Quality Assurance / Quality Improvement Activities Summary Calendar

Year 2021

In calendar year 2021, the Office of Research Integrity's Quality Assurance / Quality Improvement (QA/QI) Program was hard at work in multiple projects and activities. The QA/QI program continued to play an integral role in pivoting human subjects research activities to adapt to remote procedures as needed, and in the context of assisting the research community in maintaining compliance with human subjects protections procedures during unique and unusual circumstances. These efforts are not detailed in this report, nor are the routine activities that the QA/QI Program performs related to monthly metrics which enable the IRB and Human Research Protection Program to identify positive trends and celebrate successes, and pinpoint areas that could benefit from targeted interventions.

Below, we have noted some updates to current QA/QI program activities as well as a brief description of new initiatives specific to the QA/QI.

Update: New Investigator/Research Staff Onboarding Program (formerly named New Investigator Onboarding Program): The program name evolved given increased demand in expanding the scope of this program to include those who have been delegated by the PI to prepare and submit IRB protocols for review. Since the start of the program in May of 2019, the goals of the program have remained constant: 1) to facilitate a positive, supportive transition for new faculty and their staff to human subject research at Brown University; 2) to introduce them to HRPP and IRB policies and procedures and resources as a means of increasing the quality of IRB submissions and, subsequently, the efficiency of protocol review.

In an effort to improve program visibility to the research community, it is now included as an option for those who use the "Request A Meeting" resource on the HRPP landing page. The session is followed by a request to complete a brief evaluation of the session. Of all respondents as of 12/31/21, 95% rated the overall session as either "excellent" or "very good." We are continuing to strategize ways to improve visibility of this program and encourage participation of newer members of human subject research teams.

New: Quick Pulse Surveys: The QA/QI program launched quarterly quick pulse surveys (QPS) in early 2021. These anonymous, personalized surveys were distributed at the end of each quarter throughout the 2021 calendar year to PIs who had a new IRB Application approved in the most recent quarter. Beginning in December 2021 we also implemented a monthly QPS for Amendment submissions.

In calendar year 2021, 85 Investigators who had a new protocol approved provided feedback through the QPS. This data reflects highly positive feedback received from our research community relative to their satisfaction with HRPP team members Knowledge and Support (Figure 1) as well as their satisfaction with Turn around Times (TaTs), (the time from submission to approval) (Figure 2).

