Report on Operations Quarterly Report

Harvard University Area Advisory Committee

Quarterly Meeting, September 2022 – December 2022

December 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."

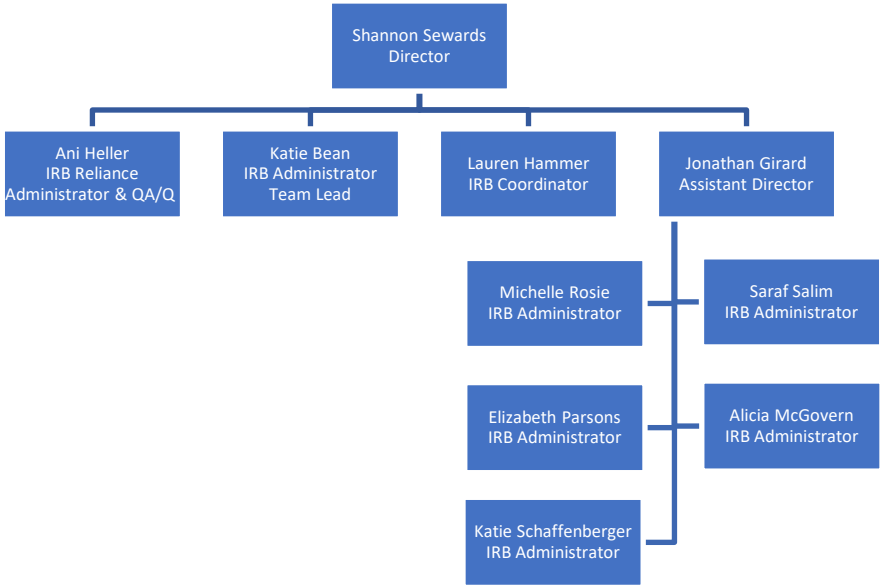
Who We Are

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 November 2022). Table 2 and Graph 2 are the same comparison however represent metrics for Calendar Year 2021 (January 2021 – November 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		Sep-22		Oct-22		Nov-22	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	16	57	7	46	14	48	12	34	11	42	16	61	18	53	18	49	17	39	10	23	0	0
Exempt	7	20	8	23	6	18	4	19	4	19	9	26	8	24	6	23	9	21	7	15	6	9
NHSR	9	21	10	27	6	9	4	8	4	15	8	11	2	5	5	12	4	8	5	9	3	5
Expedited Modification	4	10	3	7	2	6	2	9	3	9	2	5	3	7	4	8	3	7	3	5	2	3

