



# IRB METRICS

2021-2022



**BALL STATE  
UNIVERSITY**

**Institutional Review Board | Office of Research Integrity**

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## IRB METRICS 2021-2022

The Institutional Review Board (IRB) metrics show the size of the Ball State University (BSU) Human Research Protection Program (HRPP) and offer an overview of BSU IRB activities. The analysis is based on protocols submitted to and reviewed by the IRB committee, the subcommittee, and the HRPP administrator during the period June 1, 2021, to May 31, 2022. The report includes information on a variety of topics, including but not limited to the volume of IRB submissions, type of applications, colleges and departments that conduct the most research, and turnaround time of IRB review. To understand recent trends and compare the IRB activities before and after the pandemic, this report also provides data from previous years (2019-2020 and 2020-2021).

### Highlights

- IRB has 456 Active (non-exempt) studies as of May 31, 2022.
- IRB received 542 protocols during the period June 1, 2021, to May 31, 2022.
- IRB and ORI reviewed 534 protocols and took action for 488 protocols.<sup>1</sup>
- IRB approved 218 non-exempt protocols and made 215 exempt determinations.
- Average turnaround time is 18 calendar days and the median is 11 calendar days.

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<sup>1</sup> The difference between the number of reviewed protocols and the number of actions taken can be accounted for by protocols withdrawn after the IRB review (36 protocols), protocols that have been unlocked but not addressed yet (1 protocol), and protocols closed by the administrator (9 protocols).

## PROTOCOL SUBMISSIONS

### Monthly Submissions

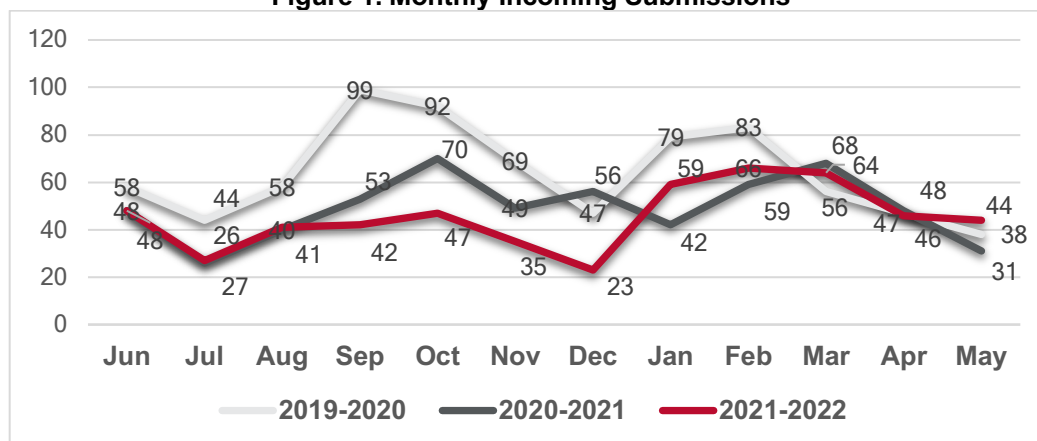
Total IRB submissions accounts for the number of submitted protocols. This helps evaluate and track the IRB total workload. Table 1 and Figure 1 present the overall volume of incoming submissions received during a given month for comparative years 2019-2020, 2020-2021, and 2021-2022. The metrics are based on the submission date, and thus protocols under review (pending status) are included. One notable implication is that the pandemic impacted the research community considering the decrease in the number of protocols after the COVID-19 outbreak (March 2020).

The revised Common Rule (effective January 2019) also impacted the number of protocol submissions. Under the revised Common Rule, continuing reviews are no longer required for most studies that qualify for the Expedited review process. As a result, the number of continuing reviews decreased from 59 in 2019-2020 to 19 in 2021-2022 (see Table 2). Also, some studies “categories” are no longer required to be reviewed (ex. oral history and journalism), which also altered the overall number of protocol submissions.

**Table 1. Monthly Incoming Submissions**

Year	Jun	July	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Total
<b>2019-2020</b>	58	44	58	99	92	69	47	79	83	56	47	38	770
<b>2020-2021</b>	48	26	40	53	70	49	56	42	59	68	48	31	590
<b>2021-2022</b>	48	27	41	42	47	35	23	59	66	64	46	44	542

**Figure 1. Monthly Incoming Submissions**



### Submission Types

IRB submissions are categorized in six types:

- New study: Initial submission of project
- Amendment/Modification: Modification request of approved protocols
- Continuing Review: Request for continued study approval
- Revision: Resubmission of deferred project

