



HRPP METRICS

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Description of Contents:

The U-M HRPP Metrics reports show the size of the U-M human research protections program (HRPP) and measures IRB activity over recent fiscal years.

This compilation of metrics contains the *Approved Projects report* for the U-M IRBs, plus four (4) reports for each IRB office:

- Quarterly Volume reports:
 - Incoming Submissions by Submission Type
 - Approvals by Review Type
 - Approvals by Submission Type
- Quarterly Turnaround Times by Review Type report

FY 2020 Impacts:

Oversight for U-M Flint research transitioned to IRB-HSBS in Q1 2020.

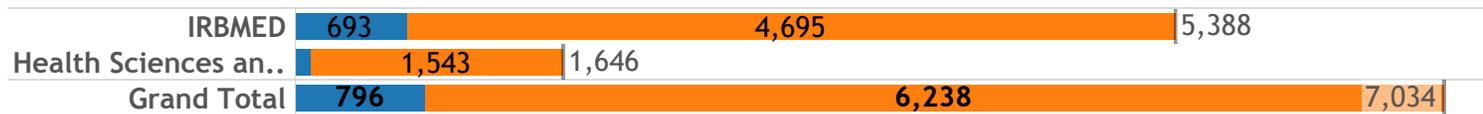
Metrics for Q4 2020 reflect the impact of COVID-19, including an increase in exempt applications resulting from: 1) An increase in exempt survey/interview projects which could be conducted remotely 2) The deactivation the exempt system-generated determination function.

FY 2021 Impacts:

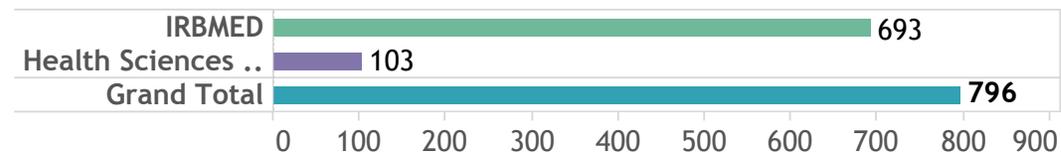
Metrics for FY2021 reflect U-M's gradual ease of restrictions on human research due to COVID-19 through Q4 in accordance to Federal, State, and University public health guidelines. Some IRB submissions from FY2021 Q1 – Q3 subject to COVID-19 restrictions on in-person research were held for future determination, impacting some turn-around times (TAT). Amendments were required to re-activate studies and/or transition back to in-person research when allowable.

Approved Projects Under the Oversight of the IRBs as of 7/1/2021 7:17:23 AM

Is U-M Review
■ U-M IRB Review
■ Other IRB Review



Number of Other IRB Review Projects

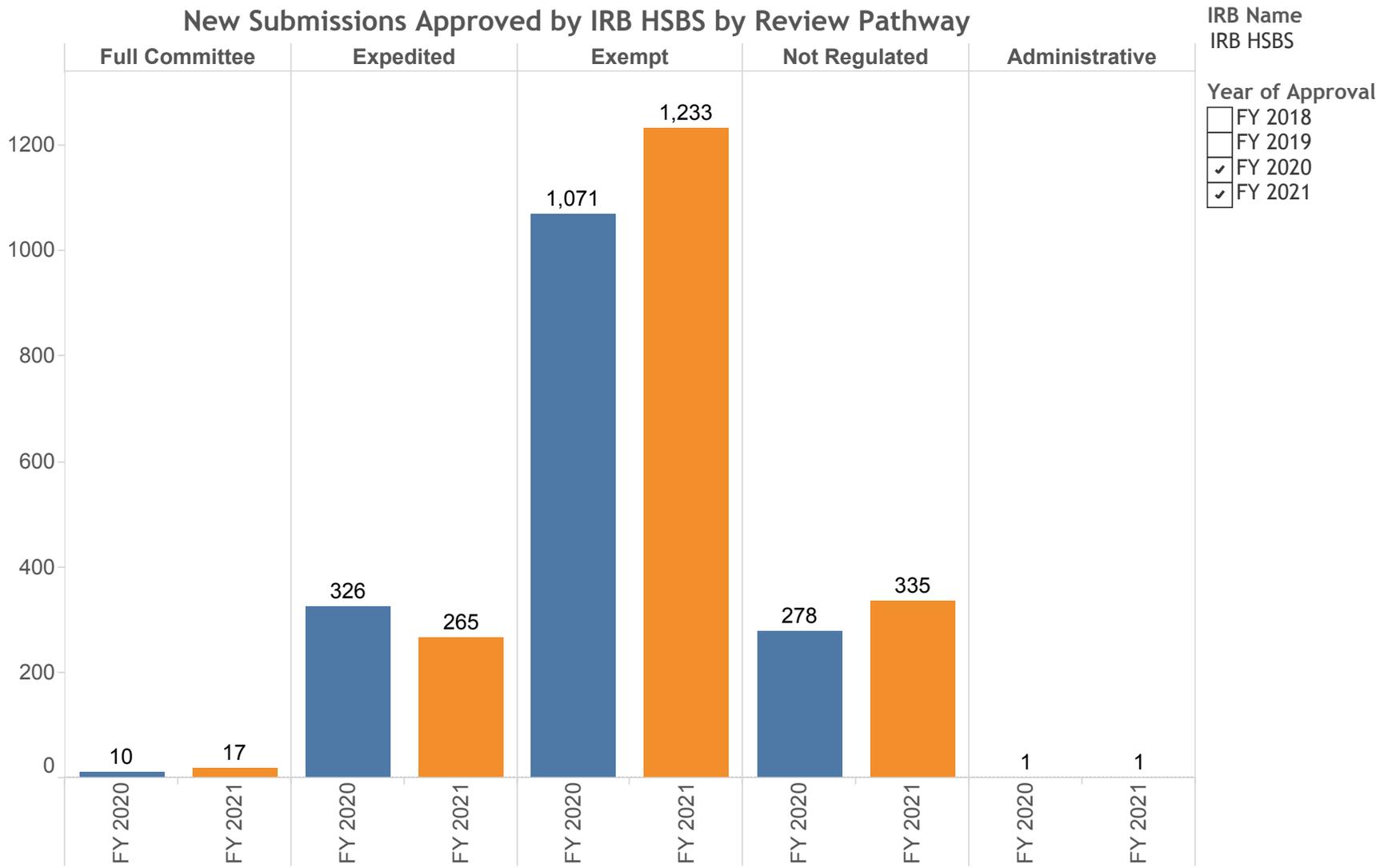


Notes:

Unique Count of Initial/New Submissions processed by U-M IRBs, for each IRB.
 Color indicates the Type of Application - U-M IRB Review and Other IRB Review (Ceding Applications)

The data is filtered on Project Status of the Initial/New Submission, including -
 Approved;
 Contingencies Pending;
 Core Committee Staff Contingency Review;
 Designated Reviewer Contingency Review;
 Validate Committee Decision

New Submissions Approved by IRB HSBS by Review Pathway



IRB Name
IRB HSBS

Year of Approval

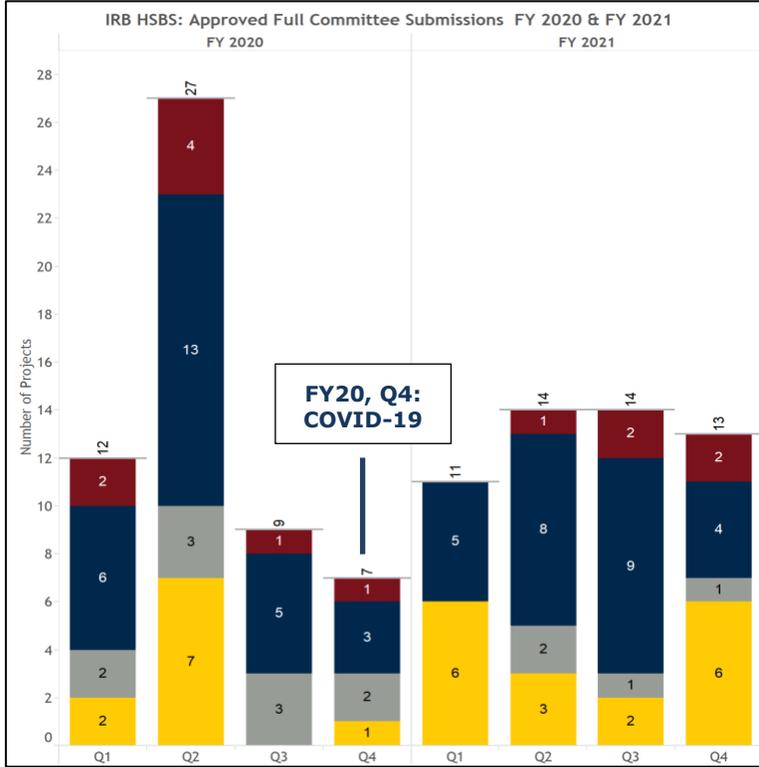
- FY 2018
- FY 2019
- FY 2020
- FY 2021

	Full Committee	Expedited	Exempt	Not Regulated	Administrative
FY 2020	10	326	1,071	278	1
FY 2021	17	265	1,233	335	1

