

# IRB Monthly Dashboard: 4/1/2023 – 4/30/2023

Average Monthly Turnaround Time for submissions requiring approval (calendar days) Service pledge = 42 days**										Total #Approvals (no RNIs) in Month by Submission Type							
	Initial Review			Continuing Review			Modifications				Initial Review		Continuing Review		Modifications		
	TAT	Last Month	YTD	TAT	Last Month	YTD	TAT	Last Month	YTD	This Month	Last Month	This Month	Last Month	This Month	Last Month		
Full Board	57/53	51/53	62	41/37	38/35	38	65/52	46/38	44	66	64	152	181	295	351		
Expedited	46/37	44/38	42	21/18	18/14	20	17/11	12/7	13	Total #Approvals (no RNIs included) in Month							
Total #Submissions in Month by Submission Type										This Month		Last Month		This Month in 2022			
Initial		Continuing Review		Modifications		RNI				513		596		534			
This Month	Last Month	This Month	Last Month	This Month	Last Month	This Month	Last Month			% of Approvals that Met the Service Pledge of 42 calendar days							
87	142	163	221	335	424	60	63			Initial Review		Continuing Review		Modifications			
Total #Submissions in Month										This Month		Last Month					
This Month		Last Month		This Month in 2022		YTD				Full Board		53%		43%			
645		850		606		2882				Expedited		49%		51%			

## INITIAL (R2R) EXTERNAL IRB METRICS

# Submissions		# Reliance Confirmed		Average TAT from Submission to Reliance Confirmed (Calendar Days)		% of Reliance Confirmed that Met the Service Pledge of 14 calendar days	
This Month	Last Month	This Month	Last Month	This Month	Last Month	This Month	Last Month
25	32	18	21	31/23	30/ <a href="#">28</a>	22%	14%

Blue # = Median TAT

**Green #** = TAT decreased >2 days from last month

**Red # = TAT increased >2 or more days from last month – see outliers on slide 2**

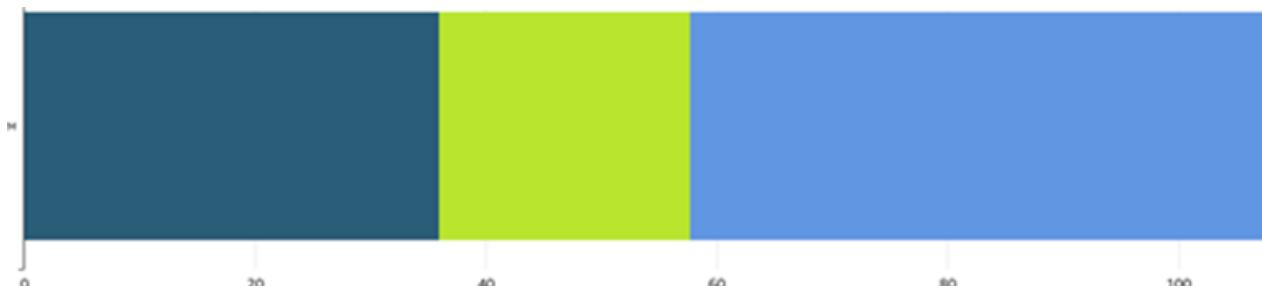
Outliers on slide 2  
Black # = TAT unchanged or less than 2 days changed from last month

\*\* Service pledge = 42 days from submission to Board meeting or Expedited approval

## Outlier Report FB INIT: Initial Review for FB projects TAT increased from 51 to 57 days.

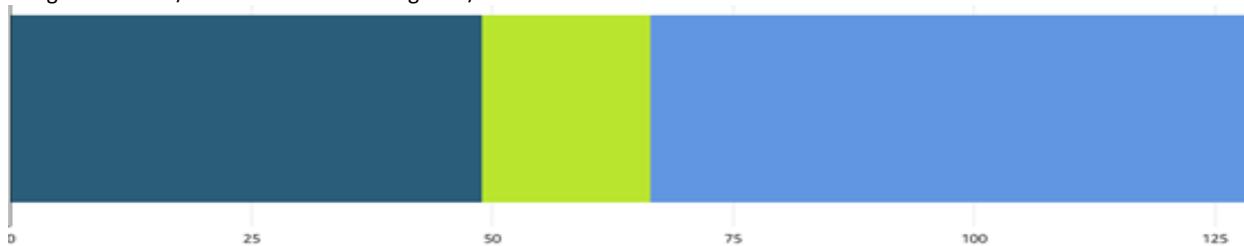
### 1. STUDY-22-01715 – 109 days

The project entered the IRB's queue on 12/13 and received a request for pre-review clarifications on 12/27. The study team took over 30 days to respond (two 'response time exceeded' messages in RUTH). This accounts for the bulk (>50%) of the delay in the project's processing time.