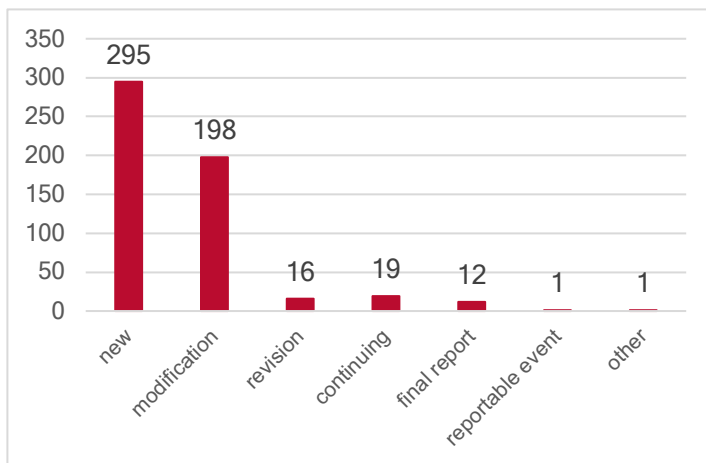
- Final Report: Request to close a project
- Reportable Event: Report of any type of reportable/unexpected/adverse event

Table 2 shows the number of each submission type. While the total submissions decreased steeply after COVID-19, the number of new study submissions shows a shallow curve compared to the total number of submissions (Figure 3). The table also depicts the decrease of continuing review reports after the revised Common Rule effective, which no longer requires a continuing review report for most expedited studies.

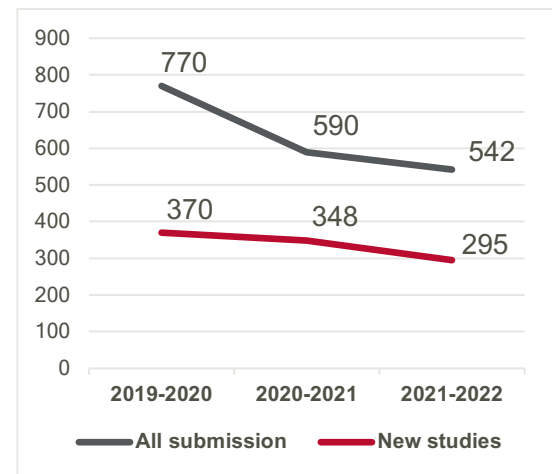
**Table 2. Incoming Submissions by Submission Type**

Year	New study	Modification	Revision	Continuing Review	Final Report	Reportable Event	Other	Total
2019-2020	370	264	34	59	34	6	3	770
2020-2021	348	178	12	31	13	3	5	590
2021-2022	295	198	16	19	12	1	1	542

**Figure 2. 2021-2022 Incoming Submissions**



**Figure 3. New Study Submissions**



## Principal Investigators' Affiliation

Table 3 presents the number of submissions by Principal Investigator (PI)'s affiliations. The number in the parentheses indicates the number of new projects. As of July 2021, the BSU IRB changed the policy on PI of record: students are no longer allowed to serve as a PI. Thus, the metrics for 2021-2022 may not reflect the actual number of student projects.

Table 4 and Figure 4 reflect the actual numbers of student projects along with faculty and staff member projects.

**Table 3. Incoming Submission by PI's Affiliation**

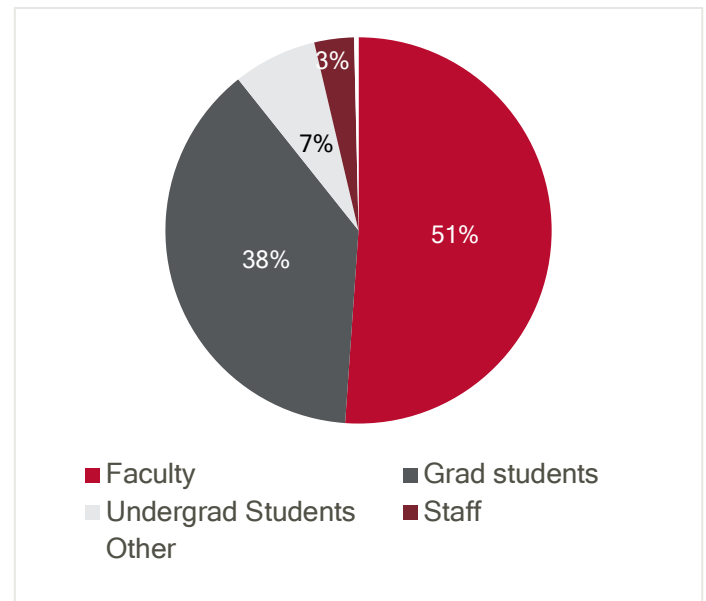
Year	Faculty	Grad Students	Undergrad Students	Staff	Other	Total
2019-2020	435 (158)	267 (164)	55 (42)	10 (4)	3 (2)	770
2020-2021	262 (125)	258 (171)	48 (38)	18 (10)	4 (4)	590