Graph 1

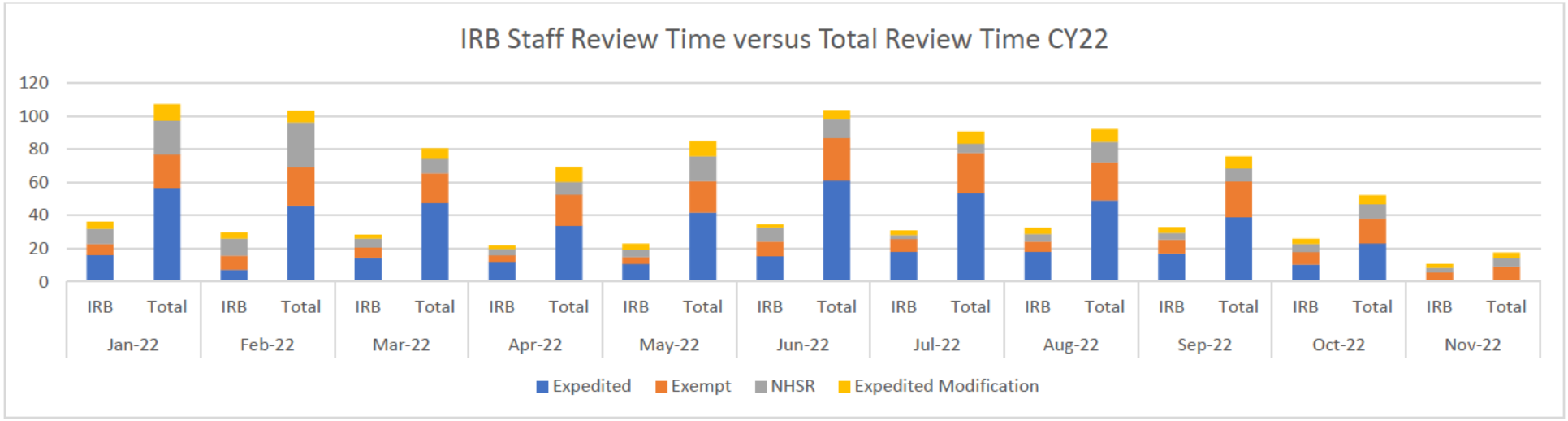


Table 2

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		Sep-21		Oct-21		Nov-21	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	19	52	11	36	13	43	16	45	14	39	20	43	14	52	17	53	26	78	24	68	20	68
Exempt	8	20	8	15	8	17	10	24	9	30	6	14	8	29	8	22	6	25	4	16	9	32
NHSR	7	14	8	11	7	16	6	13	14	26	6	13	6	13	7	16	9	16	7	11	12	14
Expedited Modification	7	12	8	13	7	14	4	9	3	5	3	7	3	6	4	8	4	9	4	8	4	9

Graph 2

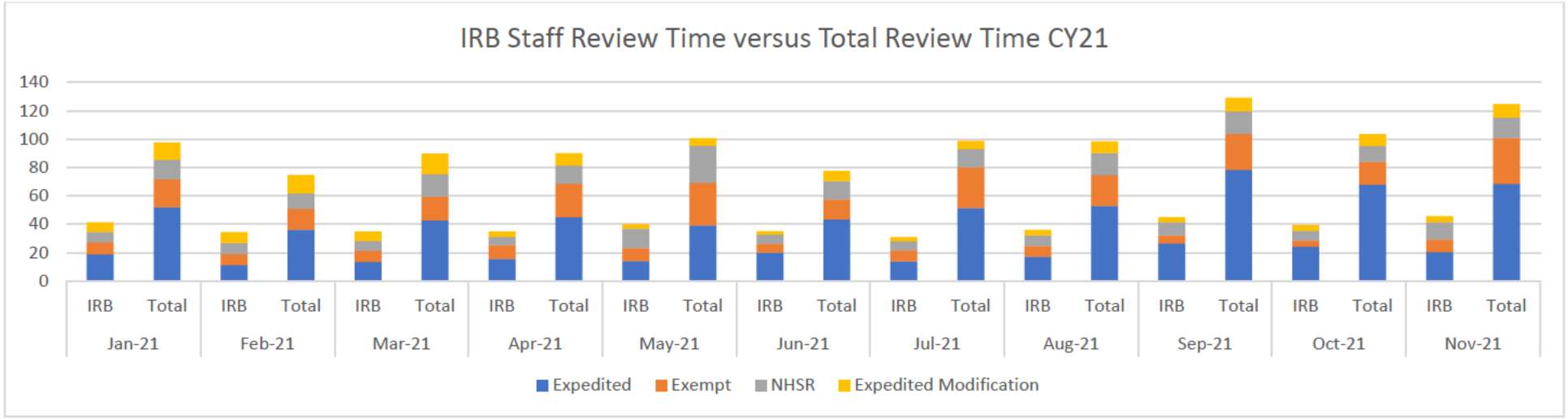


Table 3 and Graph 3 represent the overall volume of incoming submissions received during a given month for comparative Calendar Years 2020, 2021, and 2022. These submissions include "initial" submissions and "follow-on" submissions. Initial submissions are all new study submissions which following review, 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	Sep	Oct	Nov
CY20	262	211	252	284	232	282	222	190	218	235	158
CY21	184	200	229	219	224	229	196	187	207	181	186
CY22	150	186	207	203	220	255	203	193	208	177	180