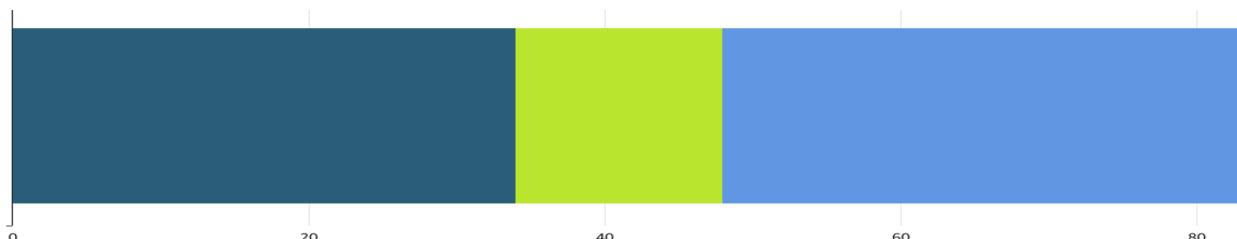
### 2. STUDY-22-01603 – 87 days

Study entered IRB queue on 11/22/22. Analyst returned clarifications on 12/2. Study was withdrawn on 1/3/23 after two response time exceeded messages (over 30 days). The study team submitted their response on 1/4, but the IRB analyst's requests were not completed, so further clarifications were sent back and forth until 2/2/23 (30 days in pre-review), when it was determined the study team would have to update their ICF to the new template given the 2/24 cutoff date and limited IRB meeting dates due to a holiday schedule. Study team did not complete the ICF transition correctly, so further clarifications were sent by the analyst on 2/10. The study team did not respond until 2/27 (17 days later). The project was assigned to the 3/28 Board C IRB meeting on 3/8.



### 3. STUDY-23-00039 – 84 days

Study entered IRB queue on 1/13/23. Analyst requested clarifications on 1/23/23. Study team responded on 2/14 (about 21 days later). The analyst's requested were not completed and there was continued back-and-forth until 3/15 (about 30 days later) when the project was assigned to the 4/4 Board D IRB meeting.



Pre-review (IRB Analyst responsible)

In Official Review (Non-Committee reviewer or Committee Reviewers responsible)

Changes Required (Study Teams responsible)

## Outlier Report FB CR: Continuing Review for Full Board Projects TAT increased from 38 to 41 Calendar Days

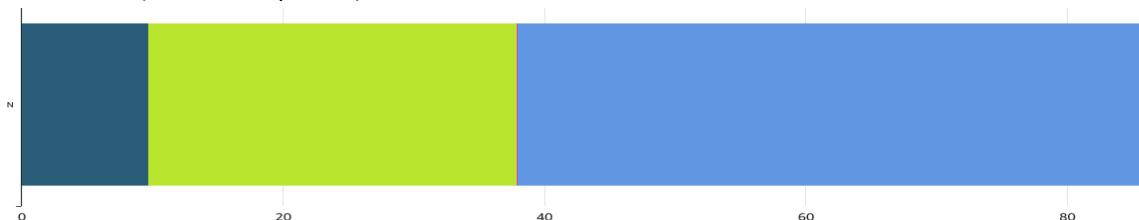
### 1. STUDY-13-00925-MODCR001 – 106 days

The project entered the IRB's queue on 12/22/22. It was processed and placed on the 2/7/23 Board D meeting, where it was MRSAd. The study team did not complete the MRSA and respond until 4/3/23, about 60 days later. This accounts for the bulk (>50%) of the delay in processing.  
summing a series or averages.



### 2. STUDY-17-00245-CR003 – 87 days

Study entered IRB queue on 1/6/23. Pre-review clarifications sent by analyst on 1/13/23. The issues were not resolved until 1/27/23, at which point the study team was told they would need to complete the ICF transition modification due to the cutoff date. The study team did not open a modification and submit response until 2/14 (about 15 days later). Study was placed on 3/7 Board D IRB. Study was moved to 3/14 Board A after the study team decided to substantially revise the study in their modification; this way both mod and CR could go to the same reviewer. CR was MRSAd due to incomplete GCO on 3/14. Study team did not complete the request until 4/3 (about 21 days later).