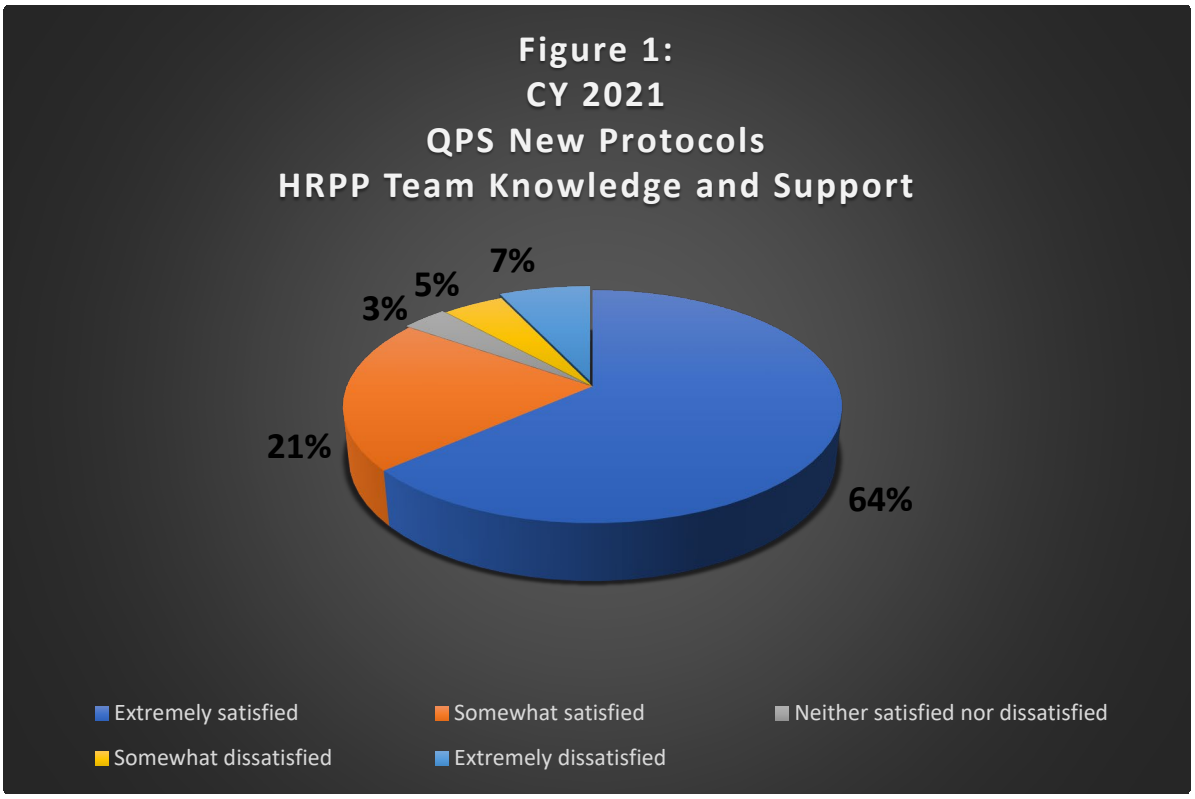


Figure 1:
CY 2021
QPS New Protocols
HRPP Team Knowledge and Support
7%
5%
3%
21%
64%
Extremely satisfied
Somewhat satisfied
Neither satisfied nor dissatisfied
Somewhat dissatisfied
Extremely dissatisfied

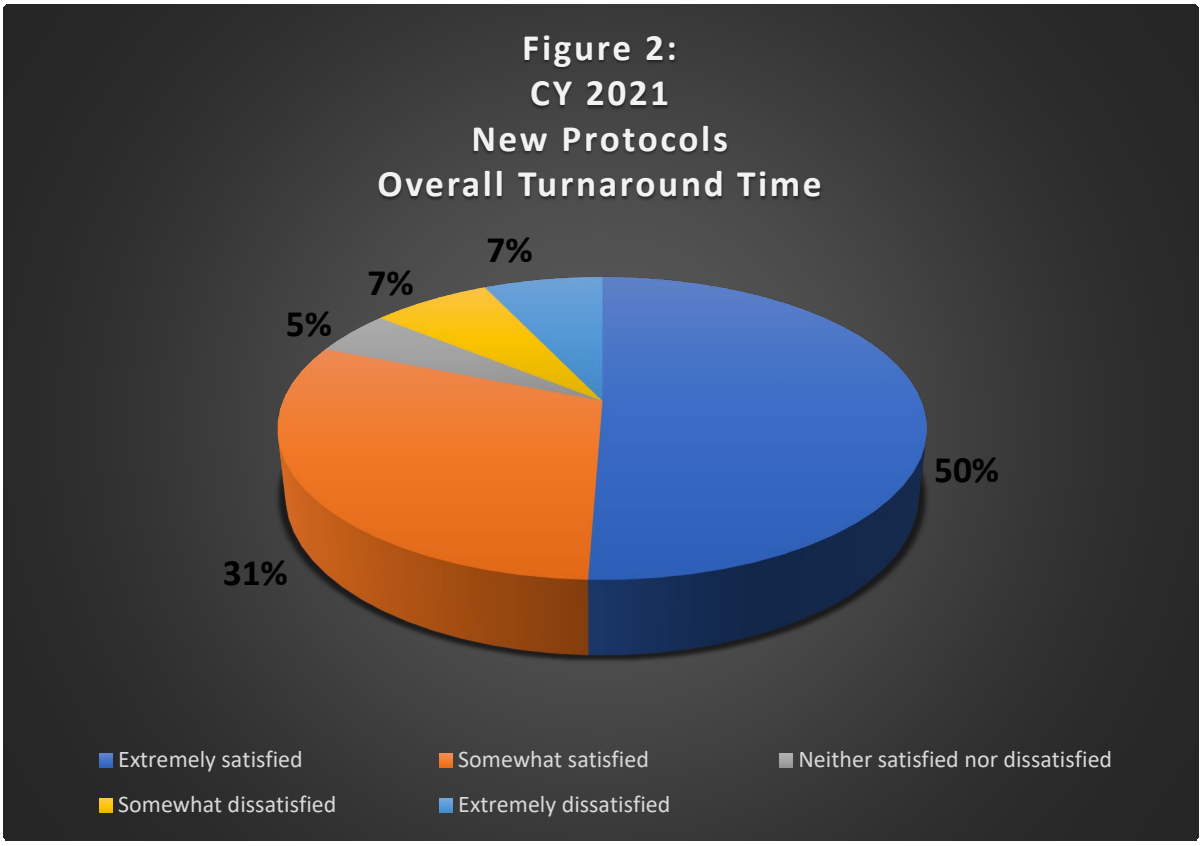
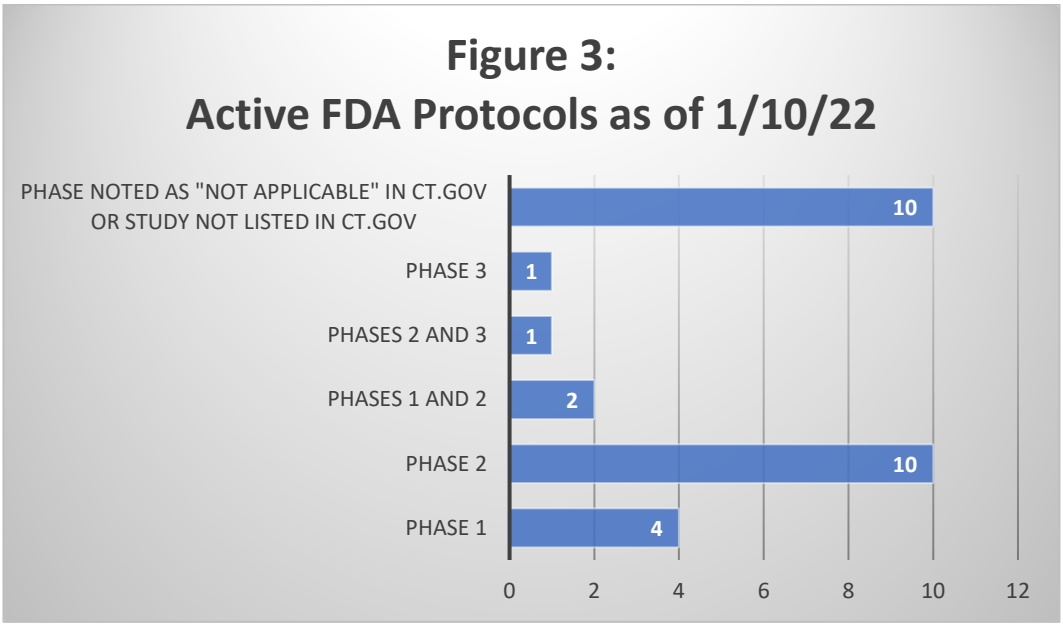