2021-2022	473 (259)	47 <sup>2</sup> (22)	2 <sup>3</sup> (2)	18 (11)	2 (1)	542
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**Table 4. Incoming Submissions by Project Type**

Project type	Submission (New study)
Faculty	277 (125)
Grad students	207 (125)
Undergrad Students	38(33)
Staff	18(11)
Other	2(1)
Total	542(295)

**Figure 2. Submissions by Project Type (PI)**

## Colleges and Departments

Tables 5 and 6 present the number of protocols submitted by colleges and departments. Department or college is assigned by the location of the PI's department as indicated in the application. If a student is listed as PI, it is assigned as the department/college of the listed Faculty Advisor. Table 5 shows the numbers of protocols submitted by each college. Table 6 and Figure 5 depict the 15 departments that submitted the most protocols.

**Table 5. Submission by College<sup>4</sup>**

Year	CAP	Business	CCIM	CFA	Health	CSH	Teachers	CI/others
2019-2020	15(10)	31(22)	69(43)	8(7)	199(74)	221(102)	201(96)	22(13)
2020-2021	17(16)	24(17)	46(34)	4(4)	165(72)	159(90)	144(95)	22(12)
2021-2022	15(11)	24(14)	33(23)	2(1)	169(75)	168(103)	113(62)	14(4)

<sup>2</sup> The number includes new protocols submitted before new PIs of record policy went into effect and modification requests of previously approved protocols.

<sup>3</sup> The number includes new protocols submitted before new PIs of record policy went into effect.

<sup>4</sup> CAP = R. Wayne Estopinal College of Architecture and Planning

Business = Miller College of Business

CCIM = College of Communication, Information, and Media

CFA = College of Fine Art

Health = College of Health

CSH = College of Sciences and Humanities

Teachers = Teachers College

CI = Center and Institutes

Table 6. Top 15 Departments for IRB Submission 2021-2022

Department	New	Modification	Revision	Continuing Report	Total	Percent (%)
Psychological Science	55	37	1	0	93	17.3
Kinesiology	23	27	3	15	76	14
Counseling Psychology, Social Psychology and Counseling	16	22	1	0	41	7.6
Educational Leadership	25	14		0	40	7.4
Educational Psychology	16	11	1	0	29	5.4
Journalism and Strategic Communication	14	7	1	0	22	4.1
Special Education	6	13	0	1	20	3.7
Nutrition and Health Science	10	7	0	0	17	3.1
Educational Studies	10	5	0	0	15	2.8
Nursing	10	2	2	0	14	2.6
Criminal Justice and Criminology	6	5	1	0	12	2.2
Speech Pathology and Audiology	6	3	0	1	12	2.2
Anthropology	4	3	2	1	11	2
Construction Management and Interior Design	8	1	2	0	11	2
Sociology	7	4	0	0	11	2

Figure 4. Top 15 Departments for IRB submission 2021-2022

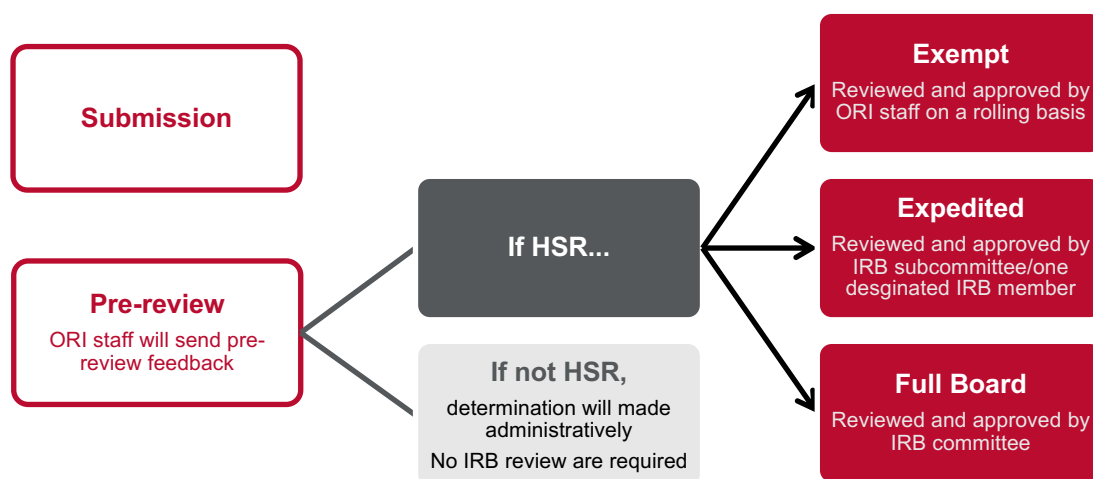


## IRB REVIEW ACTIVITY

Depending on the type of form submitted, there are various steps in the review process. Projects will be reviewed at the exempt, expedited, full board, or administrative level based on the level of risk and other factors. Figure 6 shows the basic review process of the BSU IRB.

