



## INDIANA UNIVERSITY

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

Office of Research Compliance

Dear Colleague:

We are pleased to provide you with the attached Quarterly Report for the IU Human Subjects Office (HSO). The HSO supports the institutional review boards (IRBs) which serve IU, IU Health, Roudebush VAMC, Eskenazi Health, and several other institutions in Indianapolis and the surrounding areas.

The Quarterly Report provides current metrics for the IRBs.

- **New Study Approval Comparison – IU vs. AAHRPP:** In 2011, the Association for the Accreditation of Human Research Protection Programs (AAHRPP) began collecting turnaround times from all accredited institutions, which have become the gold standard for the industry. Page 1 of the report provides a comparison of IU turnaround times with this standard. As you can see, the IU IRBs are able to review and approve new study submissions more quickly than the average AAHRPP-accredited institution.
- **Throughput:** Pages 2 to 3 provide information regarding throughput, an internal metric which compares the number of items submitted to the HSO for review with the number of item completed, for the current and previous fiscal years. While these two numbers are rarely equivalent, a positive throughput indicates that more items have been completed than received. The HSO has produced positive or nearly positive throughput overall for all time periods, demonstrated by the nearly-aligned graphical lines of items received and completed.
- **Total Protocols:** Page 4 offers a historical accounting of total active protocols managed by the HSO.

Please note that IU quarters are based on a fiscal year beginning July 1 and ending June 30. As such, quarters refer the following dates:

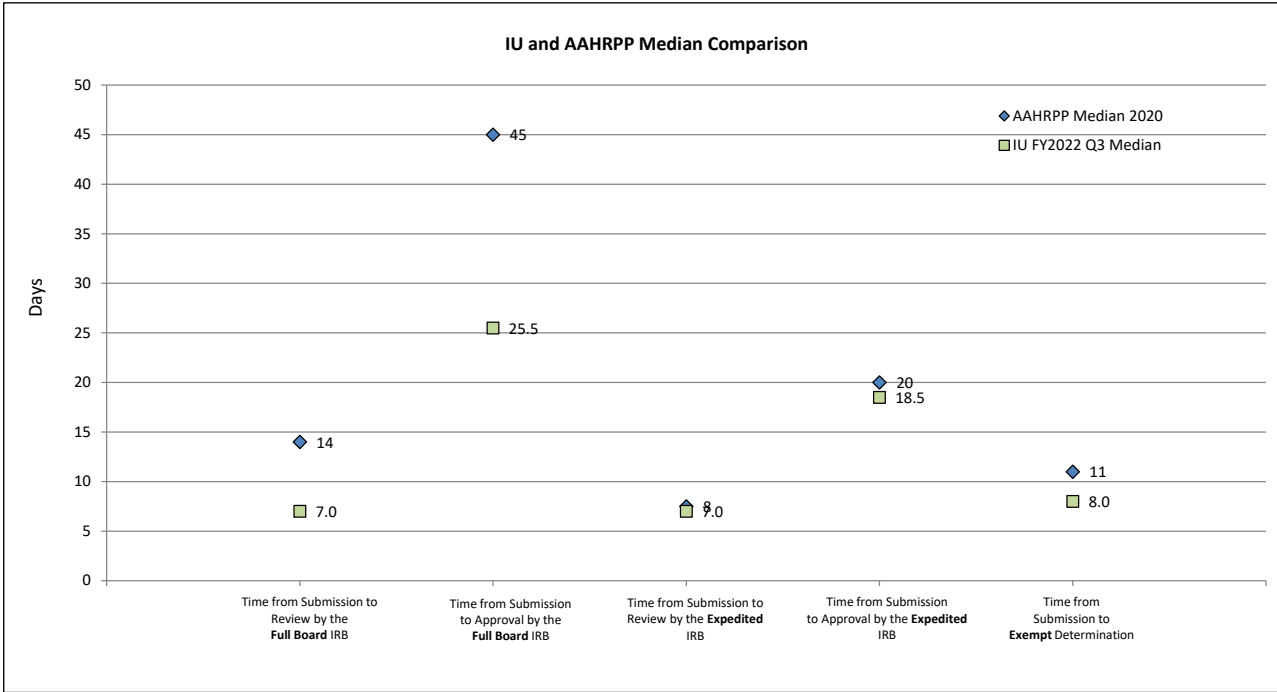
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

We are pleased to provide you with this information and encourage you to share it with your investigators and colleagues as you see fit. As always, we would be happy to discuss this information, or any questions or concerns regarding human research protections, with you at any time. Please don't hesitate to contact me at your convenience.