Figure 2:
CY 2021
New Protocols
Overall Turnaround Time
7%
7%
5%
50%
31%
Extremely satisfied
Somewhat satisfied
Neither satisfied nor dissatisfied
Somewhat dissatisfied
Extremely dissatisfied

Other QA/QI Projects:

Assessment of FDA Protocols and Clinical Trials

The QA/QI program continued the process of data cleaning in preparation for the migration of data to the Huron electronic submission system. The data cleaning for clinical trials involved reviewing each clinical trial record (n=119) to confirm if the clinical trial number (NCT) was noted in the protocol record and also if the clinical trial was FDA regulated. The FDA regulated protocol review (n=28) involved confirming if all required FDA documentation (e.g. IBD, IDE and ITP numbers) were included in the protocol record. In addition, a summary of the number active FDA regulated protocols, based on clinical trial phase (as noted in Clinicaltrials.gov), was noted (Figure 3).



Assessment of Active Protocols by Department

In CY 2020 and 2021, there was a focused effort to close any protocols that had completed data collection and met the criteria for study closure. As a result of those efforts the QA/QI program worked with the research community to close over 300 protocols. Though those closures brought the active protocol caseload down for a period of time, (FY 2021 ended with 899 active protocols). FY 2022 began with a steady increase in submission volume of new protocols on a monthly basis. That steady increase has now once again brought our active protocol moving quickly towards 1000 (and beyond) as of 12/31/21 (Figure #4). We anticipate this steady increase in volume to continue in the coming months, eventually seeing our volume well above 1000 active protocols. As this trend evolves the QA/QI program will work closely with the HRPP and the research community to further assess the impact of program growth and identify areas in which we can create and implement new or improved business practices to assist with this growth.

Figure # 4:
of Active Protocols by Fiscal Year (FY)