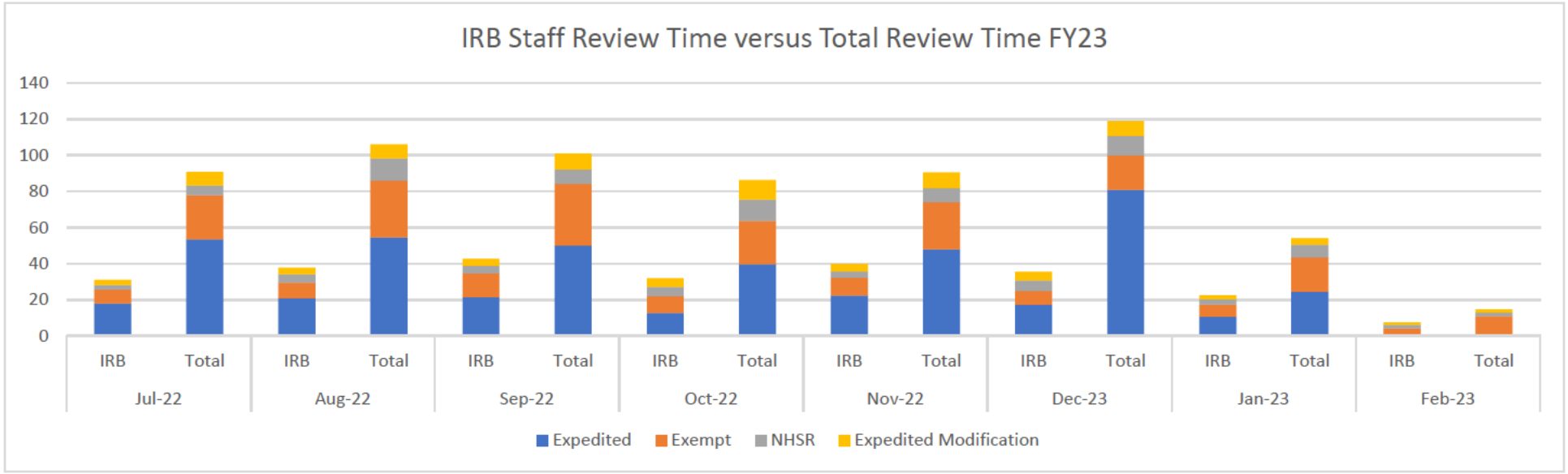


Table 2

IRB Staff Review Time versus Total Review Time FY22																
	Jul-21		Aug-21		Sep-21		Oct-21		Nov-21		Dec-22		Jan-22		Feb-22	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	14	52	17	53	27	82	24	68	20	68	17	77	16	57	7	46
Exempt	8	29	8	22	6	25	4	16	9	32	15	42	7	20	8	23
NHSR	6	13	7	16	9	16	7	11	12	14	24	36	9	21	10	27
Expedited Modification	3	6	4	8	4	9	4	8	4	9	5	14	4	10	3	7

