

VCU HRPP Metrics

Quick Statistics on VCU's Portfolio	Submission Volume	Total Approval Volumes	Initial Study Approval Volumes	Review Process Diagram & AAHRPP Metrics	Time to Approval by Role and Point in the Review Process
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Overview of VCU's portfolio of active human research studies

Number of Active Studies

Review Category	IRB of Record		Grand Total
	VCU IRB	External IRBs	
Exempt	1,462	1	1,463
Expedited	545	48	593
Fu I Board	150	507	657
Grand Total	2,157	556	2,713

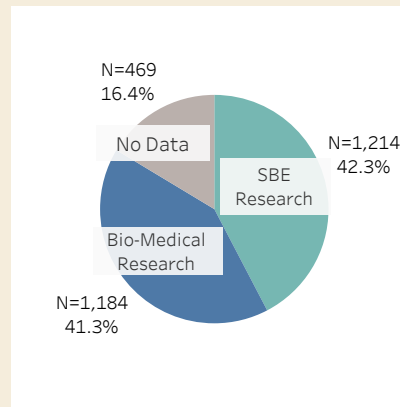
Quick Statistics

829	Principal Investigators
328	Student/Trainee Initiated Studies
682	Clinical Trials
805	Clinical Research Studies
612	FDA Regulated Studies
19	Expanded Access Protocols

Active Studies by School/College

Primary Department (group)	IRB of Record	
	VCU IRB	External IRBs
School of Medicine	1,113	227
College of Humanities & Sciences	253	6
School of Education	153	3
School of Pharmacy	140	1
Massey Cancer Center	103	251
School of Dentistry	91	1
College of Health Professions	80	
School of Business	68	3
Missing Department	55	119
Wilder School	54	
School of Nursing	41	3
School of Social Work	31	1
Other Administrative Units	28	1
School of Engineering	23	
School of Arts	11	
VCU Life Sciences	2	
University College	1	
Summer Program	1	
Mathematical Sciences	1	
Honors College	1	
Continuing Education - Medicine	1	
Grand Total	2,251	616

Types of Research Topics



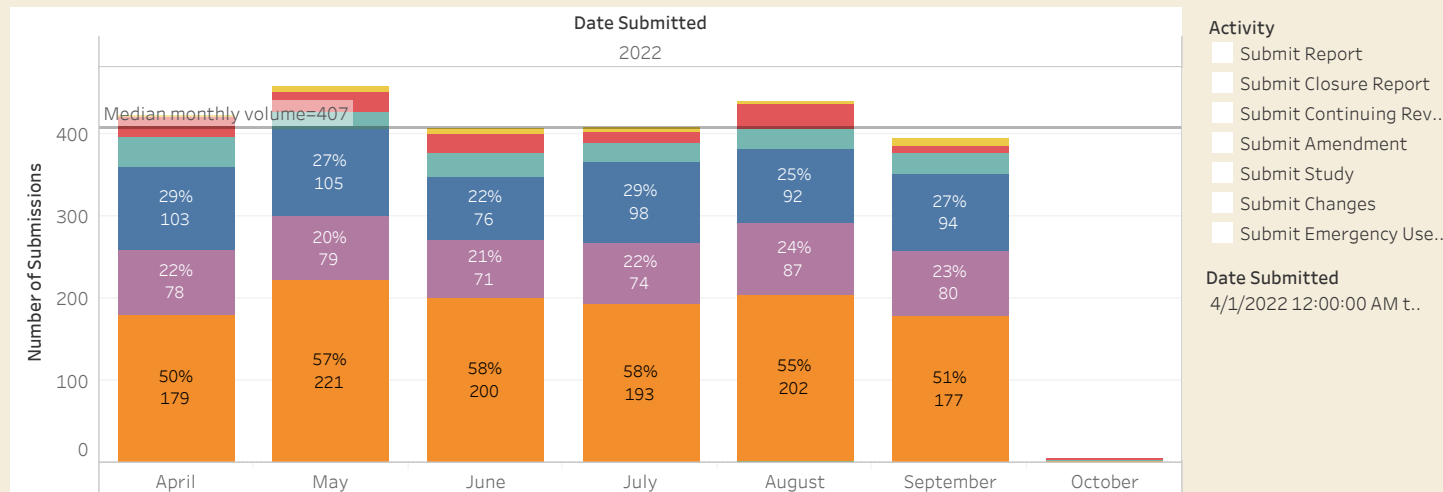
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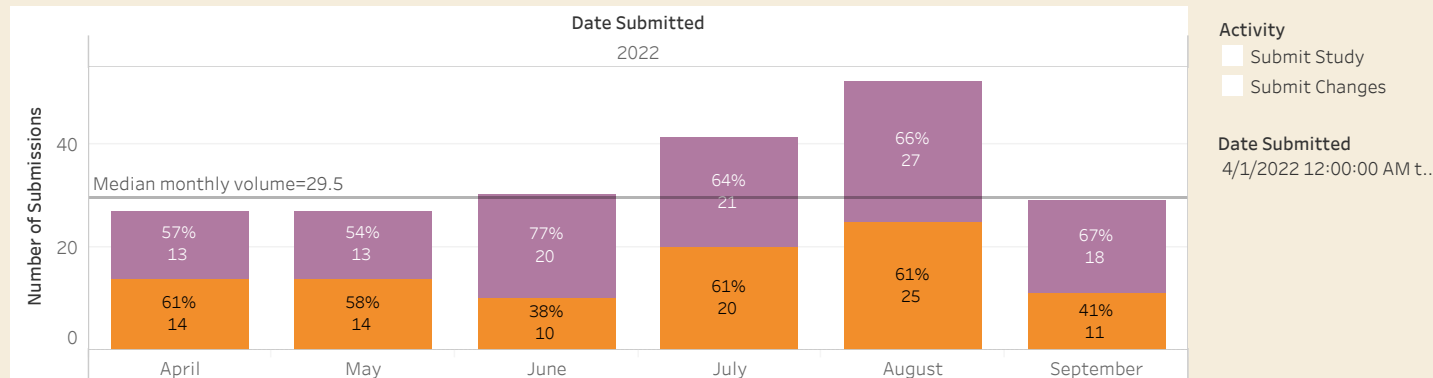
Submission Volume Statistics