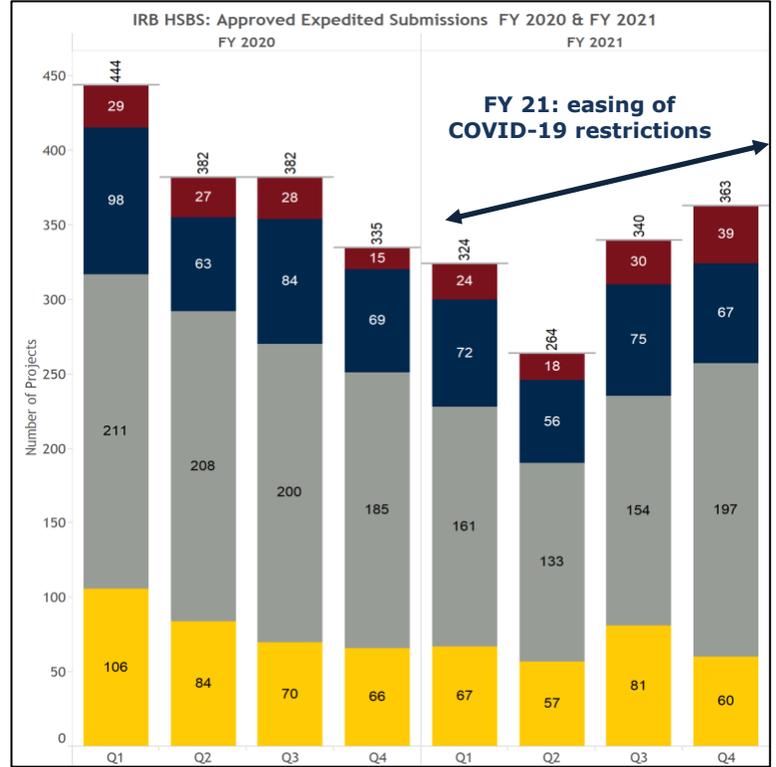
Notes:
 Unique count of Initial/New Submissions for each Year of the IRB Approval date, broken down by Review Type.
 Color shows the Year of the IRB Approval date.
 The data is filtered on IRB Initial Approval Date to include only the last 5 fiscal years.