Graph 3

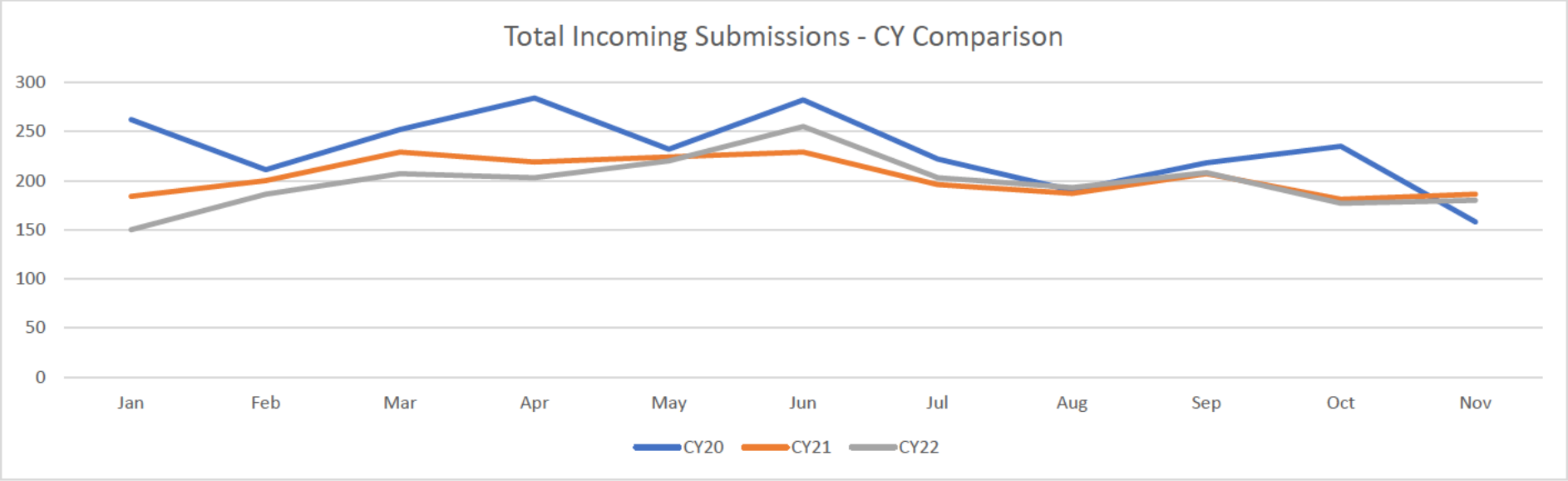


Table 4 represents the IRB's completion rate from January 2022 through November 2022. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

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*	*Aug-22*	*22-Sep*	*22-Oct*	*22-Nov*
Initial Study Total Received	**66**	**73**	**107**	**114**	**107**	**96**	**86**	**85**	**78**	**77**	**91**
Approved Full	0	0	0	0	0	0	0		0	0	0
Approved Expedited	1	3	3	2	5	0	3	1	1	2	0
Approved Exempt	16	20	30	4	26	28	21	22	17	14	20
Not Human Research	12	7	15	31	20	6	8	10	15	11	12
Human Research, Not Engaged	0	0	0	16	0	2	1	0	0	0	0
Disapproved	0	0	0	1	0	0	0	0	0	0	0
Review Complete	**29**	**30**	**48**	**54**	**51**	**36**	**33**	**33**	**33**	**26**	**32**
Clarification Requested (Pre-Review & Designated Review)	18	30	37	41	34	33	32	38	29	40	46
Modifications Required	0	0	1	1	3	1	2	0	1	0	0
Pre-Review	19	13	21	19	18	22	19	14	15	11	13
In-Review	**37**	**43**	**59**	**61**	**55**	**56**	**53**	**52**	**45**	**51**	**59**
Percent Complete per Month	**44%**	**41%**	**45%**	**47%**	**44%**	**38%**	**38%**	**39%**	**42%**	**34%**	**35%**

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
October	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
October (alternate)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
November	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
December	[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
September	*Yes*	*None*	*January 3, 2023*
October	*Yes*	*None*	*January 3, 2023*
November	*Yes*	*Submission ID is present, but the title of the study is not linked.*	*January 3, 2023*

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

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from September 1, 2022, through November 30, 2022, our website had over 12,000 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), *IRB main webpage*, and *required ethics training*.