### 3. STUDY-14-00024-MODCR001 – 72 days

Entered IRB queue on 2/12/23 as Not-GTMR. Processed and sent to a chair for NCR on 3/23/23. Chair noted that project seemed to be incorrectly categorized. Staff & manager got involved. On 4/10/23 it was determined that the project had been modified in 2020 and should have been re-categorized as GTMR. Assigned to 4/18 IRB board B.



Pre-review  
(IRB  
Analyst  
responsible  
)

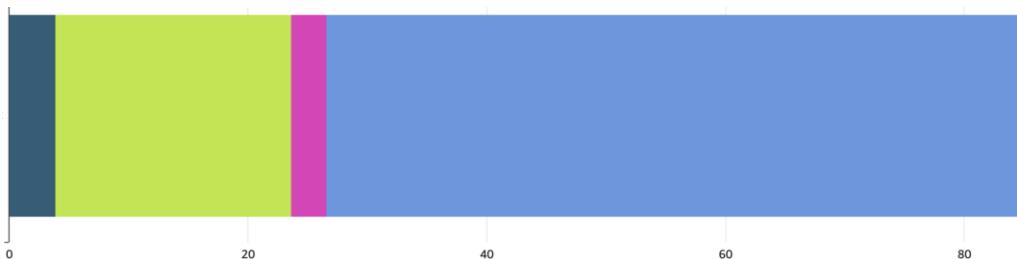
In Official Review  
(Non-Committee  
reviewer or  
Committee Reviewers  
responsible)

Changes  
Required  
(Study Teams  
responsible)

## Outlier Report EXP CR: Continuing Review for Expedited Projects TAT increased from 18 to 21 Calendar Days

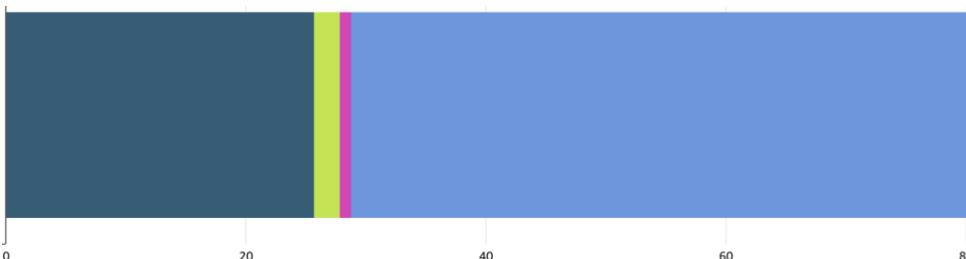
### 1. STUDY-20-00453-CR004 – 86 days:

This is a final report submission that was made on 1/24 and was assigned to a designated reviewer on 2/6. The primary delay came during the official review, where it spent a cumulative 51 days with the study team in the “clarifications requested” state. The final response was submitted on 4/13 and finalized on 4/20.



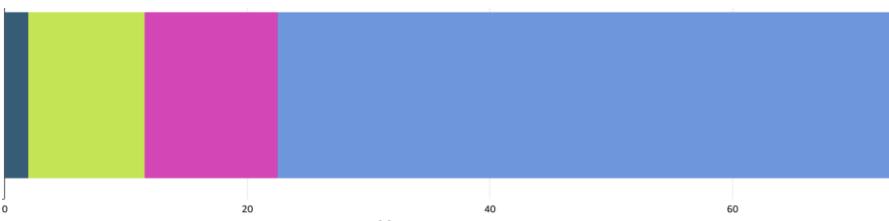
### 2. STUDY-17-00796-MODCR001 – 81 days:

This continuing review/modification combination submission was made on 2/2 and sent to a designated reviewer on 3/2. The primary delay came here where it spent cumulatively 50 days in the “modifications required” state with the study team – MRSA comments were managed, but the majority of the time was waiting for the GCO review to be completed. The submission was ultimately returned on 4/24 and approval issued same day.



### 3. STUDY-20-00232-CR003 – 74 days:

This continuing review was submitted on 2/6. The primary delay came during the pre-review where it spent a cumulative 48 days with the study team. The study was sent to a designated reviewer on 3/28, and MRSA comments sent from the IRB Chair on 4/5 and then again on 4/10. The team responded on 4/20 and approval was issued on 4/21.