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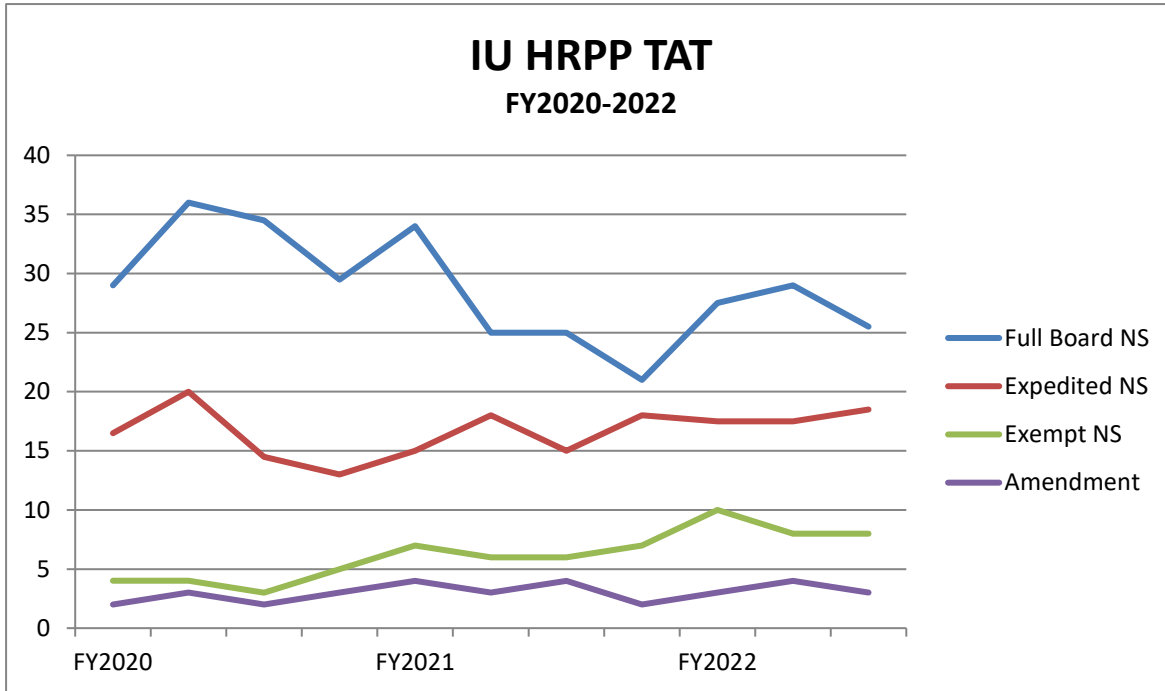
New Study Approval Comparison: IU vs. AAHRPP - FY2022 Q3					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2020	14	45	8	20	11
IU FY2022 Q3 Median	7.0	25.5	7.0	18.5	8.0



Notes:

1. AAHRPP metrics for academic institutions released 2021, based on 2020 annual report data.
2. Full Board N = 34; Expedited N = 136; Exempt N = 543
3. Means in order of the chart: Full Board - 8, 45; Expedited - 7, 24; Exempt - 12

IU Turnaround Times (TAT) - FY2022 Q3							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1327	6.6	10.0	3	91	0	91
Exempt Protocols	543	11.7	10.9	8	67	0	67
Expedited Protocols	136	24.2	18.4	18.5	93	0	93
Full Board Protocols	34	44.6	55.1	25.5	256	4	260
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	392	7.9	12.4	2	84	0	84
Full Board Protocols	34	44.6	55.1	25.5	256	4	260
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	609	5.8	7.5	4	55	0	55
Exempt Protocols	207	12.5	9.2	9	44	0	44
Expedited Protocols	73	20.0	15.1	16	93	0	93
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	326	6.5	10.5	4	91	0	91
Exempt Protocols	336	11.2	11.8	7	67	0	67
Expedited Protocols	63	29.0	20.6	21	76	2	78