The VCU IRB receives and processes about 3,000 submissions per year and 400-450 submissions per month, including new studies, amendments, continuations, closures, and reports. **Over half of what the IRB's processes in any given month is re-submitted changes.**

VCU IRB Submission Volume



External IRB Submission Volume



VCU HRPP Metrics

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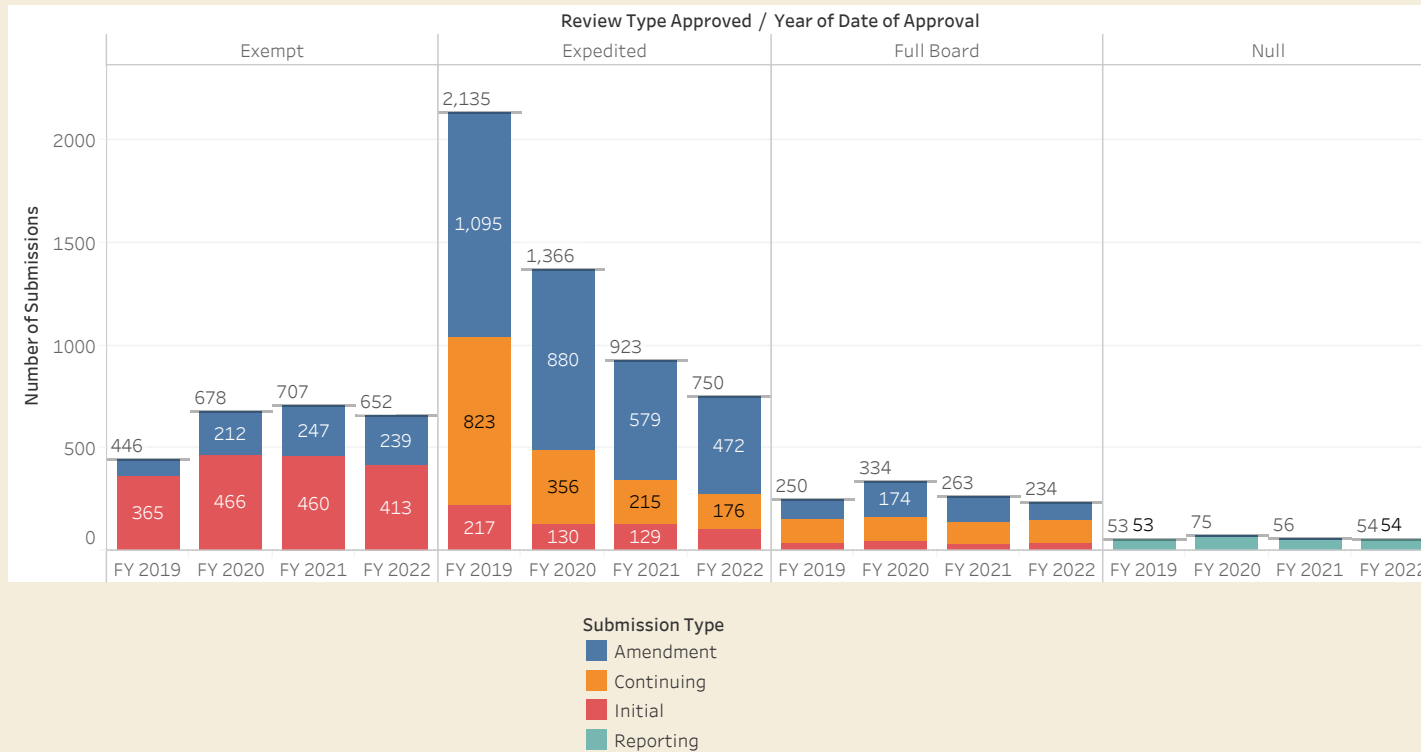
Approval Volume Statistics