- Exempt Review: Meets categories of exemption from IRB review. Review is conducted by experienced ORI staff.
- Expedited Review: Not greater than minimal risk study. Review is conducted by at least one IRB committee member.
- Full Committee Review: Greater than minimal risk study. Review is conducted by the full board at a convened IRB meeting.
- Administrative Review: Final report or minor modification requests may be reviewed by administrators and not HSR determination made at the administrative level.

**Figure 5. BSU IRB Review Process**



### IRB Review

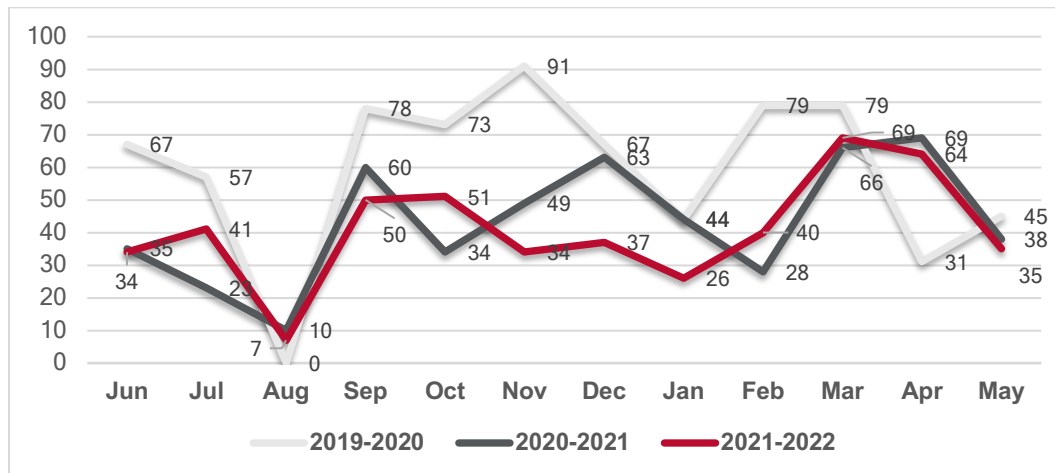
Table 7 and Figure 7 present the number of protocols that were reviewed by the IRB or determined to be exempt or not HSR during the period June 2021 to May 2022. Please note that the metrics include only protocols with review completion and thus do not include pending status. Withdrawn and closed projects are also not included<sup>5</sup>.

**Table 7. IRB Review Activity by Month**

Year	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Total
<b>2019-2020</b>	67	57	0	78	73	91	67	44	79	79	31	45	711
<b>2020-2021</b>	35	23	10	60	34	49	63	44	28	66	69	38	519
<b>2021-2022</b>	34	41	7	50	51	34	37	26	40	69	64	35	488

<sup>5</sup> 36 protocols were withdrawn and 9 protocols were closed during this period.

Figure 6. IRB Review Activity by Month



## IRB Action

Table 8 shows the number of exempt studies, approved studies, deferred studies, and not HSR. A noticeable point is the approved studies at the expedited level. Since July 2020, the BSU IRB has reviewed expedited studies with a mixed approach: review by one or two designated reviewers on a rolling basis and review by subcommittee discussion. The data in Table 8 and Figure 9 imply that this change may affect the increase in the number of expedited studies and the approval rate.

Table 8. IRB Action by Board Type

Board Type Year	Exempt	Expedited		Full board		Administrative		Total
	Exempt	Approved	Deferred	Approved	Deferred	Approved	Not HSR	
<b>2019-2020</b>	355	124	23	55	12	88	52	709
<b>2020-2021</b>	293	105	12	36	2	23	48	519
<b>2021-2022</b>	215	148	17	36	3	34	35	488