Graph 2

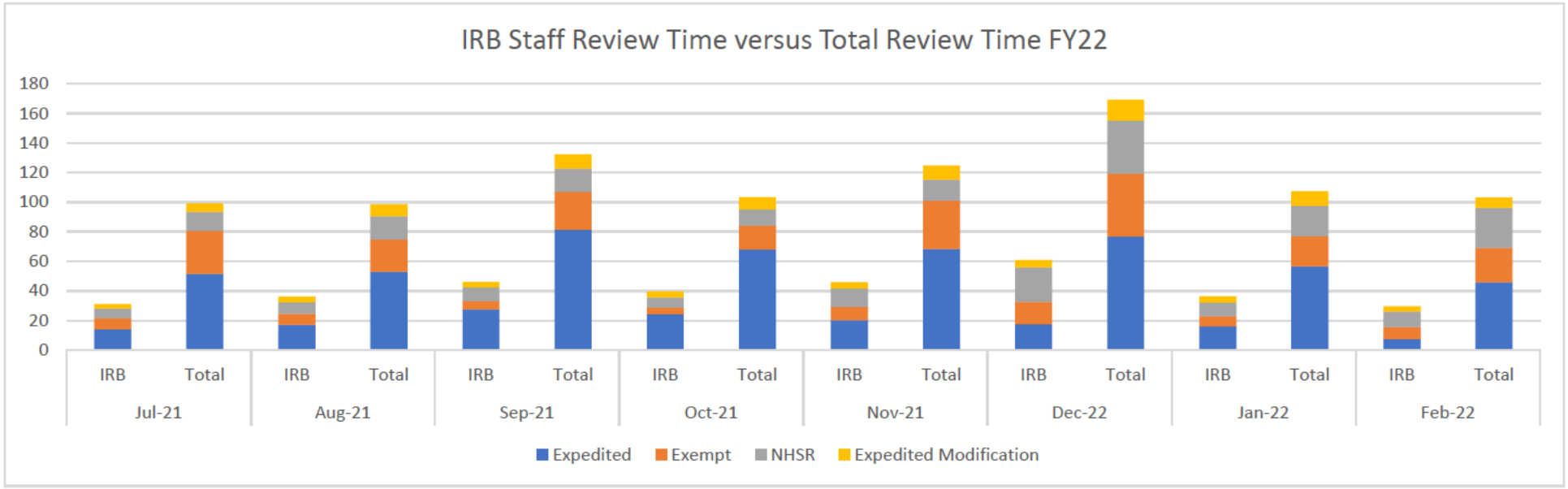


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for comparative Fiscal Years 2021, 2022, and 2023. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions which following review, 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
FY21	**221**	**190**	**218**	**234**	**158**	**144**	**184**	**200**
FY22	**195**	**186**	**206**	**181**	**186**	**113**	**150**	**186**
FY23	**201**	**190**	**205**	**171**	**160**	**102**	**184**	**182**

