

Quality Assurance / Quality Improvement Activities Summary

Calendar Year 2020

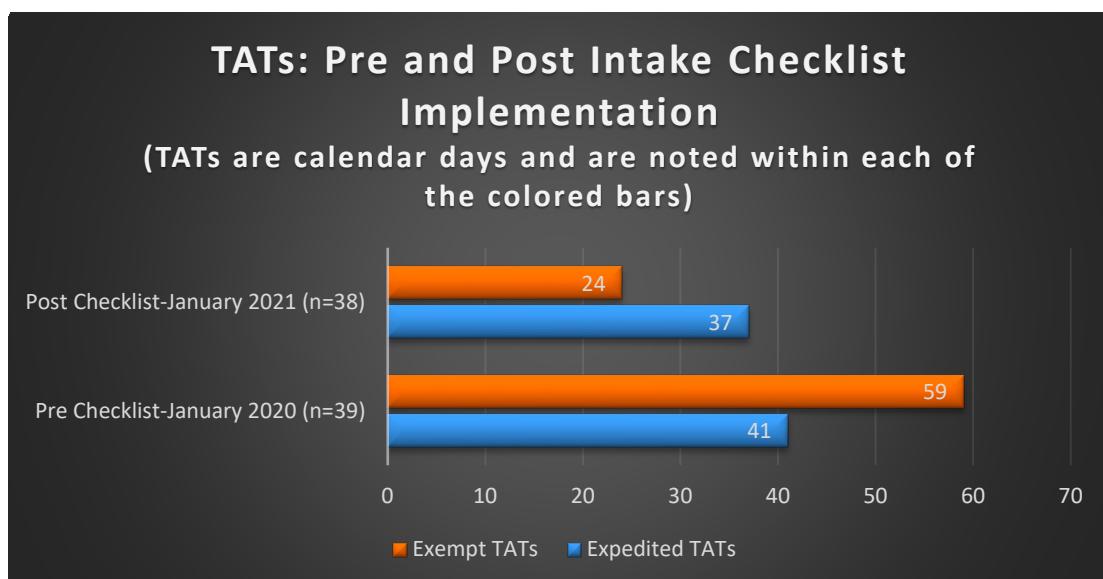
In calendar year 2020, the Office of Research Integrity's Quality Assurance / Quality Improvement (QA/QI) Program played an integral role in pivoting human subjects research activities to remote procedures and developing guidance and processes to promote human subjects research continuity both domestically and globally. 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. The New Investigator Onboarding Program, launched in 2019, continued its success throughout 2020. Efforts to increase this Program's outreach will be a focus in 2021.

Two major QA/QI initiatives were launched in CY20: one quality improvement project aimed to streamline the IRB Application intake process with the intended goal of shortening time-to-approval, and a second (described in two parts) intended to clean existing protocol data and improve compliance prior to migrating the human subjects research program into a new electronic system in 2021.

Major Initiative 1: Submission Intake Checklist

In collaboration with the Human Research Protection Program (HRPP) team, the QA/QI program helped to develop an IRB Submission Intake Checklist, designed to streamline the intake process, particularly for expedited and exempt submissions, by identifying and addressing common researcher errors and omissions. The goal was to ensure that when a submission reached an HRPP member or IRB member for review, the quality of the submission was higher as it had satisfied certain baseline criteria.

The Checklist was implemented on August 1, 2020 following several months of careful development. Both quantitative and qualitative analyses were conducted to assess the impact on turnaround times (TATs) as well as the Principal Investigators' and HRPP/IRB reviewers' experiences. The quantitative assessment comparing the TATs for the months of January 2020 and January 2021 indicates that TATs have decreased for both expedited and exempt reviews:



In addition to quantitative data, the QA/QI program also collected qualitative data from HRPP team members and PIs who received an approval or exempt determination since implementing the Checklist. This information reflected that the Checklist contributed to improved TATs and reduced the number of follow-up communications during the review process. Of those HRPP team members and PIs providing feedback, the chart below represents the % that reported fewer communications and shortened TATs from each perspective:

	Fewer communications	Shortened TATs
HRPP Feedback	100%	75%
PI Feedback	50%	50%

Additional qualitative feedback received from the PI respondents was also very positive and reflected a greater sense of satisfaction with the review process overall:

- *The research team appreciated the efficiency and diligence that Christina Bonney exhibited throughout the submission process to approval. We look forward to future submissions.*
- *I worked closely with Alana Chetlan and I found her very helpful. She had some good suggestions that I incorporated into the study.*
- *I thought the process ran smoothly, and I particularly appreciated the help from Sheila Vandal.*
- *Everyone I've corresponded with in the IRB office (Vanessa and Grace) has always been prompt and helpful.*

We will continue to monitor and assess the impact of the Checklist and will make adjustments as needed to help assure continued and improved expeditious review and approval of submissions.

Major Initiative 2: Data Cleaning

The data cleaning project focused on two protocol types: protocols involving an IRB Authorization Agreement (IAA) and Exempt protocols.

- 1) **IAA Project:** An extensive review of all active IAA protocols took place beginning in June of 2020. In the context of Covid-19 and associated public health concerns during the pandemic, Brown University implemented several new procedures applicable to conducting human subject research within the guidelines of state, local and federal agencies for the protection of all members of society. One of these new procedures was the requirement of attestations relative to research where an IAA was in place and Brown University ceded IRB review to another institution. Implementing this new procedure required outreach to the Brown PI of each of these studies individually. While this project was initiated in large part due to Covid-19, it was quickly identified as a quality assurance opportunity to confirm the active status of these IAA protocols, and subsequently close any protocols that were no longer active.

- There were 250 active IAA protocols at the outset of this initiative; PIs of these protocols were contacted individually to confirm project status
 - As a result, 68 IAA protocols were determined to be completed and/or otherwise able to be closed (as of 2/16/21)
 - 199 IAA protocols were confirmed to remain active and the PI provided the requisite Covid-19 IAA Attestation
 - Importantly, given OSP relies on IAA status to determine whether it can move forward to set-up a new award or continuation of an existing award involving human subjects, this initiative served a dual purpose of ensuring the accuracy of the IAA data in Coeus for award set-up.
- 2) **Exempt Research Protocols Project:** The second extensive review began in October 2020 and involved contacting PIs to determine the current status of Exempt protocols. Exempt protocols do not require a continuing review process, and as with all protocols, it is the PI's responsibility to inform the HRPP when a protocol is completed and should be closed. This review focused on older Exempt protocols active prior to 2020. An initial report of Exempt protocols reflected >350 such "active" protocols from 309 PIs. The QA/QI program reached out to all 309 PIs to learn the most recent status.
- There were 353 active Exempt protocols from 309 PIs, each of whom was contacted individually
 - As a result, 200 Exempt protocols were determined to be complete and/or otherwise able to be closed (as of 2/16/21)
 - 145 Exempt protocols were confirmed to remain active (as of 2/16/21)
 - Importantly, this project (and the IAA project) resulted in extensive data cleaning in Coeus to improve the integrity and accuracy of the data migrated to the new electronic system. It also served as a critical reminder to PIs of their responsibility to close out inactive protocols.