IRB Outreach & Training

For the period from September 1, 2022, through December 1, 2022, the HUA IRB office has held the following outreach and training sessions:

- 63 IRB office hour sessions (general meetings)
- 7 IRB office hour sessions with HKS affiliates
- 3 IRB office hour sessions with HLS affiliates
- 0 IRB office hour session with affiliates from the Psychology Department
- 2 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.

Also of significance, there have been 1,700 completions of the Undergraduate Research Training Program (URTP) decision form and 8,500 completions of the Harvard Non-Affiliate Protecting Human Research Participants (PHRP) training to date.

IRB Newsletter

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

- **October 2022**: Reminder! Ensure that Your Study Team is Up to Date in ESTR, This is a Busy Time of Year for Us, and the Do you Speak IRB? topic, Research that Might Require IRB Oversight.
- **November 2022**: Are You Ready for the New NIH Data Management and Sharing Policy?, CITI Training Completion Now Available in the Harvard Training Portal, and the Do You Speak IRB? topic, Study Team Members.

- **December 2022**: More Resources to Prepare You for the NIH Data Safety Management Policy, Plan for Winter Recess, GSAS Student Dissertations and Agency, Remember to Use the Most Current Version of the IRB Protocol Template, and the Do You Speak IRB? topic, Scientific and Scholarly Review.

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: available IRB member resources, scientific review refresher, and what is a RNI refresher.

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: Harvard sponsored role policy, FERPA, research ethics and oversight in the digital age (webinar), NIH DSMP, FDA harmonization with the 2018 requirements, IRB meeting disapprovals, student dissertation research, research culture and respect, ESTR record deletion plans, among others.

Updates: September - December 2022

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.

The previous HUA HRPP QA/QI program met this threshold at the very basic level. To build a more comprehensive program and to incorporate existing QA/QI efforts, we created a more robust program that is outlined in the new standard operating procedure, "HRP-061 - SOP - HUA - QAQI Program". The new SOP provides a comprehensive overview of the following components of a QA/QI program: breadth of scope, prioritization, methods of assessment and monitoring, analysis and corrective action plan, reporting, documentation, and records.

The program is effective immediately and will also include our existing measures of quality and compliance, the Investigator QI assessment, and the assessment of minutes with regulatory compliance.

fCOI Form for COI Determinations

To minimize the actual or potential conflict of interest in research that involves human subjects, the IRB is required to ensure that all individuals involved in the design, conduct, or reporting of the research report related financial interests. The IRB relies on each School's fCOI officer to review the reported potential conflict and to inform the IRB of whether there is a conflict as well as how the conflict has been removed, reduced, or managed. The IRB uses the specifics from the fCOI officer and the details of the management plan to ensure that these measures are included in the research study. For example, if it has been determined that a fCOI should be disclosed to study participants, the IRB must ensure that proper and sufficient language is included in the study's informed consent form.

The IRB recognizes that in some instances the management plan may involve significantly more information than it needs, and there might be confidentiality reasons which prevent the Schools from sharing the full plan. To address these constraints, the HUA IRB office created a fCOI disclosure form, "HRP-450 - CHECKLIST - HUA - fCOI Determination". This form is completed by the fCOI officer to report various aspects of a fCOI when a (potential/actual) conflict has been identified on an IRB submission. The completed form is then shared with the IRB. The fCOI Council has provided its support of the form and the revised process began on December 1.

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!

Annual Billing Estimate for IRB Services

It is that time of the year again - shortly, you will receive your School's estimate for the Fiscal Year 2024. As a reminder, the estimates will be based on the estimated HUA IRB budget for the following fiscal year and the most recent full calendar year of distribution percentages of IRB actions. For example, the estimated IRB bill for FY24 will be based on total IRB actions for CY22 and the HUA IRB *estimated* budget for FY24.