Report on Operations

Harvard University Area Advisory Committee
Quarterly Meeting, January – March 2022
March 10, 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."

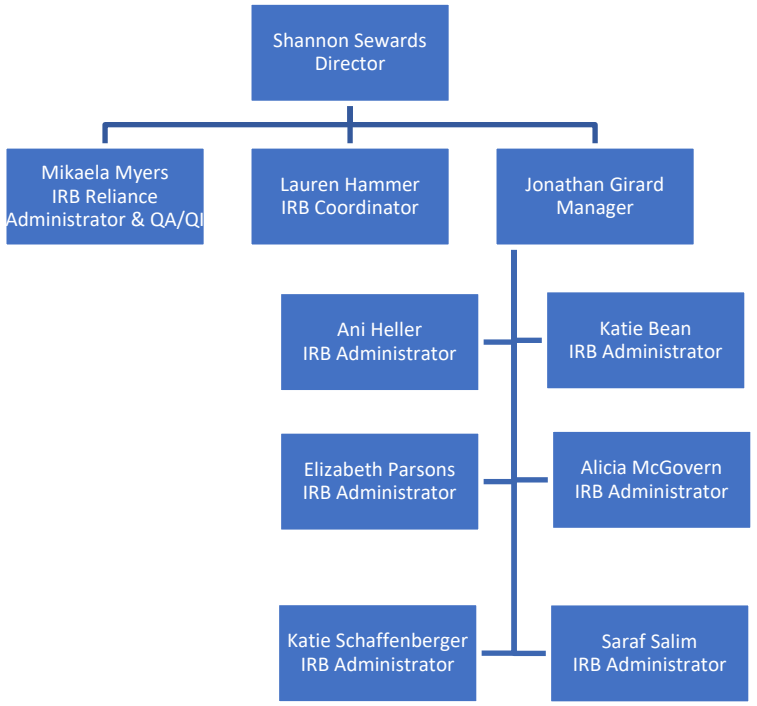
Who We Are

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 Fiscal Year 2022 to date (July 2021 – February 2022). Table 2 and Graph 2 are the same comparison however represent metrics for Fiscal Year 2021 (July 2020 – February 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 FY22																
	Jul-21		Aug-21		Sep-21		Oct-21		Nov-21		Dec-21		Jan-22		Feb-22	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	11	31	17	53	25	68	19	53	11	52	18	44	6	7	3	12
Exempt	8	29	8	22	5	20	4	12	9	29	10	27	5	12	5	8
NHSR	6	13	7	16	9	16	7	11	12	14	16	25	5	7	4	5
Expedited Modification	3	6	4	8	2	8	4	8	4	9	4	11	2	5	1	2