Figure 8. Exempt Board Review

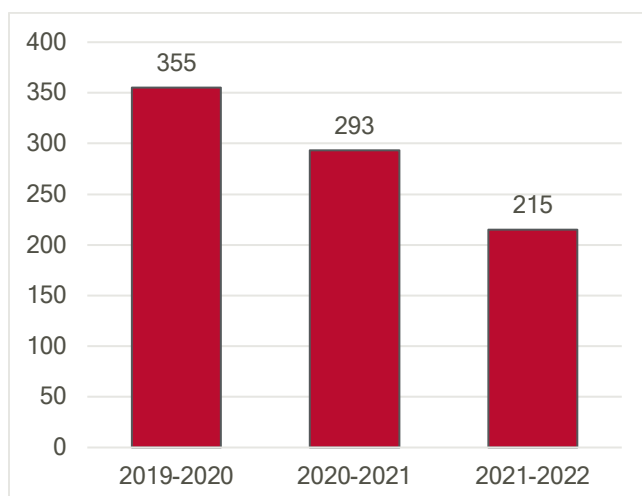


Figure 9. Expedited Board Review

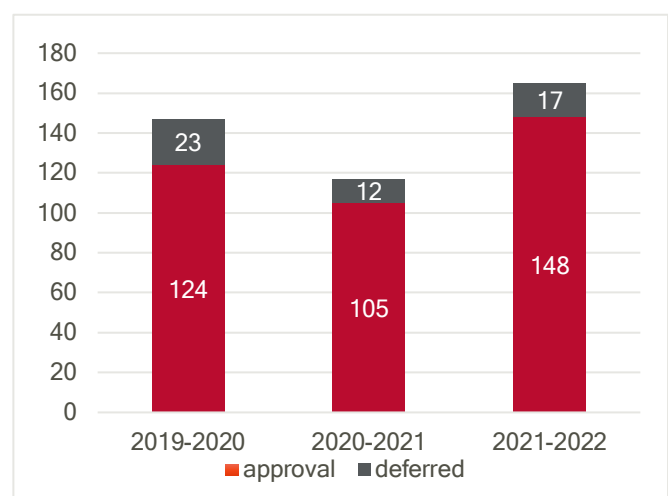


Figure 10. Full Board Review

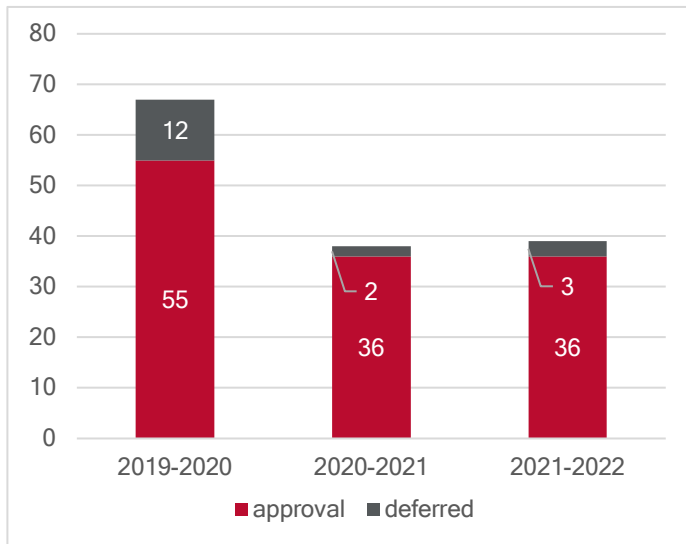
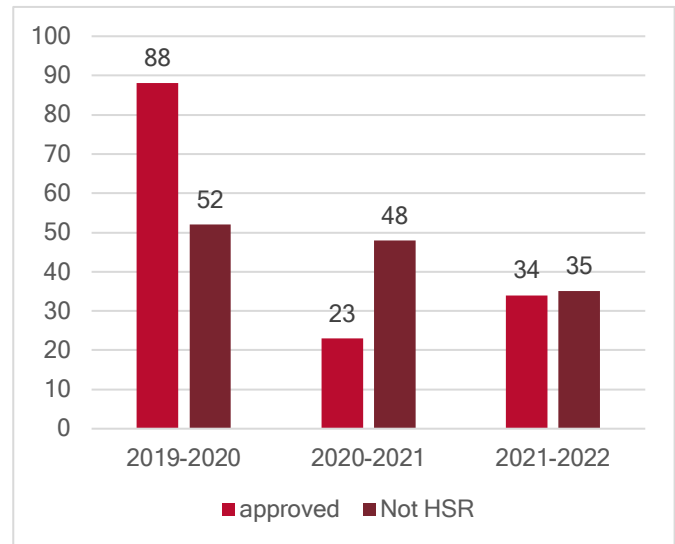


Figure 11. Administrative Review



## TURNAROUND TIME

Turnaround time is calculated from the initial submission date to the IRB determination date. It encompasses:

- Prereview of the application for completeness and accuracy
- Required application changes to be made by the researchers and submitted to the IRB
- IRB assignment to the committee/reviewer
- IRB determination

Figure 12 shows the expected number of days needed for each step in the review process. Please note that repeated emails and late responses may delay the process.