The 2018 Common Rule is the federal regulations that govern human subjects research. It went into effect in January 2019, and among the major changes were: expanding the categories of exemption, changing the requirements for continuing reviews for expedited studies.

The impact of the 2018 Common Rule can be seen in the below.

- Studies that used to require expedited review are now qualifying for exemption.
- Approximately one-third of the expedited volume was made up of continuing reviews, which no longer need to be submitted (studies submit annual status updates instead).
- A large number of amendments were approved that converted studies from the Pre-2018 Common Rule to the 2018 Common Rule requirements.

Approval Volume for All VCU IRB Submissions



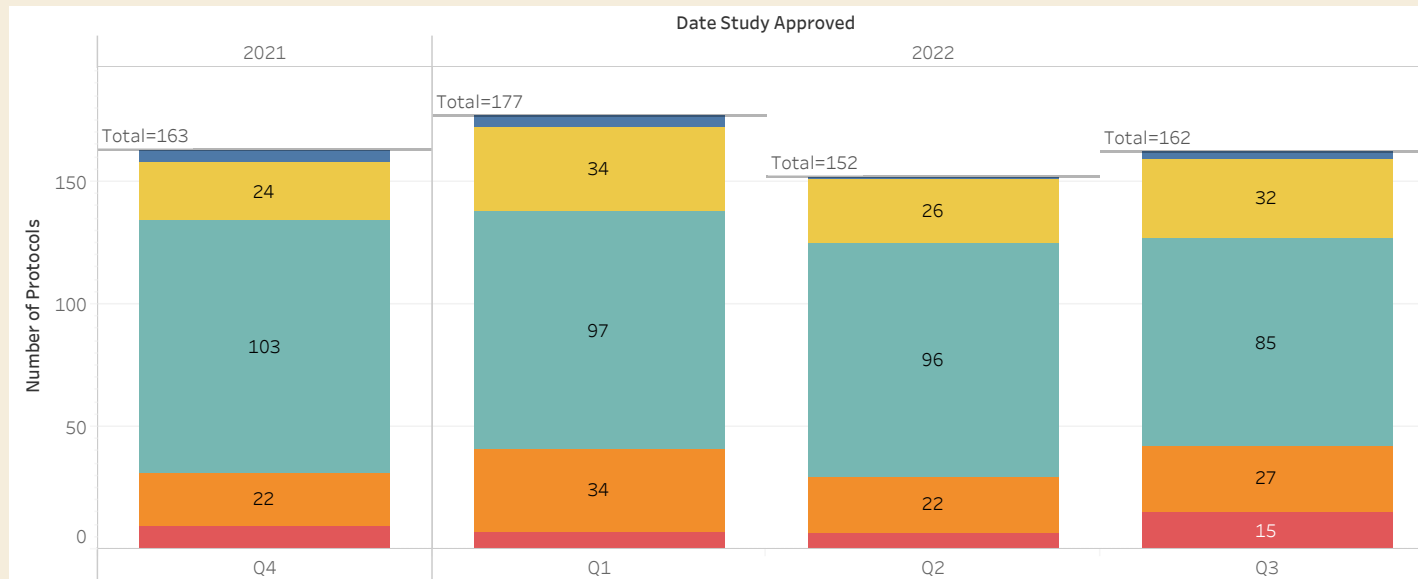
VCU HRP Metrics



Recent Initial Study Approval Volume Statistics

Since March 2020, fewer interventional expedited and full board studies were being submitted. More exempt chart review, survey, and interview studies were being performed. The full board approves between 2 and 5 new studies per month.