Pre-review  
(IRB  
Analyst  
responsible  
)

In Official Review  
(Non-Committee  
reviewer or  
Committee Reviewers  
responsible)

Review  
Complete  
(IRB Analyst  
responsible)

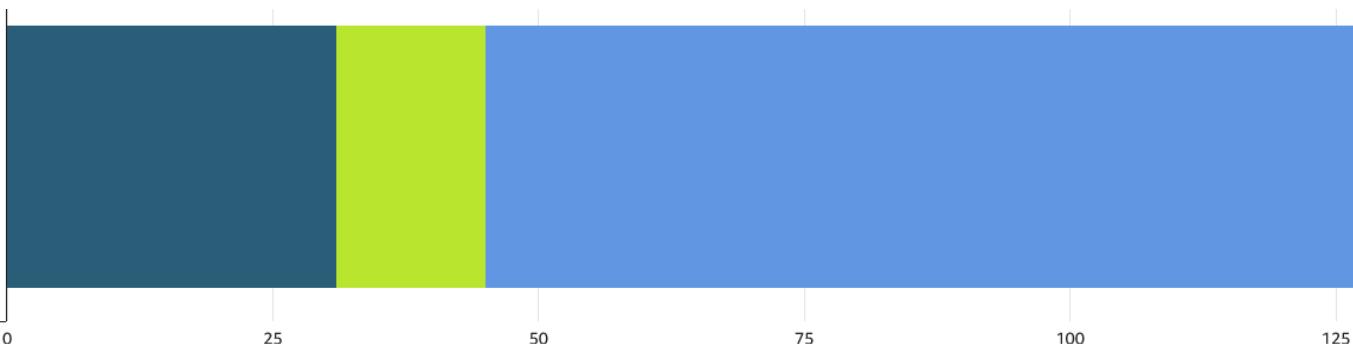
Changes  
Required  
(Study Teams  
responsible)

## Outlier Report FB MOD: Modification Review for Full Board Projects TAT increased from 46 to 65 Calendar Days

\*Note : N=6 for April 1.

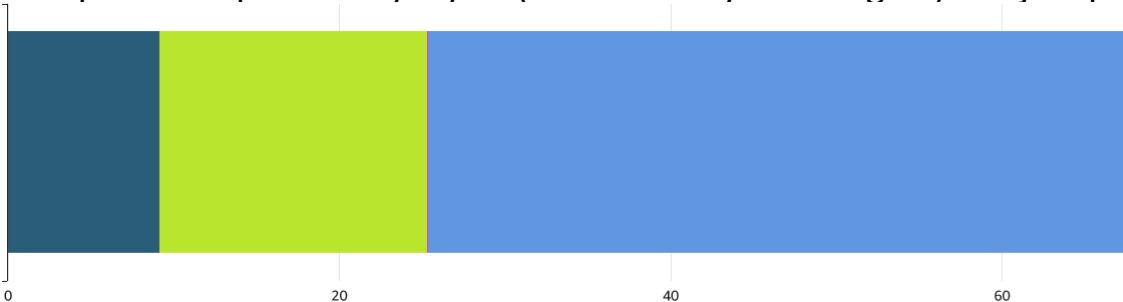
### 1. STUDY-20-01272-MOD0013 – 128 days:

Project entered IRB on 12/20/2022. Analyst requested clarifications on 12/22. Study team did not resolve all issues until 2/7/23 (about 45 days later), at which point study would need to transition ICFs over to new template due to cutoff date. Study team took until 3/21/23 to complete the request (Another 45 days later – should also have been withdrawn due to 2 response time exceeded messages). Issues remained as ICF was not transitioned correctly. Continued back-and-forth with analyst until 4/14/23 (about 25 days later). Project placed on 4/25 Board C meeting.



### 2. STUDY-22-00669-MOD002 – 69 days:

Project entered queue on 1/30/2023. Clarifications requested due to ICF transition required. Team responded 2/21 (about 22 days later). Study team did not complete the transition correctly; bounced back on 2/24. Team completed request on 3/13/23 (about 21 days later again). Project placed on 3/28 Board C meeting.