Figure 12. Expected Timeline at Each Step

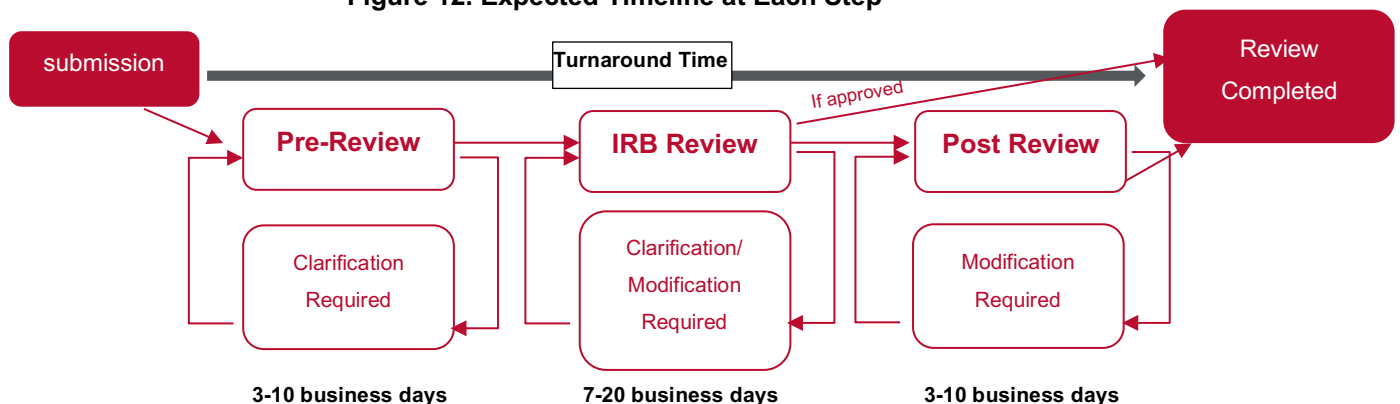


Table 9 presents the average turnaround time (18 calendar days) and median (11 calendar days) during 2021-2022. It also shows that 60% of protocols were determined within 15 days and 80% of protocols were determined within 25 days during 2021-2022.



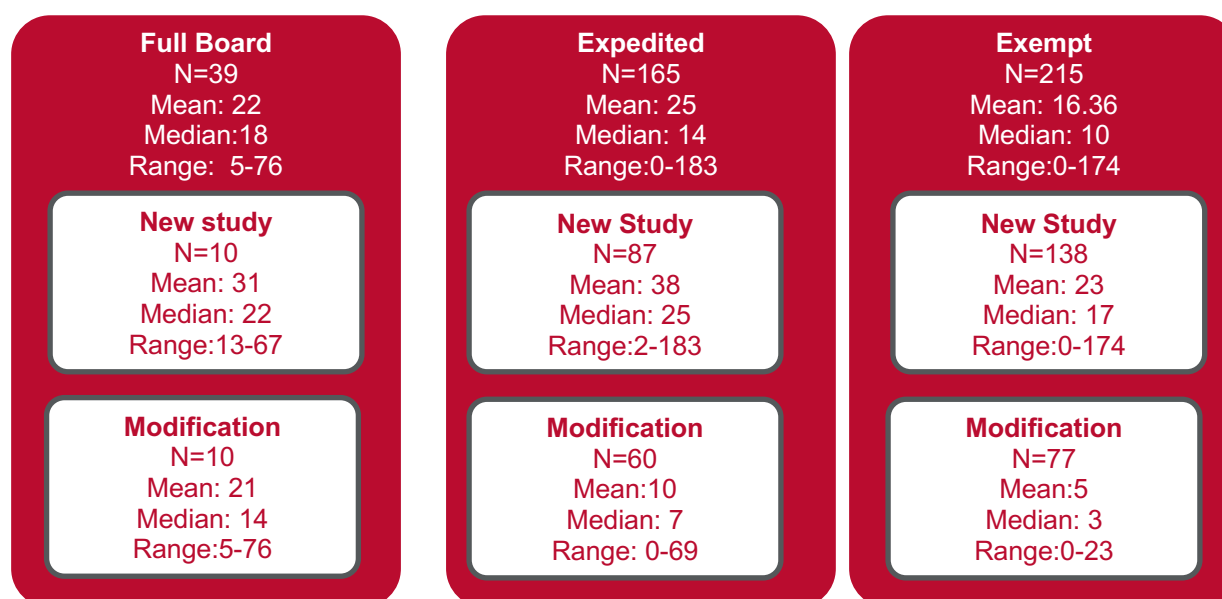
**Table 9. Turnaround Time (Calendar Days)**

		2019-2020	2020-2021	2021-2022
<b>Number of protocols</b>		711	519	488
<b>Mean</b>		14	21	18
<b>Median</b>		8	14	11
<b>Minimum</b>		0	0	0
<b>Maximum</b>		409	324	183
<b>Percentile</b>	60	11	17	15
	80	21	31	25

The average turnaround time is 21 calendar days for full board review and 24 calendar days for expedited studies. Exempt studies were determined in an average of 16 calendar days and not HSR determinations were made in an average of 9 calendar days (Table 10). Figure 13 provides some details by board type and submission type.