Graph 1

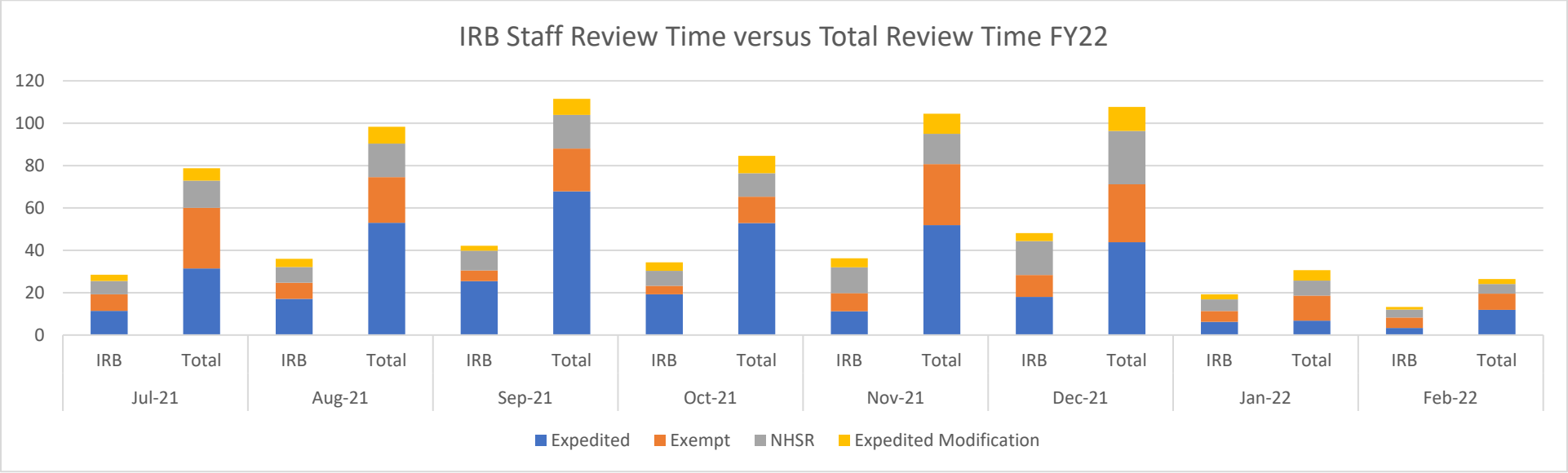
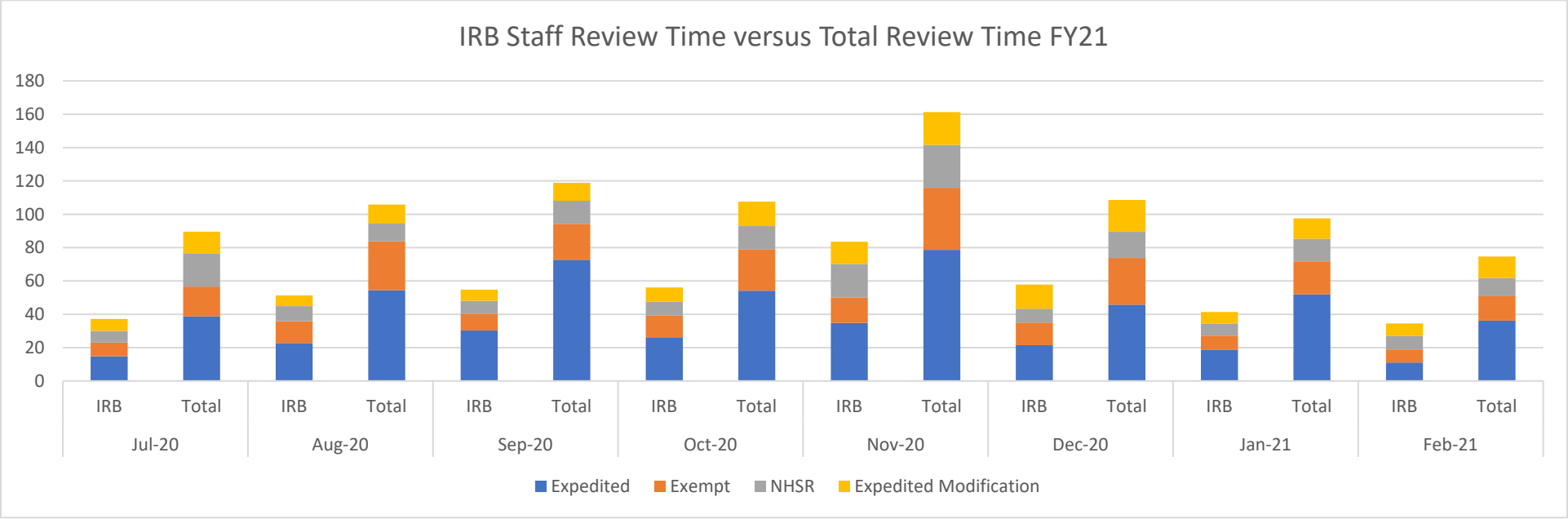