IRB-HSBS: FY 2021 Approvals by Review Type

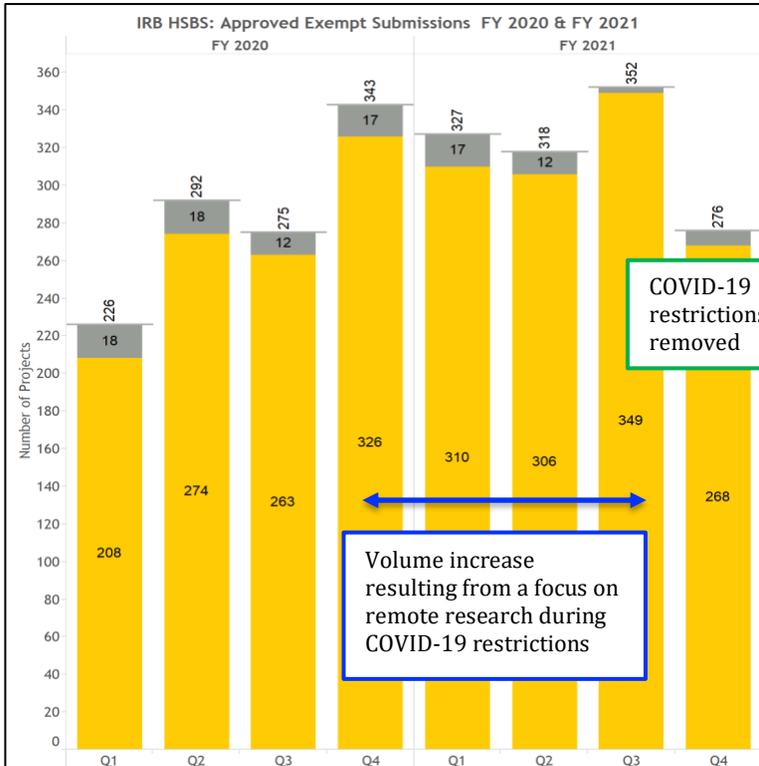
Full Committee



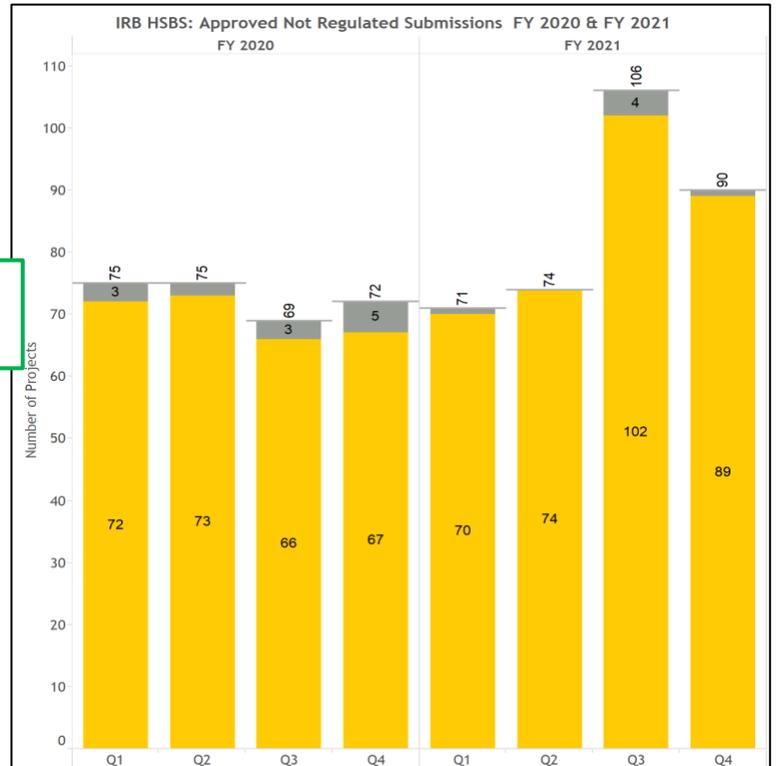
Expedited



Exempt



Not Regulated



Color shows the Submission Type

Submission Type
■ AE/ORIO

■ SCR

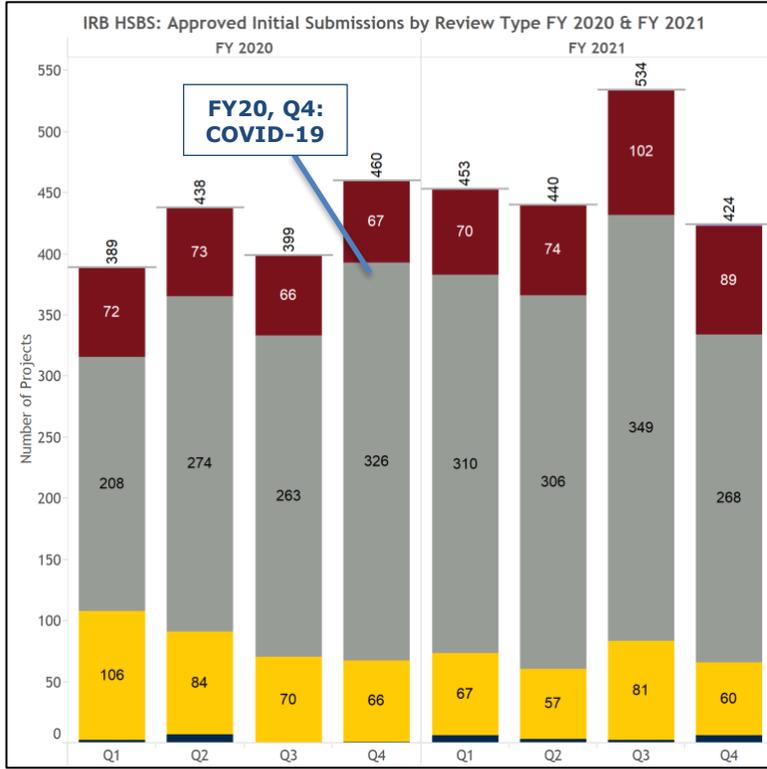
■ Amendment

■ Initial Submission

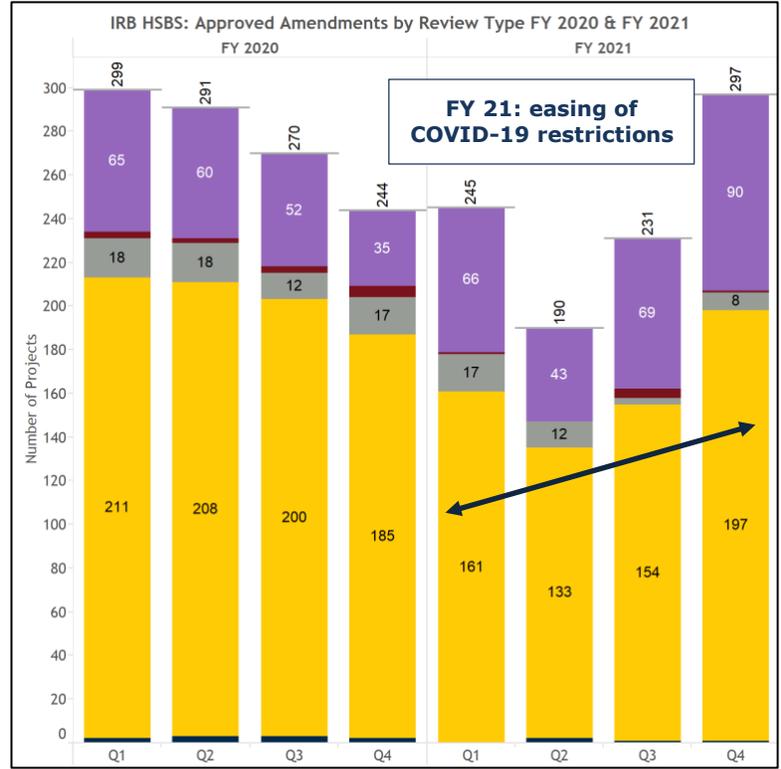
The *Number of Projects* scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