Pre-review  
(IRB  
Analyst  
responsible  
)

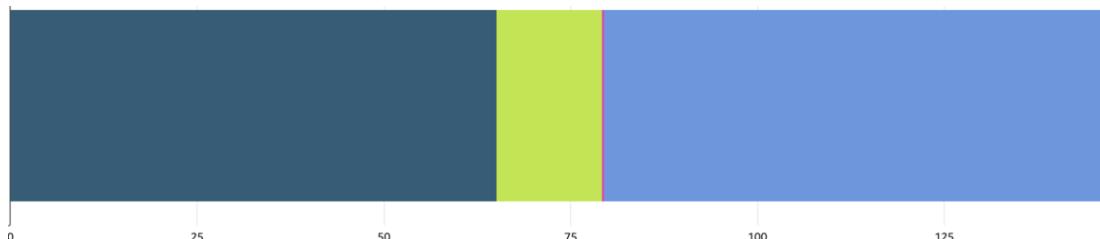
In Official Review  
(Non-Committee  
reviewer or  
Committee Reviewers  
responsible)

Changes  
Required  
(Study Teams  
responsible)

## Outlier Report EXP MOD: Modification Review for Expedited Projects TAT increased from 12 to 17 Calendar Days

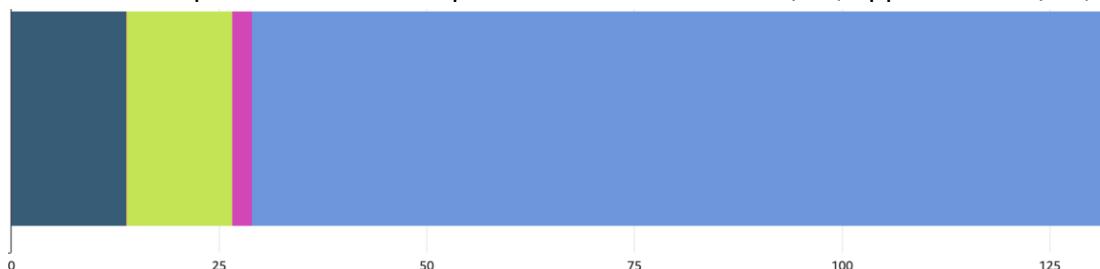
### 1. STUDY-19-00795-MOD0012 – 149 days:

This modification was submitted on 11/23/22. The primary delay came during the pre-review, where the study spent 128 days total – equal between the IRB and study team. The submission was sent to a designated reviewer on 3/31 and MRSA comments sent on 4/13. The response was submitted on 4/21 and approval issued same day.



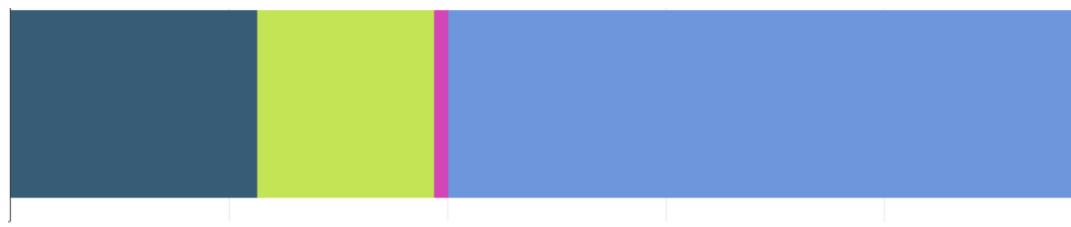
### 2. STUDY-16-01321-MOD0010 – 134 days:

This modification was submitted on 12/22/22. The first delay came during the pre-review, where it spent 36 days with the study team. It was sent to a designated reviewer on 2/2 and the second delay came here, where the submission spent 69 days with the study team in two rounds of “modifications required”. The final response was submitted on 4/20, approved on 4/26, and the letter sent on 4/27.



### 3. STUDY-21-00171-MOD003 – 124 days:

This modification was submitted on 11/30/22. The first and primary delay came during the pre-review, where the study spent 48 days with the study team. The submission was sent to a designated reviewer on 2/14 and MRSA comments were sent on 2/23. The second delay came here where it spent 27 days with the study team. It was assigned back to designated review on 3/28 and approved on 4/3.



Pre-review  
(IRB  
Analyst  
responsible  
)

In Official Review  
(Non-Committee  
reviewer or  
Committee Reviewers  
responsible)

Review  
Complete  
(IRB Analyst  
responsible)

Changes  
Required  
(Study Teams  
responsible)