Table 2

IRB Staff Review Time versus Total Review Time FY21																
	Jul-20		Aug-20		Sep-20		Oct-20		Nov-20		Dec-20		Jan-21		Feb-21	
	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total	IRB	Total
Expedited	15	39	23	54	30	73	26	54	35	79	21	46	19	52	11	36
Exempt	8	18	13	29	10	22	13	25	15	37	14	28	8	20	8	15
NHSR	7	20	9	11	8	14	8	14	20	26	8	16	7	14	8	11
Expedited Modification	7	13	6	11	7	11	9	15	13	20	15	19	7	12	8	13

Graph 2



Graph 3 and Table 3 represent the overall volume of incoming submissions received during a given month for comparative Fiscal 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 - FY Comparison								
	Jul	**Aug**	**Sep**	**Oct**	**Nov**	**Dec**	**Jan**	**Feb**
FY20	339	270	329	255	247	221	262	211
FY21	223	190	219	237	159	144	184	201
FY22	196	191	208	185	193	121	157	206

Graph 3

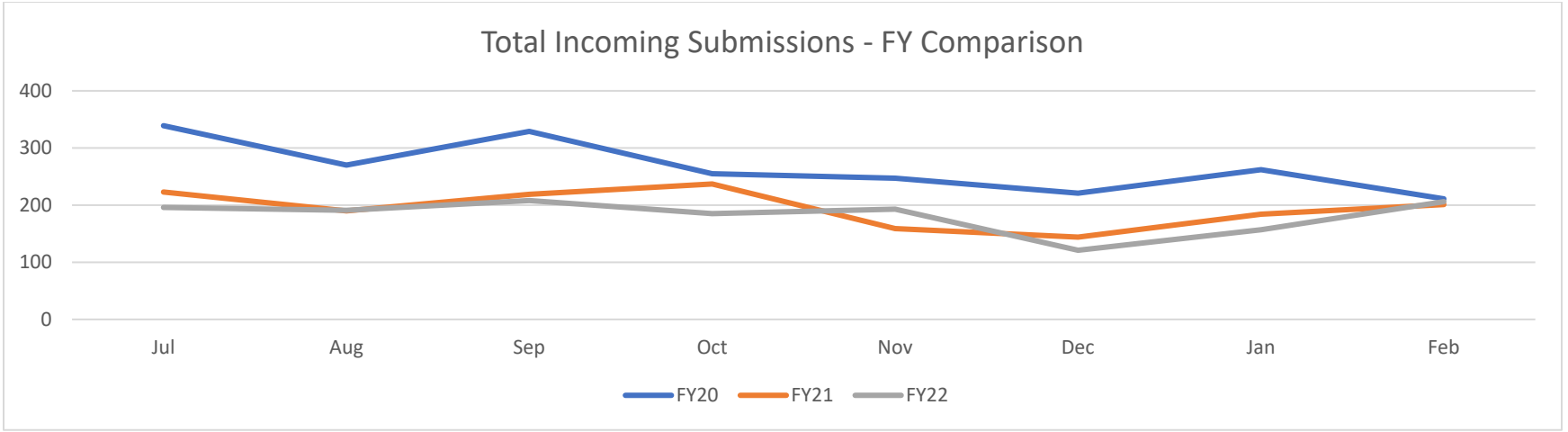


Table 4 represents the IRB's completion rate from January 2021 through February 2022. Please note that the numbers represented here only comprise initial submissions in any given month and do not include follow-on submissions such as modifications or continuing reviews.

As an example, in 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[1].