IRB-HSBS: FY 2021 Approvals by Submission Type

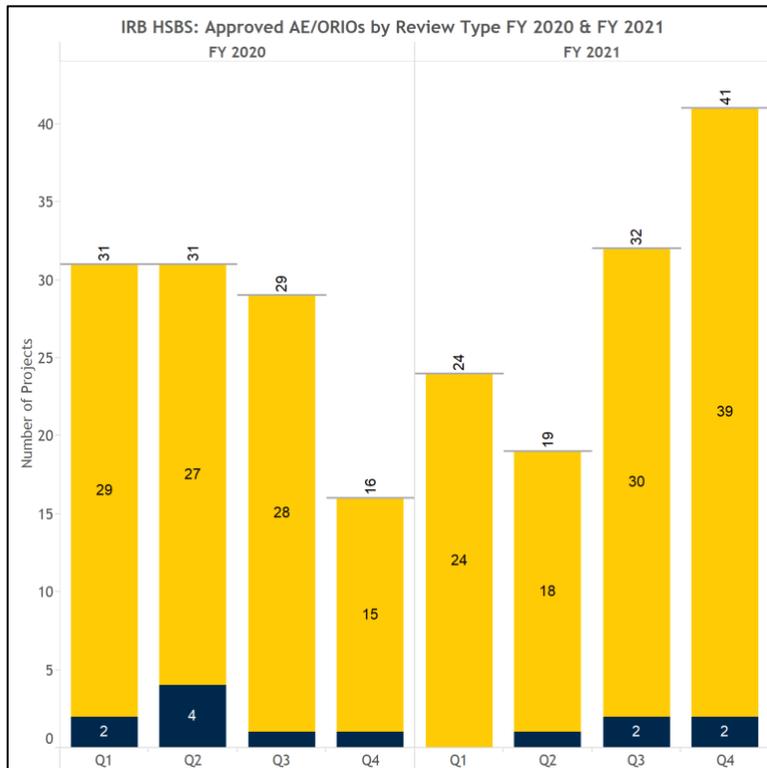
Initial



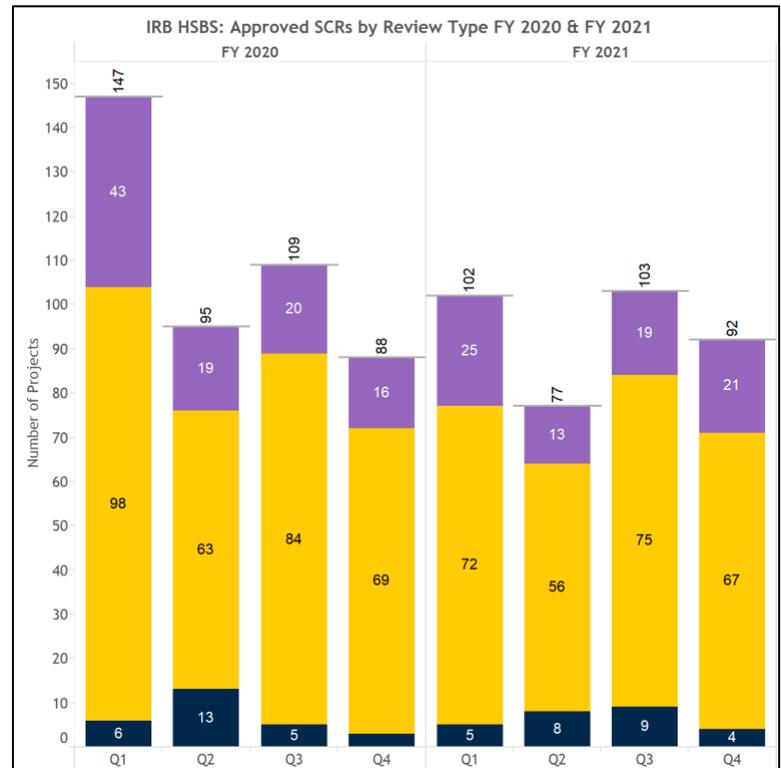
Amendment



AE/ORIO



SCR



Color shows the Review Type

Review Pathway

Administrative Not Regulated Exempt Expedited Full Committee

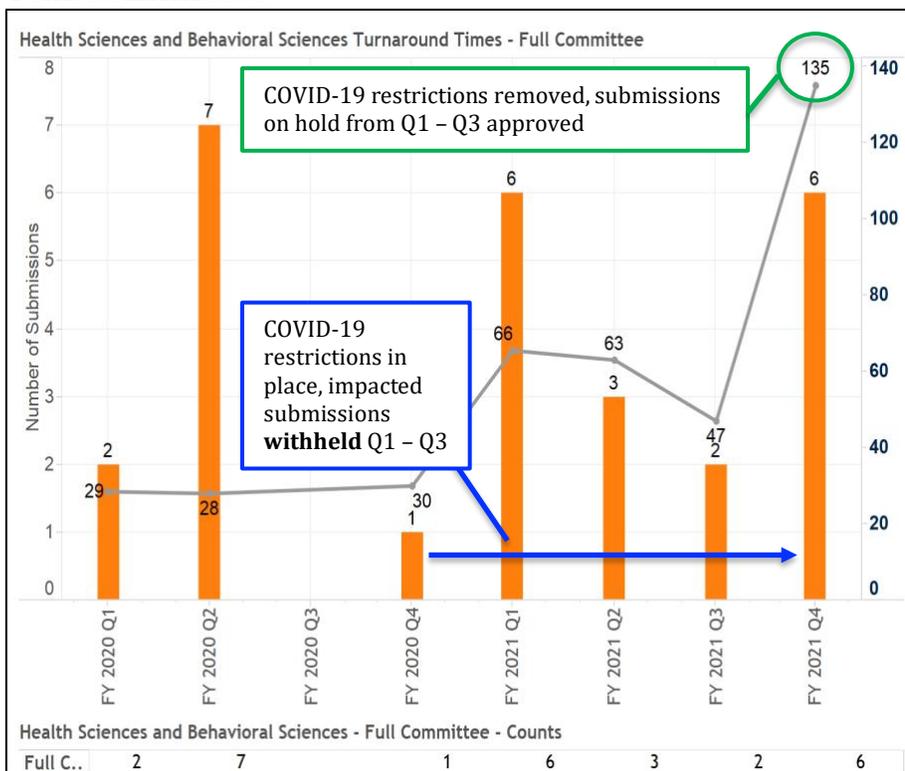
The Number of Projects scale (left) changes for each graph. Graphs show the unique count of all Submissions for each Quarter of the IRB Approval date, broken down by Review Type. Data is filtered on the IRB Initial Approval Date.

IRB HSBS: Turnaround Time by Review Type

The graphs and numbers below represent the **broadest range** used to calculate median turnaround time (TAT), which is from the study team's initial submission to the IRB determination. This median TAT calculation encompasses:

- The initial IRB Office review of the application for completeness and accuracy,
- Required application changes to be made by the study team and submitted to the IRB,
- IRB assignment to the committee/reviewer once the application criteria are met, and
- IRB determination

Full Committee



Legend

The *Number of Submissions* scale changes per graph

The *Median Turnaround Time* scale is calendar days

- Q1 = July – September
- Q2 = October – December
- Q3 = January – March
- Q4 = April – June

Average Full Committee Turnaround Times:

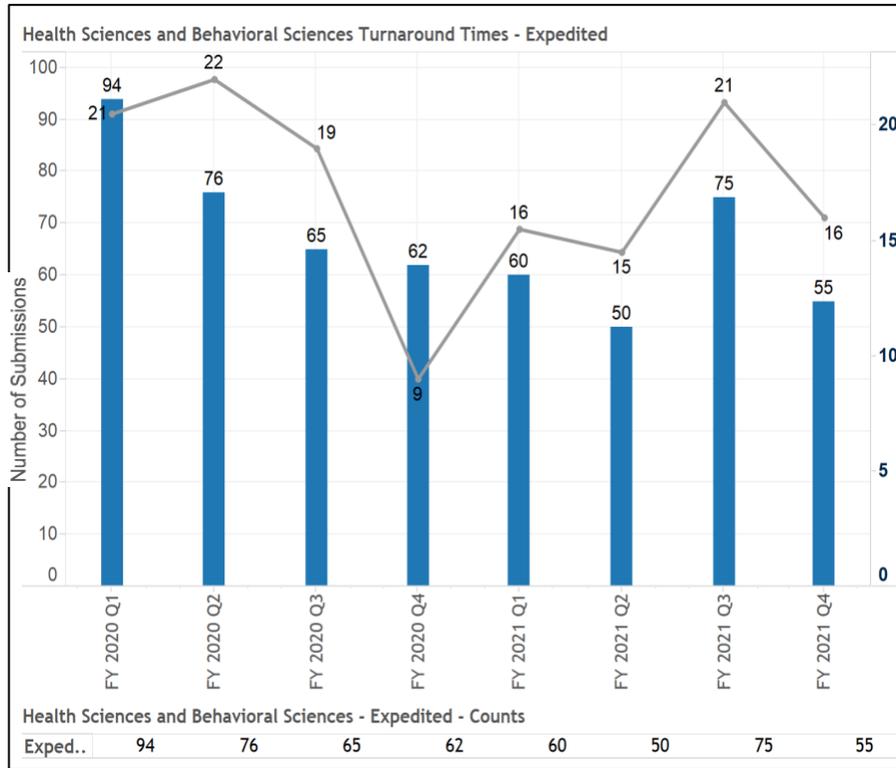
- FY 2021 = 77.75 days
- FY 2020 = 21.75 days
- FY 2019 = 90.00 days
- FY 2018 = 69.75 days
- FY 2017 = 75.75 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)

IRB HSBS: Turnaround Time by Review Type

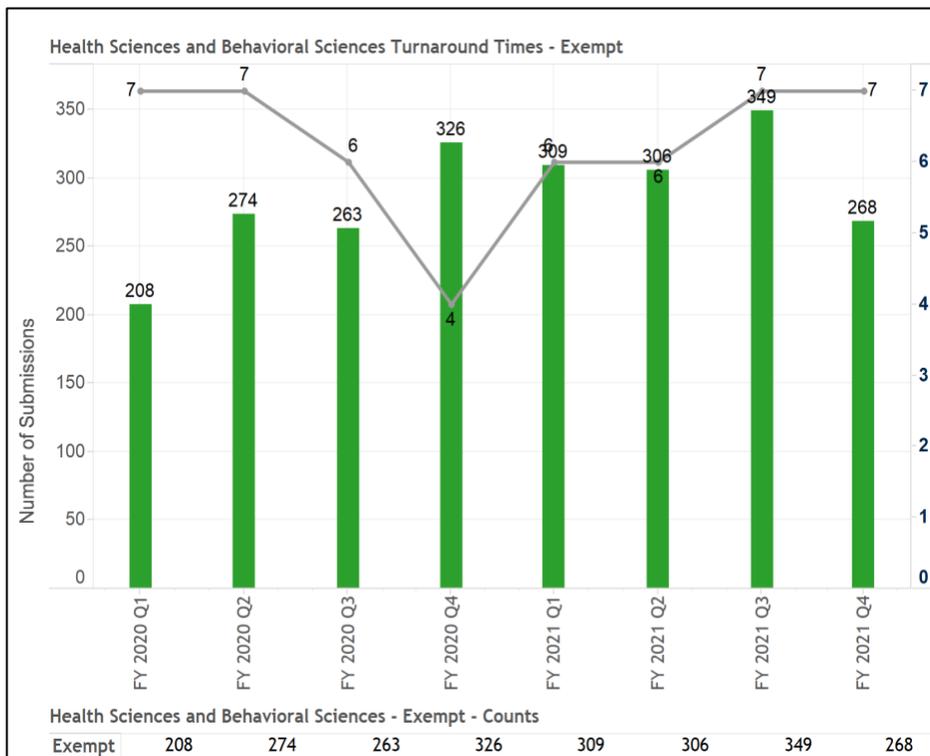
Expedited



Average Expedited Turnaround Times:

FY 2021 = 17.00 days
 FY 2020 = 17.75 days
 FY 2019 = 22.50 days
 FY 2018 = 25.50 days
 FY 2017 = 22.50 days

Exempt



Average Exempt Turnaround Times:

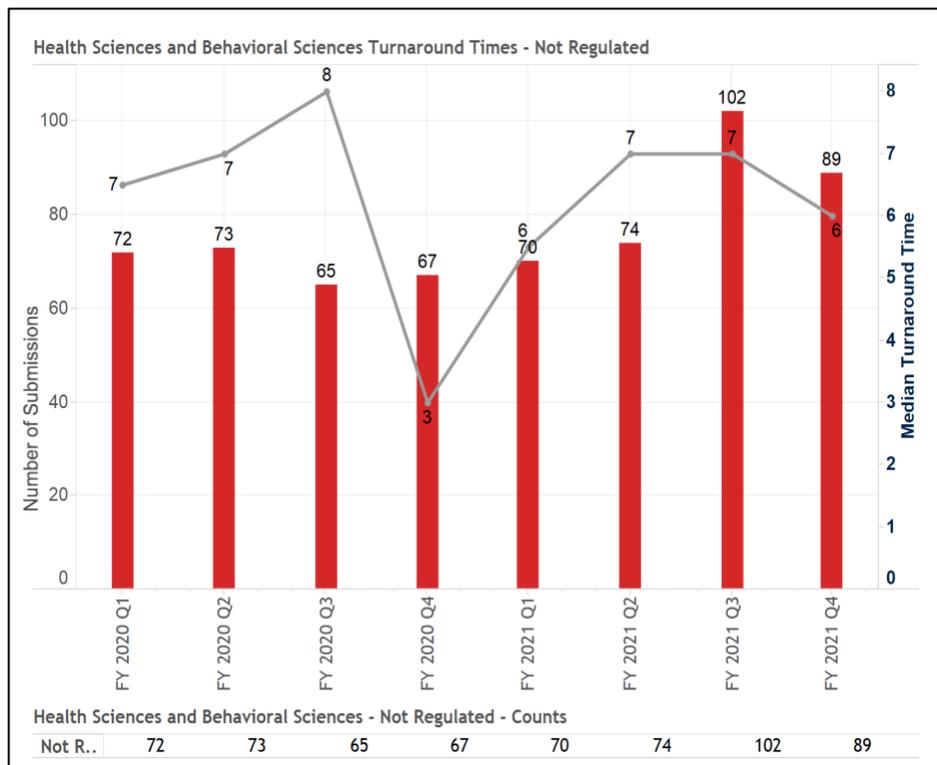
FY 2021 = 6.50 days
 FY 2020 = 6.00 days
 FY 2019 = 6.25 days
 FY 2018 = 6.25 days
 FY 2017 = 3.75 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

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- Application Type – excludes Applications for Other IRB Review (Ceding)

IRB HSBS: Turnaround Time by Review Type

Not Regulated



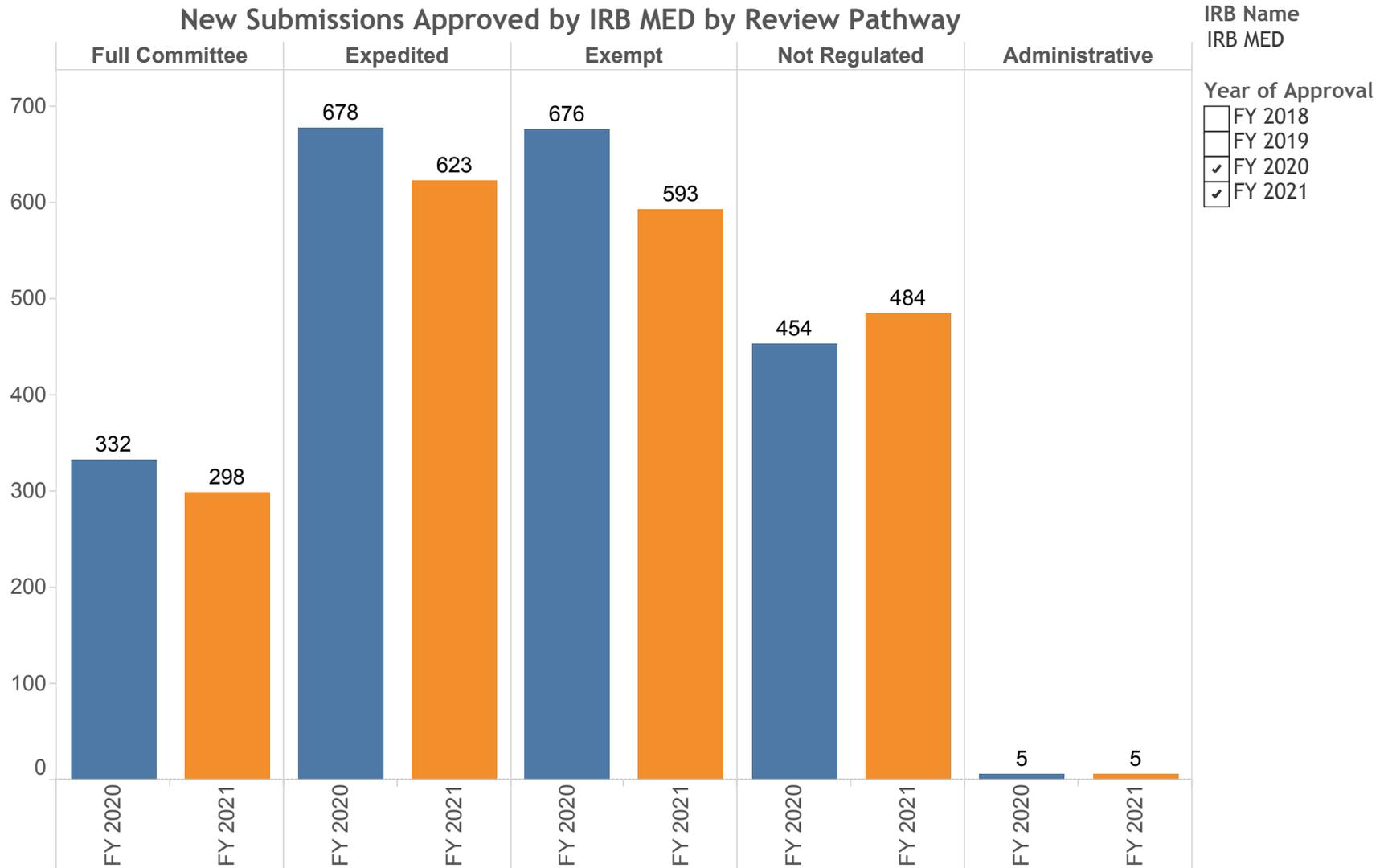
Average Not Regulated Turnaround Times:

- FY 2021 = 6.50 days**
- FY 2020 = 6.25 days
- FY 2019 = 7.50 days
- FY 2018 = 6.50 days
- FY 2017 = 4.00 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

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New Submissions Approved by IRB MED by Review Pathway



IRB Name
IRB MED

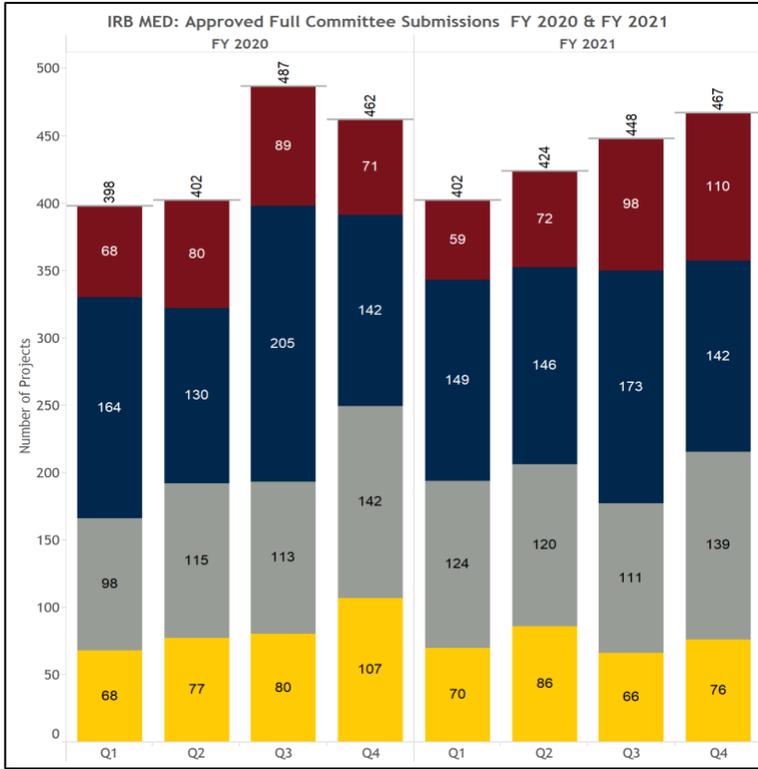
Year of Approval
 FY 2018
 FY 2019
 FY 2020
 FY 2021

	Full Committee	Expedited	Exempt	Not Regulated	Administrative
FY 2020	332	678	676	454	5
FY 2021	298	623	593	484	5