Initial Study Approval Volume



IRB of Record, Review Type Approved

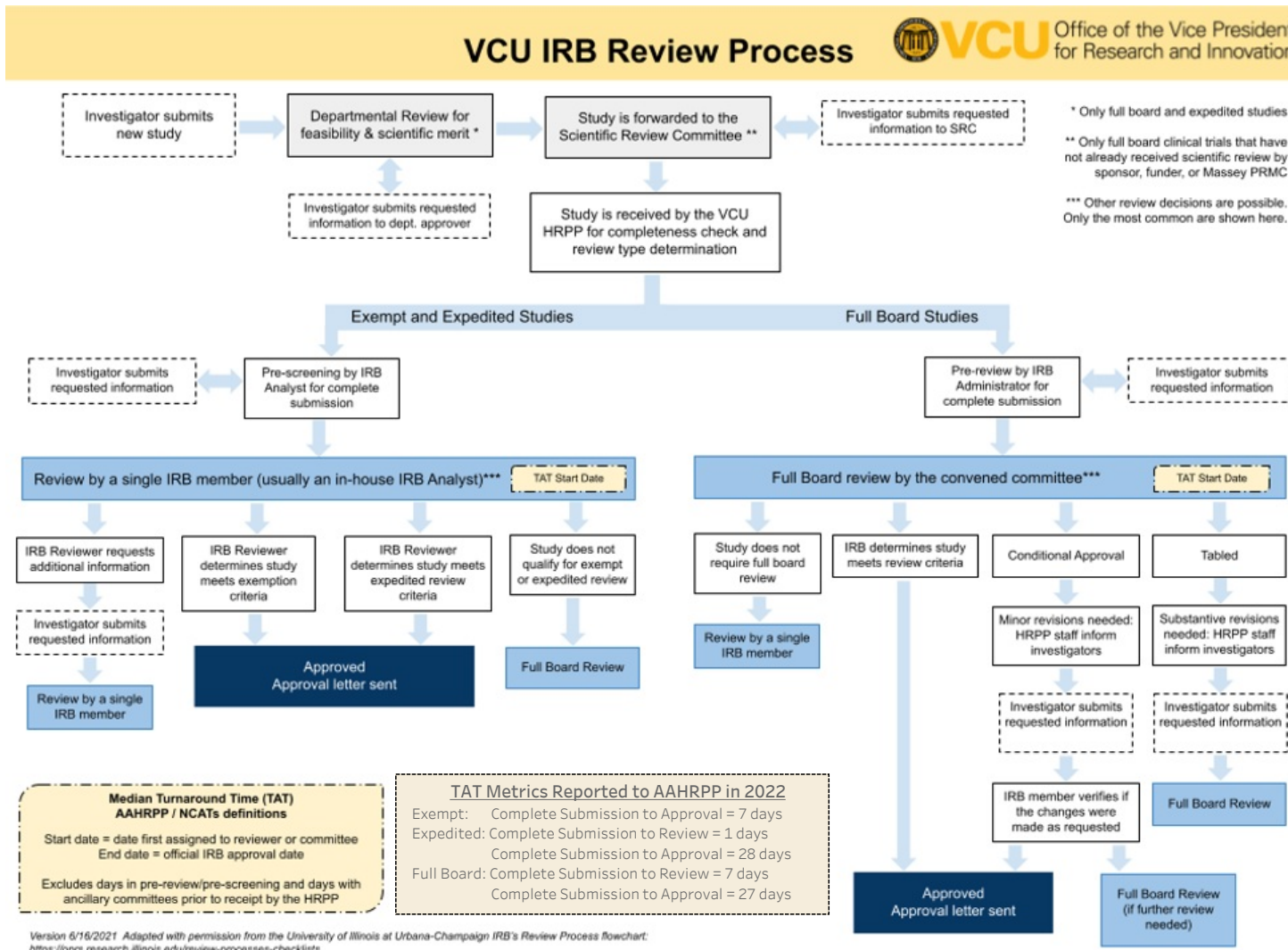
- External IRBs, Expedited
- External IRBs, Full Board
- VCU IRB, Exempt
- VCU IRB, Expedited
- VCU IRB, Full Board

Date Study Approved

10/1/2021 12:00:00 AM to ..