Table 4

Complete vs. in-Review (for initial submissions only)														
	Jan-21	*Feb-21*	*Mar-21*	*Apr-21*	*May-21*	*Jun-21*	*Jul-21*	*Aug-21*	*Sep-21*	*Oct-21*	*Nov-21*	*Dec-21*	*Jan-22*	*Feb-22*
Initial Study Total Received	**92**	**83**	**105**	**106**	**78**	**90**	**87**	**76**	**66**	**83**	**108**	**60**	**66**	**73**
Approved Full	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Approved Expedited	5	4	4	6	6	9	4	5	2	2	3	1	1	3
Approved Exempt	29	26	35	30	15	30	25	24	20	21	21	16	16	20
Not Human Research	8	8	12	12	8	14	10	6	9	11	12	2	12	7
Human Research, Not Engaged	0	0	1	0	0	0	0	1	0	1	1	0	0	0
Disapproved	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Review Complete	**42**	**38**	**52**	**48**	**29**	**53**	**39**	**36**	**31**	**35**	**37**	**19**	**29**	**30**
Clarification Requested (Pre-Review & Designated Review)	27	30	33	25	26	22	28	26	19	33	45	16	18	30
Modifications Required	2	0	1	1	2	0	0	0	0	2	1	1	0	0
Pre-Review	21	15	19	28	21	15	20	14	16	13	25	24	19	13
In-Review	**50**	**45**	**53**	**54**	**49**	**37**	**48**	**40**	**35**	**48**	**71**	**41**	**37**	43
Percent Complete per Month	**46%**	**46%**	**50%**	**45%**	**37%**	**59%**	**45%**	**47%**	**47%**	**42%**	**34%**	**32%**	**44%**	**41%**

[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)*

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	Quarterly Check-In Date
January	[redacted]	[redacted]	[redacted]	*March 18, 2022*
February	[redacted]	[redacted]	[redacted]	*March 18, 2022*

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
January	*Yes*	*None*	*March 18, 2022*
February	*Yes*	*Chair was not recorded in meeting minutes, because she was not in attendance. Chair Pro-Tem listed as substitution.*	*March 18, 2022*

Training, Outreach, and Other Initiatives: January – March 2022

HUA IRB Website

Our website continues to be a good resource for the research community. For the period from mid-December 2021 through the end of February 2022 our website had 8,361 new visitors and 1058 returning visitors. 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 mid-December 2021 through the end of February 2022, the HUA IRB office has held the following outreach and training sessions:

- 45 IRB office hour sessions (general meetings)
- 6 IRB office hour sessions with HKS affiliates
- 3 IRB office hour sessions with HLS affiliates
- 1 IRB office hour session with affiliates from the Psychology Department
- 1 training session with HGSE Pier Fellowship students
- 1 training session with FAS Anthropology/Archaeology program students
- 1 training session with FAS Anthropology (Ethnography) students

IRB Newsletter

Topics for our January, February, and March 2022 newsletters included the following:

- January 2022 – ESTR Unavailable 1/13-1/14; IRB office remote again; PIPL data considered sensitive; Changes to documentation requirements for GDPR, and the Do You Speak IRB topic - Exculpatory.
- February 2022 – Is it human subjects Research? We've got a form for that; If scheduling your IRB office hours using the online booking tool, check your spam/junk folder; What type of data is this; From the Office for Human Research Protection (OHRP) also known as our federal regulators - Free Webinar Series on the Basics of the Common Rule. Register Now; and the Do You Speak IRB topic – Human subjects research.

- March 2022 – New NIH data sharing policy; Proposed revisions to the NIH GDS policy; URTP training dates now posted; and the Do You Speak IRB topic – does oral history research require IRB 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: FDA basics, what to do when using a consultant for an IRB review, and expedited review categories.

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: Special considerations for research in Brazil, OHRP educational videos, not human subject determination considerations, identifiability of neuroimages, reliance agreements, MA State privacy law, return of results, NIH GDS policy, NIH data sharing policy, new NSF data sharing platform, and criteria for consent, among others.

Updates: January – March 2022

Return to the office

The IRB office has re-returned to the office beginning March 1, 2022. We have embraced a hybrid work model with our "anchor" day being Tuesday. Staff previously 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.

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 Community Members that will begin their membership with our March IRB meeting.

Revision to School and Department Distribution Delayed

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. We expect this revision to occur in mid-April 2022.

As a reminder, 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.

Annual Toolkit Review

As an AAHRPP accreditation requirement, we are amid our annual HRPP toolkit review to identify inconsistencies, and errors, as well as make any needed updates. Our toolkit includes all standard operating procedures, forms, worksheets, checklists, among other items used during our day-to-day business process.