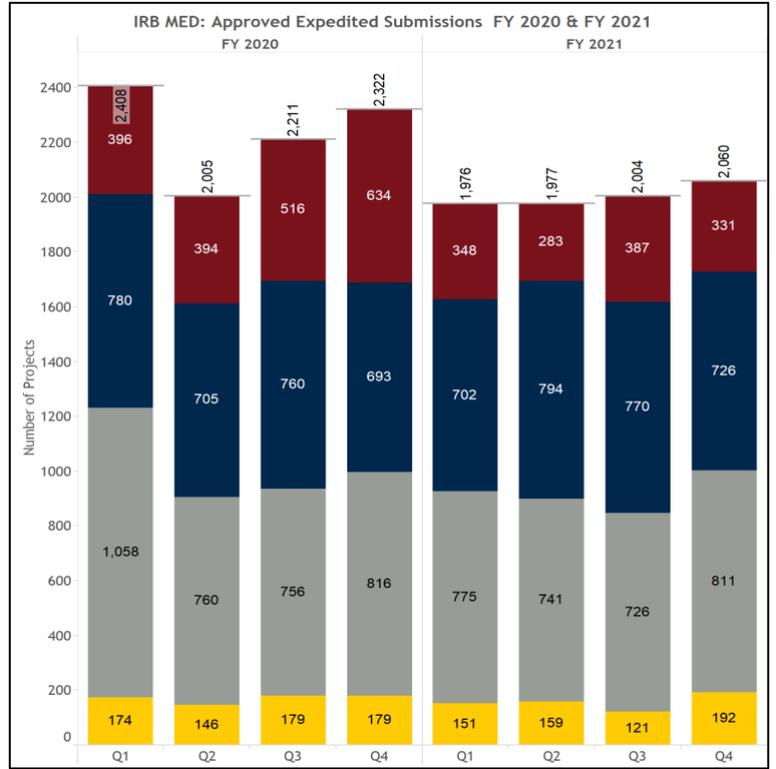
Notes:
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IRBMED: FY 2021 Approvals by Review Type