Graph 3

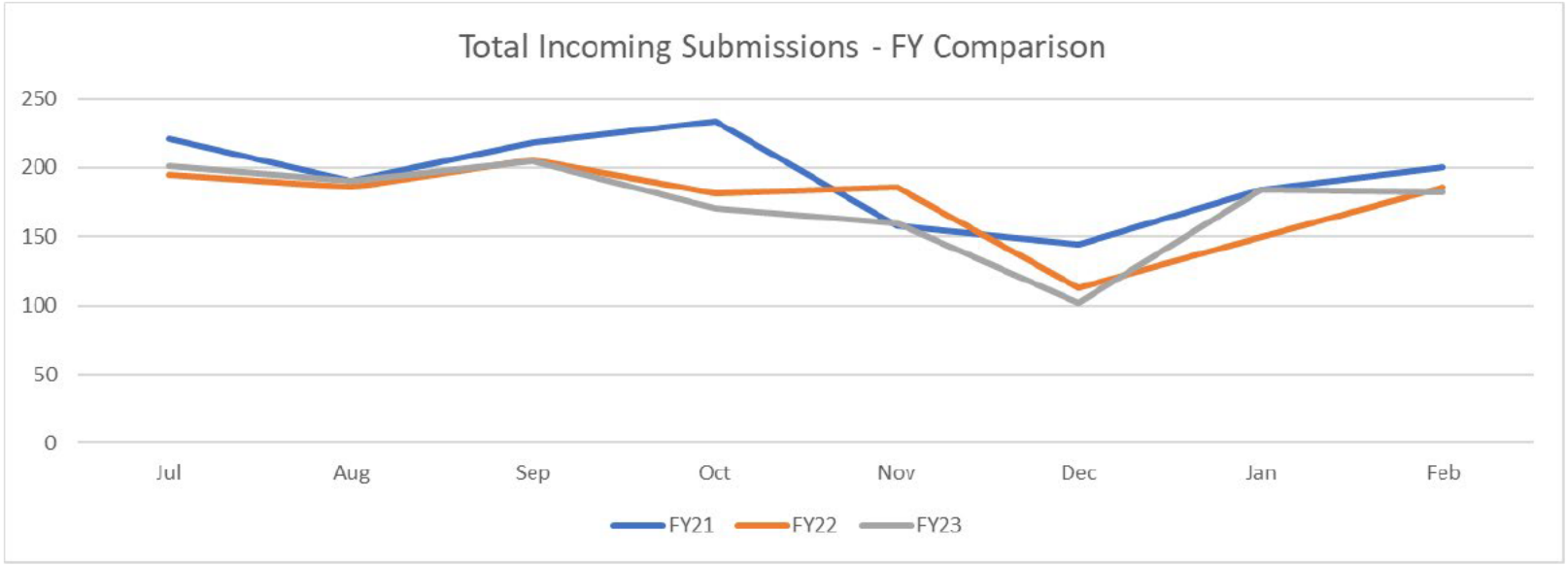


Table 4 represents the IRB's completion rate for Fiscal Year 2023 (July 2022 through February 2023). Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in September 2022, the IRB office received a total of 78 initial submissions. Of those 78 submissions, 33 received a determination or approval by month's end while 45 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-Jul	*Aug-22*	*22-Sep*	*22-Oct*	*22-Nov*	*22-Dec*	*23-Jan*	*23-Feb*
Initial Study Total Received	**86**	**85**	**78**	**77**	**91**	**71**	**79**	**77**
Approved Full	0		0	0	0	0	0	0
Approved Expedited	3	1	1	2	0	0	3	0
Approved Exempt	21	22	17	14	20	22	11	21
Not Human Research	8	10	15	11	12	5	12	9
Human Research, Not Engaged	1	0	0	0	0	1	0	0
Disapproved	0	0	0	0	0	0	0	0
Review Complete	**33**	**33**	**33**	**26**	**32**	**28**	**26**	**30**
Clarification Requested (Pre-Review & Designated Review)	32	38	29	40	46	21	32	32
Modifications Required	2	0	1	0	0	0	0	0
Pre-Review	19	14	15	11	13	22	20	14
In-Review	**53**	**52**	**45**	**51**	**59**	**43**	**52**	**46**
Percent Complete per Month	**38%**	**39%**	**42%**	**34%**	**35%**	**39%**	**33%**	**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	Department/School	Quarterly Check-In Date
December	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
January	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
February	[redacted]	[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
December	*Yes*	*Consultant language was missing from a study that received a consultant review.*	*4/4/2023*
January	*Yes*	*No issues noted.*	*4/4/2023*
February	*Yes*	*Study is missing the language "Per IRB policy, any Consultant Reports are retained in the study record." It does include the name and does list the title of the document.*	*4/4/2023*

Training, Outreach, and Other Initiatives: January – March 2023

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from January 1, 2023, through March 1, 2023, our website had over 16,000 visitors with over 19,000 page views. 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 January 1, 2023, through March 1, 2023, the HUA IRB office has held the following outreach and training sessions:

- 42 IRB office hour sessions (general meetings)
- 3 IRB office hour sessions with HKS affiliates
- 2 IRB office hour sessions with HLS affiliates
- 2 IRB office hour session with affiliates from the Psychology Department
- 4 requested trainings for specific courses, departments, or programs including HGSD, HGSE, FAS Sociology, Davis Center, and the HLS.

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

Also of significance, there have been over 1,750 completions of the Undergraduate Research Training Program (URTP) decision form and 8,750 completions of the Harvard Non-Affiliate Protecting Human Research Participants (PHRP) training to date.