**Table 10. Average Turnaround Time by Board Type and Action (Calendar Days)**

Year	Exempt	Expedited		Full Board		Administrative		Overall Average
	Exempt	Approved	Deferred	Approved	Deferred	Approved	Not HSR	
<b>2019-2020</b>	10	27	23	25	29	3	11	14
<b>2020-2021</b>	22	24	22	24	22	6	12	21
<b>2021-2022</b>	16	24	36	21	31	3	9	18

**Figure 7. Summary of Turnaround Time 2021-2022 (Calendar Days)**

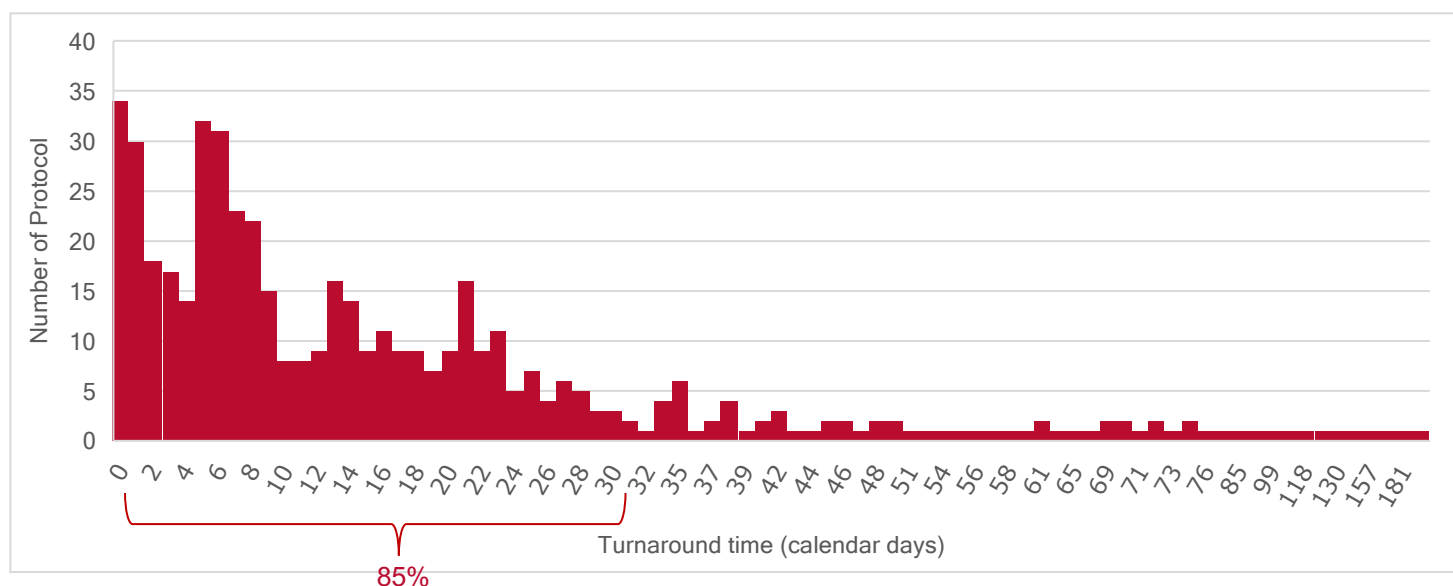
**Figure 8. Number of Protocols by Turnaround Time 2021-2022**

Figure 14 shows the feature of the overall IRB turnaround time during 2021-2022. Overall, 85% of protocols were decided within 30 days. Table 11 shows some factors that impacted the delay of review completion, which may account for some of the outliers and longer turnaround times.