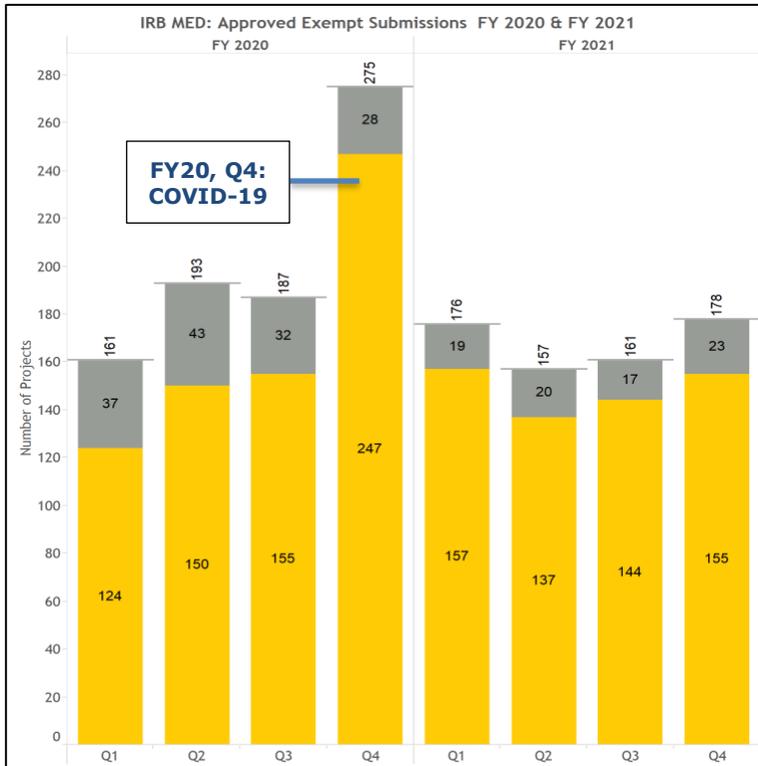
Full Committee



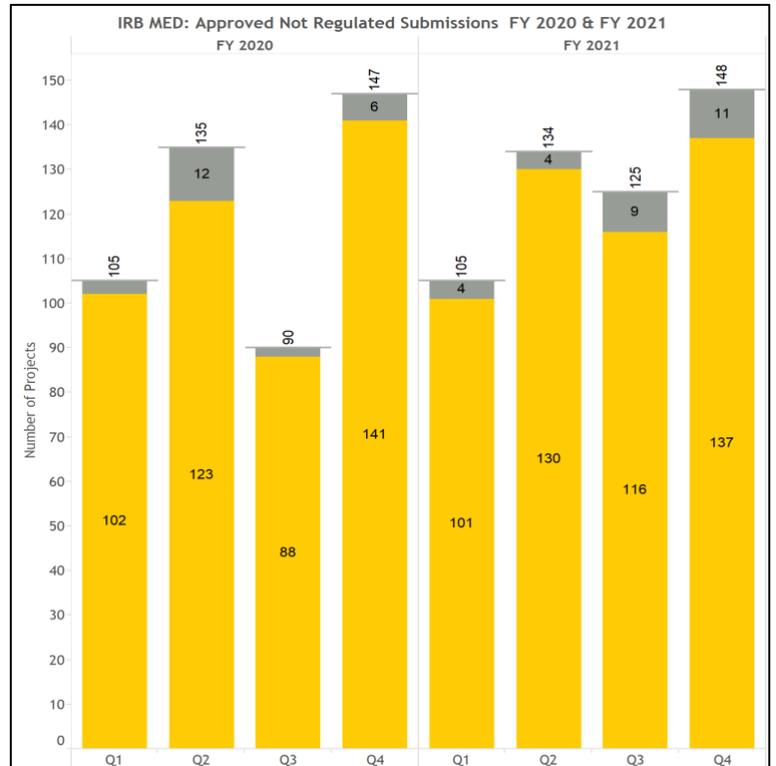
Expedited



Exempt



Not Regulated



Color shows the Submission Type

Submission Type
■ AE/ORIO

■ SCR

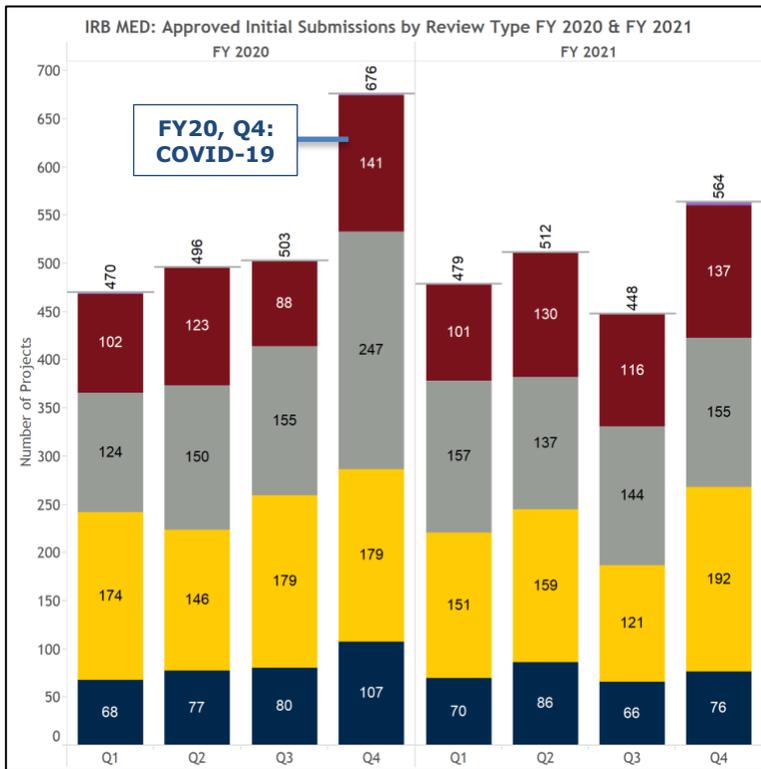
■ Amendment

■ Initial Submission

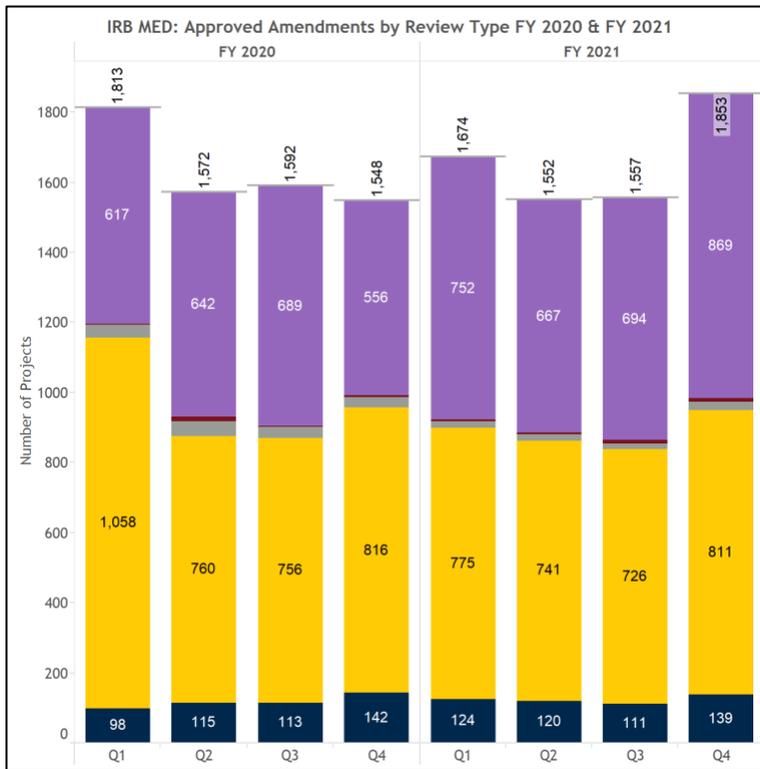
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IRBMED: FY 2021 Approvals by Submission Type

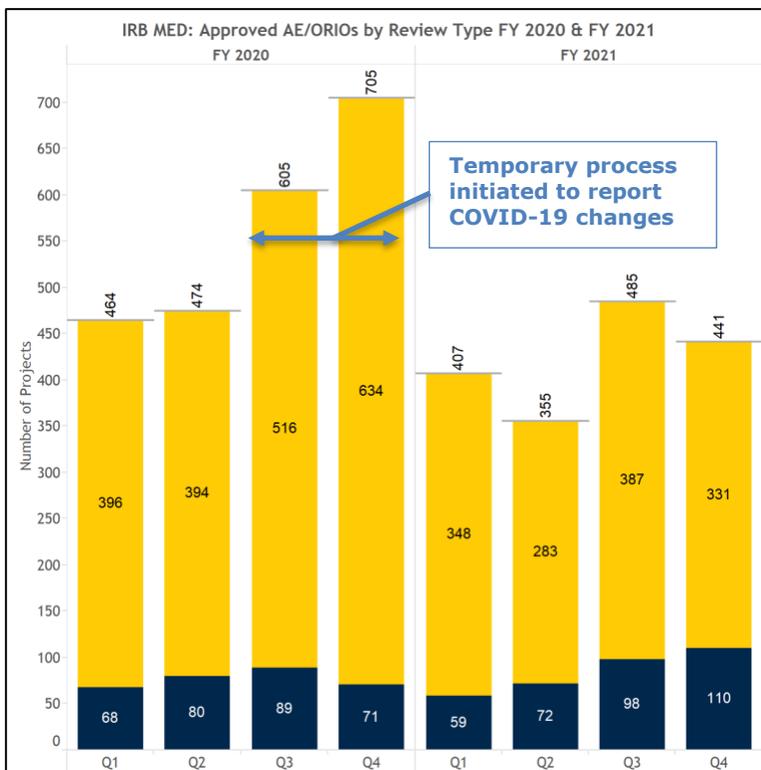
Initial



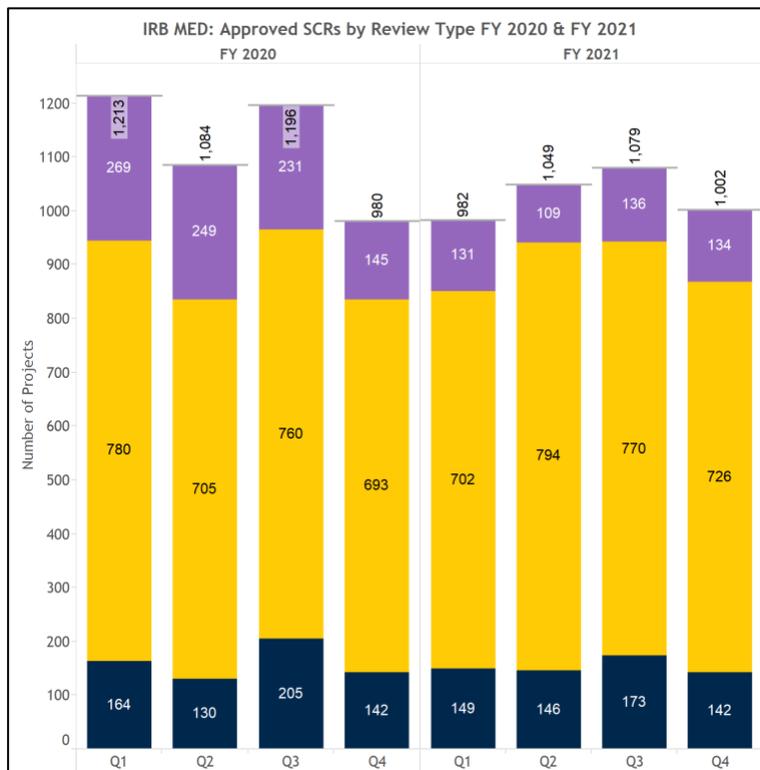
Amendment



AE/ORIO



SCR



Color shows the Review Type

Review Pathway

Administrative Not Regulated Exempt Expedited Full Committee

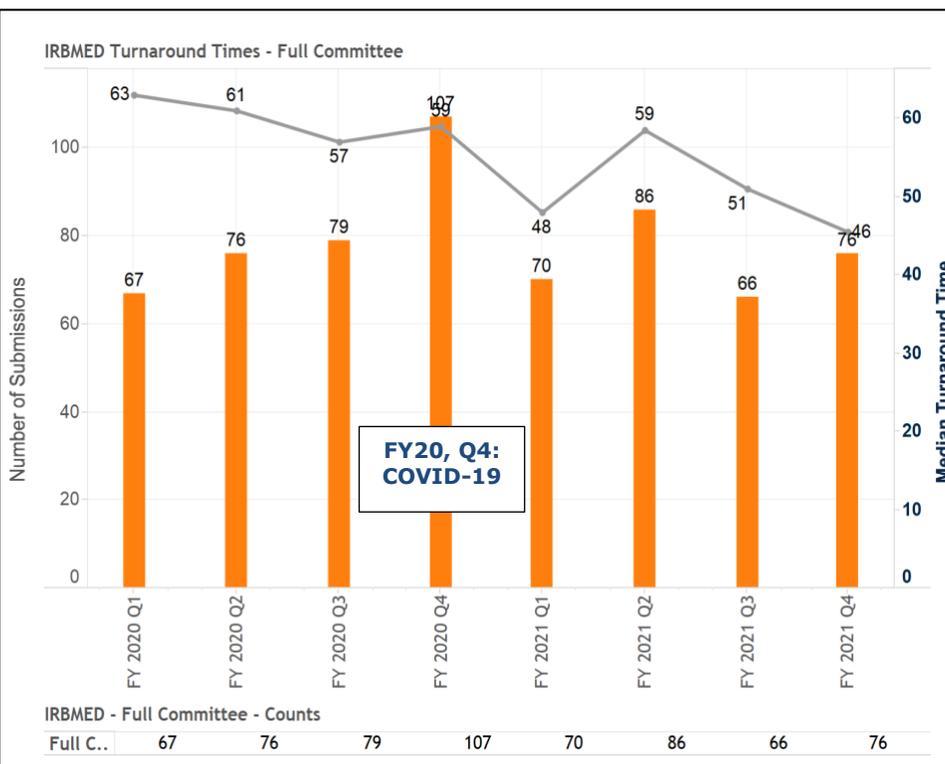
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IRBMED: Turnaround Time by Review Type

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Full Committee



Legend

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Average Full Committee Turnaround Times:

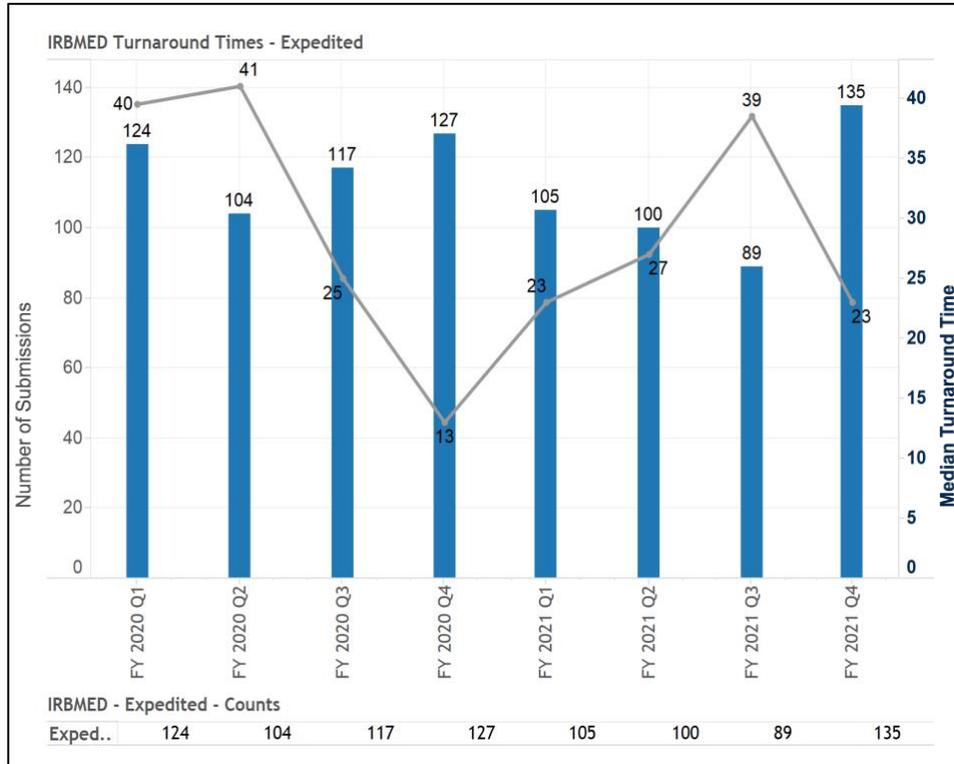
- FY 2021 = 51.00 days
- FY 2020 = 60.25 days
- FY 2019 = 63.75 days
- FY 2018 = 48.75 days
- FY 2017 = 53.00 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

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IRBMED: Turnaround Time by Review Type

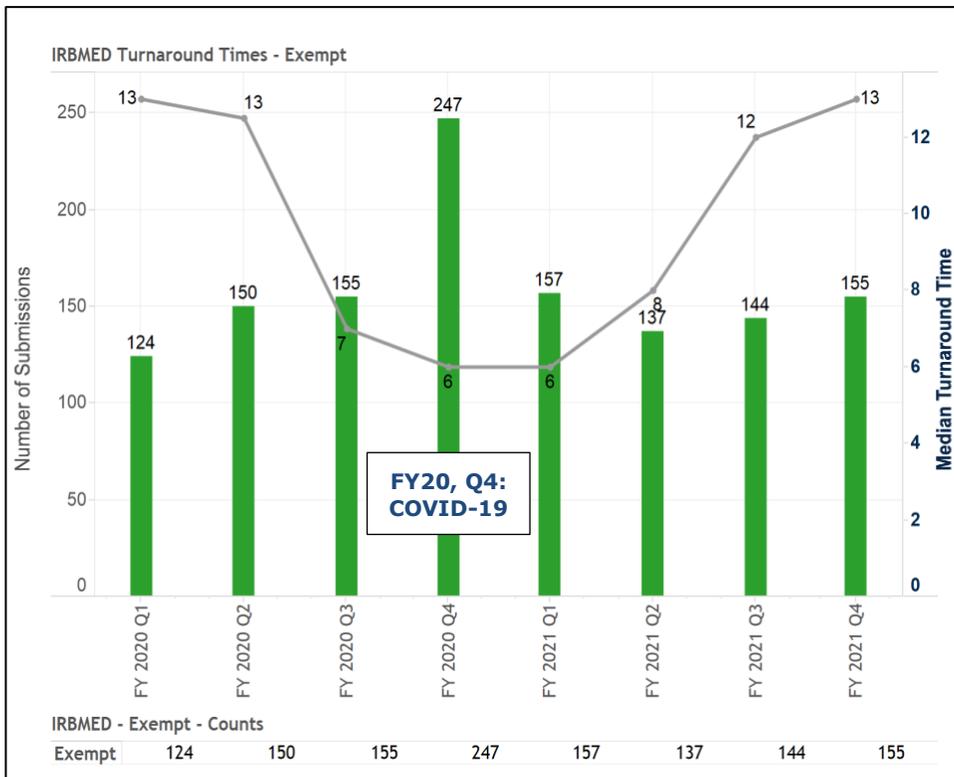
Expedited



Average Expedited Turnaround Times:

FY 2021 = 28.00 days
 FY 2020 = 29.75 days
 FY 2019 = 49.25 days
 FY 2018 = 33.50 days
 FY 2017 = 34.50 days

Exempt



Average Exempt Turnaround Times:

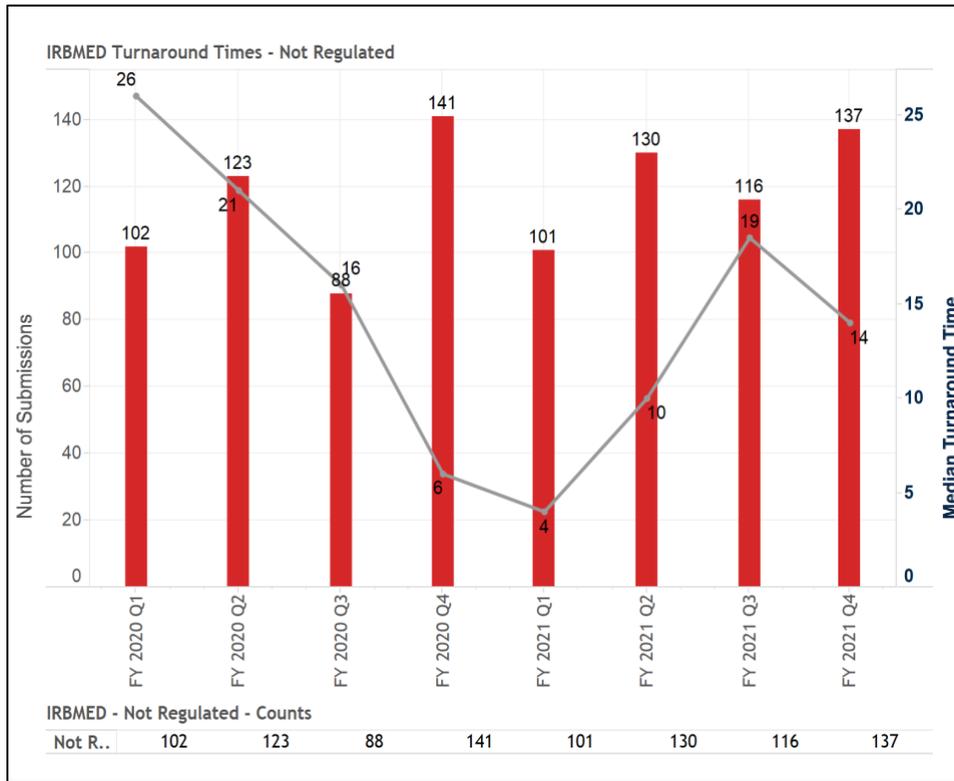
FY 2021 = 9.75 days
 FY 2020 = 10.00 days
 FY 2019 = 41.25 days
 FY 2018 = 22.50 days
 FY 2017 = 20.75 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)

IRBMED: Turnaround Time by Review Type

Not Regulated



Average Not Regulated Turnaround Times:

FY 2021 = 11.75 days
 FY 2020 = 17.25 days
 FY 2019 = 26.50 days
 FY 2018 = 14.25 days
 FY 2017 = 15.00 days

Graphs show the trend of distinct counts of Projects and Median Days between the IRB receipt and IRB initial approval for each IRB Approval Date Quarter. The data is filtered on these attributes:

- IRB Receipt Date – includes only Projects received by IRB (and not self-determinations)
- IRB Initial Approval Date
- Application Type – excludes Applications for Other IRB Review (Ceding)