IRB Newsletter

Topics for our January, February, and March newsletters included the following:

- **January 2023**: Welcome back from Winter Recess, New Year Resolution – suggestions for common problems, and the Do you Speak IRB? topic, Engagement.
- **February 2023**: NIH DMSP Now Live, NIH DMSP Survey to Assess Needs of the Harvard Research Community, and the Do You Speak IRB? topic, Determination versus Approval.

- **March 2023**: NIH DMSP Survey to Assess Needs of the Harvard Research Community, GAO Report on the Oversight and Effectiveness of IRBs, and the Do You Speak IRB? topic, Pilot studies - Do they require IRB oversight?

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: overview of the types of studies that have oversight by COMS and the ancillary review process, overview of the types of studies that have oversight by Radiation Safety and the ancillary review process, the Office of Undergraduate Review criteria and process, and the Provostial Review criteria and process.

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: "agency", dealing with difficult people, AI in human subjects research, AI chat bots, NIH DMSP, Neuroscience and Law webinar, balancing risks and benefits, OHRP updates, and exempt categories refresher, among others.

Updates: January – March 2023

New and Improved HUA IRB Quality Assurance/Quality Improvement Program

AAHRPP Elements I.5.A, I.5.B, and I.5.D speak to the importance of a quality assurance program for all accredited Human Research Protection Programs (HRPP). A comprehensive QA/QI program should work to ensure compliance with applicable laws, regulations, codes, and guidance. According to AAHRPP, each part of the HRPP must be evaluated to assess the HRPP for compliance and quality, efficiency, and effectiveness of the HRPP.

Since mentioned at our previous meeting, we are working toward creating a more robust method of evaluating IRB member performance and how we might better evaluate the research communities compliance following IRB approval.

Clarity on Agency

Which IRB is the correct IRB to go to when you are a student working in several institutions for your dissertation research? What if you are a faculty member with multiple appointments? The answer rests in the regulatory concept of "agency". Given the many facets of Harvard and the

relationship between Harvard and affiliated hospitals, determining agency becomes quite complicated. The HUA IRB office has partnered with the HLC IRB office to work with OGC on establishing a clearer definition of agency. The definition will also include thinking points to create more transparency with how agency and which IRB one should report to is determined.

NIH DMSP Outreach

The HUA IRB has been actively engaged in the roll-out of the recent NIH Data Monitoring and Safety Policy (DSMP) at Harvard University: membership on the NIH DMSP Working Group, posting information on DSMP training opportunities on our website, in our newsletter, as well as training IRB staff on the policy and how we can assist the research community to be compliant.

URTP Update

The HUA IRB Undergraduate Research Training Program (URTP) continues to be successful. With over 1,750 students taking part, the program has not only educated students to be better researchers but has provided oversight of student research activity. The URTP is governed by an Advisory Committee which meets on a regular basis. At the last meeting, discussion centered on how we might revise the URTP decision form to create more inclusive language for students from all educational disciplines. As a reminder, the URTP decision form provides students with a decision on whether their research requires IRB oversight. We will be working toward this end in the coming months.

Website

We recently created a First Time Submitters Guide. The Guide covers the various tools available to those new to the IRB process including links to our IRB Lifecycle Guide, Harvard University Human Research Protection Program (HRPP) Plan, Investigator Manual, newsletter library, and ESTR User Guides. The First Time Submitters Guide also provides sage advice on timing and what to expect when submitting to the IRB. This section covers the various ancillary reviews as well as a link to our metrics portal. The First Time Submitters Guide can be accessed here.

Re-Accreditation Effort

Initial AAHRPP accreditation is active for three years with the re-accreditation application due one year prior. This means that we are currently working on our re-accreditation application. This process requires that we review every document that is part of our toolkit and to re-examine our processes to ensure that we are following AAHRPP requirements and recommendations. This entails a great deal of work but fully worth the effort.

We have submitted our Step 1 application to AAHRPP and are awaiting the evaluation of our materials. Following, we will submit a Step 2 application with the final step being an AAHRPP site visit of our HRPP.