

Dear Boston Medical Center and Boston University Medical Campus researchers:

During the period of the COVID-19 pandemic, the IRB has received an extremely high volume of submissions. As shown in the below graph, there was a ~50% increase in the number of new submissions in the 3-month moving average starting in March. The total volume of submissions has now nearly reverted back to pre-COVID totals, but there are a couple of important factors that continue to impact the IRB's turnaround times:

1) While the total volume of submissions has slowed in the last six weeks, the amount of submissions the IRB was receiving during the height of the pandemic resulted in a considerable backlog. The IRB is working hard to winnow this list down to pre-COVID numbers, but the sharp increase takes time to work through.

2) The IRB continues to receive many new amendments seeking to incorporate changes being made to comply with institutional COVID-19 policies and Research Restart restrictions/risk mitigation plans. These amendments include changes such as adding new remote consent processes, modifying visit schedules to accommodate virtual visits, and adding new screening procedures (which may involve things such as new blood draws). These amendments are often very complicated and require a significant amount of review time. Please see FAQ #32 in [FAQs: Impact of COVID-19 on Human Subjects Research](#) for IRB guidance on submitting such amendments.

This is a “new world” for both study teams and the IRB, and effectively implementing these changes while maintaining compliance with HRPP policy and research and HIPAA regulations requires careful thought and collaboration between the IRB and the study team. There are many considerations, such as how to obtain consent/authorization signatures (or whether a waiver is justifiable), how to conduct appropriate recruitment outreach, and how to communicate study-related changes that are being made in response to COVID-19. The amount of effort needed to rework these protocols (and ensure that all changes are made consistently throughout) means that the total number of submissions an analyst is able to review each day is often fewer than we would ideally prefer.

Please also note that the IRB continues to need to implement a prioritization system in response to the current research environment. The IRB continues to prioritize certain types of COVID-related submissions, along with studies with strict funding deadlines and studies that are permitted to continue research activities during this period of COVID policies and restrictions on research. As a result, studies that are not directly COVID-related, especially those where enrollment is currently on hold, may be subject to delayed review times as compared to our usual turnaround time frame.

Please always feel free to reach out to discuss your particular submission and relay any relevant information by contacting medirb@bu.edu. We thank you for your patience and understanding.