**Table 11. Factors Impacting IRB Turnaround Time and Examples**

Factors	Examples
Quality of Submission	<ul style="list-style-type: none"> <li>Submissions that are incomplete or do not adhere to IRB submission guidelines require additional time for review and approval.</li> </ul>
Delayed response/ disconnected communication	<ul style="list-style-type: none"> <li>After pre-review or review feedback was sent, researchers did not address the requests in a timely manner. Please note that the ORI staff usually sends a reminder email after 30-45 days from the last time the protocol is unlocked.</li> </ul>
Simple Mistakes	<ul style="list-style-type: none"> <li>After pre-review, researchers failed to relock the project on the system. ORI staff cannot receive a notification from the IRBNet if researchers have not relocked their projects.</li> </ul>
Risk level and safeguard	<ul style="list-style-type: none"> <li>Studies involving greater than minimal risk should provide a strong justification(s) and safeguard(s) that minimize the risk. Insufficient justification and unsatisfactory safeguards may require more time to communicate with researchers.</li> </ul>
New submission system	<ul style="list-style-type: none"> <li>Since a new submission system, the Wizard form, was launched in July 2021, some researchers who just submitted the old PDF form have had difficulty converting the old application to the new Wizard format.</li> </ul>
Expedite review process change	<ul style="list-style-type: none"> <li>As the IRB has adopted a mixed process for expedited review, the expedited review turnaround time has increased because the majority of studies were unlocked for modification instead of deferring decision. This change affected the increased approval rate but also affected the turnaround time.</li> </ul>
COVID- 19	<ul style="list-style-type: none"> <li>Some researchers suffered from COVID-19 and asked to extend the due date.</li> </ul>

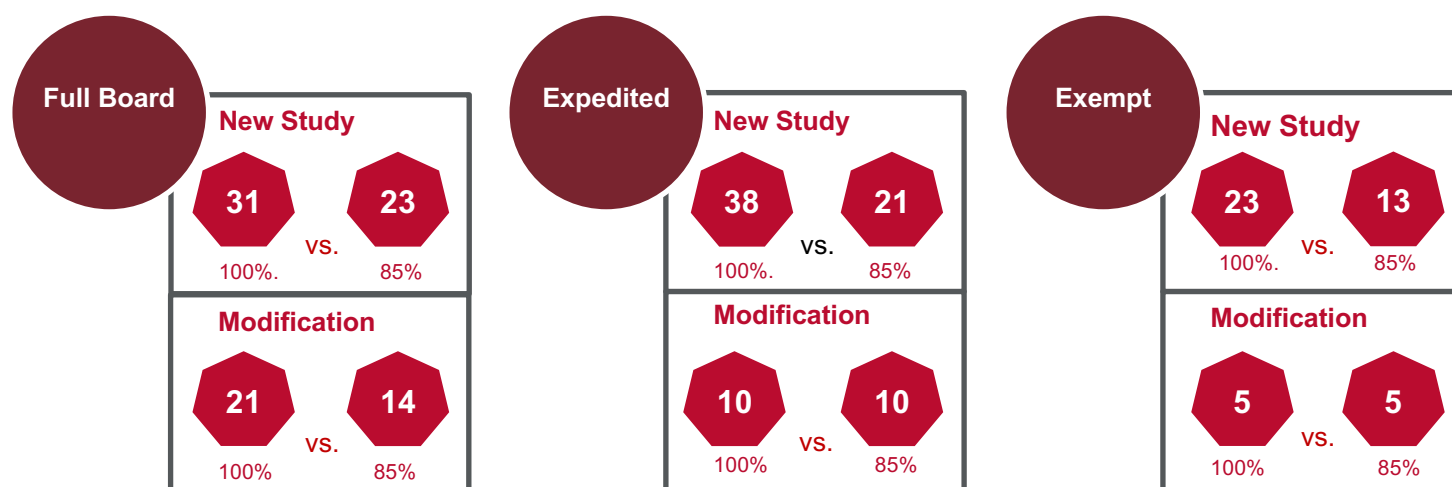
	<ul style="list-style-type: none"> <li>Some researchers had to pause their studies due to COVID-19 during the review process.</li> </ul>
External Site Study	<ul style="list-style-type: none"> <li>A few researchers had a hard time obtaining letters of support from external organizations and asked for an extension.</li> </ul>

Table 12 shows the comparison of the average turnaround time between all review activities and activities completed within 30 days, which accounts for 85% of the entire protocols. By removing outliers and exceptional delays, this helps the BSU researcher community understand more sensible turnaround time. The comparison of all IRB actions and protocols that completed review within 30 days by board type and submission type can be seen in Figure 15.

**Table 12. Average Turnaround Time for Overall IRB Review and Average Turnaround Time for IRB Review Completed Within 30 Days 2021-2022 (Calendar Day)**

Board N	Exempt	Expedited		Full Board		Administrative		Overall Average
	Exempt	Approved	Deferred	Approved	Deferred	Approved	Not HSR	
100%(n=488)	16	24	36	21	31	3	9	18
85% <sup>6</sup> (n=414)	10	12	20	17	15	3	8	10

**Figure 9 Summary of Comparison of Average Turnaround Time between Overall IRB Review and IRB Review Completed Within 30 Days 2021-2022 (Calendar Day)**



<sup>6</sup> The number includes protocols that IRB completed review for and took action within 30 days, which accounts for 85% of entire protocols.