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Time to Approval Statistics

Time to approval has remained steady for exempt and expedited submissions since January 2020 when the IRB instituted several operational changes and hired additional staff. The full board team has been understaffed for the past 6 months. Note that the median days in each part of the review process is low, indicating process efficiency. Longer timelines result from incomplete submissions that require multiple rounds of changes.

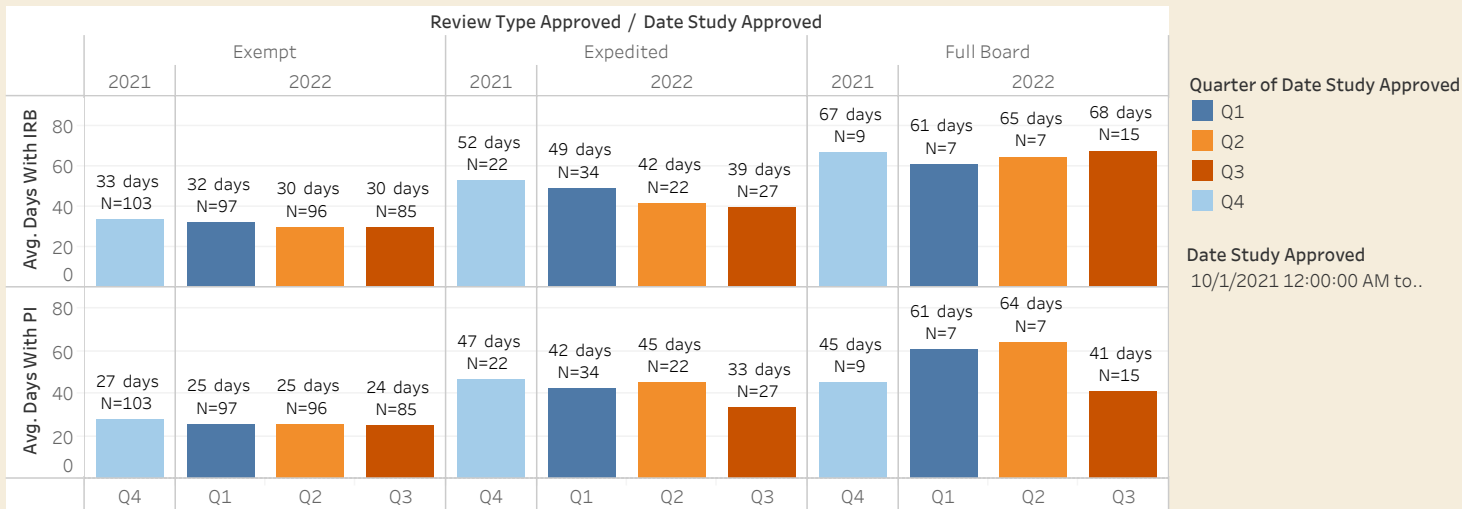
Median Days in Role for VCU IRB Studies

Timepoint in IRB Review Process	Review Type Approved			
	Exempt	Expedited	Full Board	Grand Total
Time with HRPP Staff for Screening/Pre-Review	11 (1 - 16) N=7	9 (0 - 20) N=12	5 (0 - 42) N=38	6 (0 - 42) N=57
IRB Review Time	8 (0 - 18) N=5	9 (0 - 28) N=9	8 (0 - 35) N=38	8 (0 - 35) N=52
Time with PI for Revisions	6 (0 - 57) N=5	4 (0 - 56) N=8	5 (0 - 60) N=31	5 (0 - 60) N=44

Date Study Approved
10/1/2021 12:00:00 AM to..

Median # Days (min - max days) and number of distinct studies (N).
Currently approved VCU IRB studies only. Only initial submissions approved during the previous 12 months.

Average Days with the VCU IRB and with Study Teams



VCU IRB studies only. Only initial submissions approved in the previous 12 months.
Days with the IRB includes time during screening/pre-review before a complete submission is ready + time under IRB review.