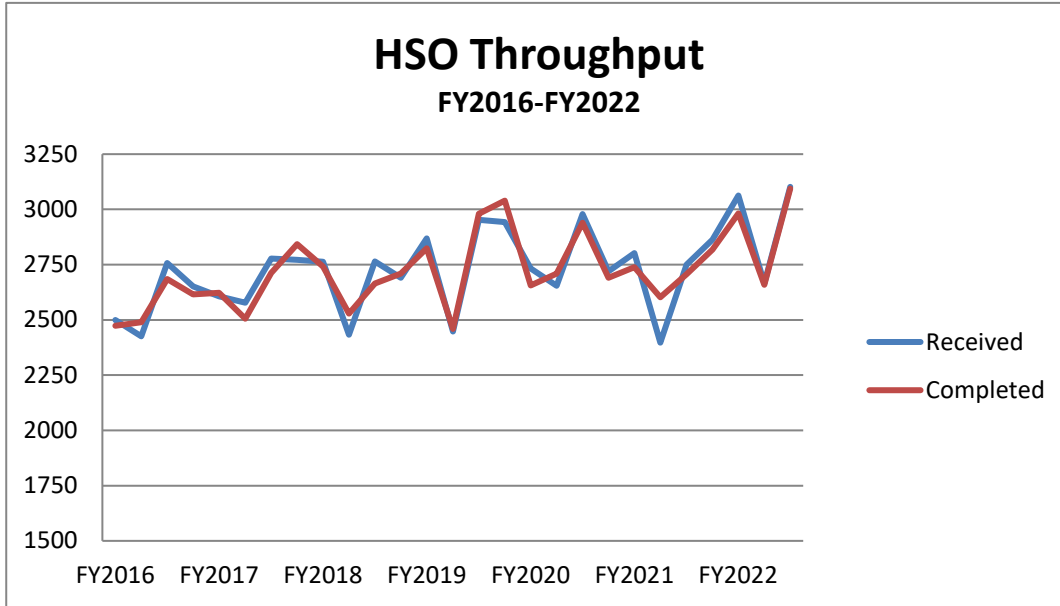


Year	Quarter	Full Board NS	Expedited NS	Exempt NS	Amendment
FY2020	Q1	29	16.5	4	2
	Q2	36	20	4	3
	Q3	34.5	14.5	3	2
	Q4	29.5	13	5	3
FY2021	Q1	34	15	7	4
	Q2	25	18	6	3
	Q3	25	15	6	4
	Q4	21	18	7	2
FY2022	Q1	27.5	17.5	10	3
	Q2	29	17.5	8	4
	Q3	25.5	18.5	8	3

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Throughput - FY2022 Q3				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1356	1378	22	-1.6%
Closeouts	173	178	5	-2.9%
Continuing Reviews	225	197	-28	12.4%
General Info (FYI)	57	59	2	-3.5%
Not Human Subjects Protocols	70	73	3	-4.3%
Exempt Protocols	611	590	-21	3.4%
Expedited Protocols	156	158	2	-1.3%
Full Board Protocols	48	49	1	-2.1%
Reliance Team	406	412	6	-1.5%
<b>Total</b>	<b>3102</b>	<b>3094</b>	<b>-8</b>	<b>0.3%</b>
Greater than Minimal Risk Team				
Amendments	386	404	18	-4.7%
Closeouts	36	38	2	-5.6%
Continuing Reviews	134	117	-17	12.7%
General Info (FYI)	57	59	2	-3.5%
Full Board Protocols	33	36	3	-9.1%
<b>Total</b>	<b>646</b>	<b>654</b>	<b>8</b>	<b>-1.2%</b>
Biomedical Team				
Amendments	613	629	16	-2.6%
Closeouts	77	80	3	-3.9%
Continuing Reviews	88	79	-9	10.2%
Not Human Subjects Protocols	44	48	4	-9.1%
Exempt Protocols	209	218	9	-4.3%
Expedited Protocols	77	82	5	-6.5%
Full Board Protocols	13	12	-1	7.7%
<b>Total</b>	<b>1121</b>	<b>1148</b>	<b>27</b>	<b>-2.4%</b>
Social/Behavioral/Educational Team				
Amendments	357	345	-12	3.4%
Closeouts	60	60	0	0.0%
Continuing Reviews	3	1	-2	66.7%
Not Human Subjects Protocols	26	25	-1	3.8%
Exempt Protocols	402	372	-30	7.5%
Expedited Protocols	79	76	-3	3.8%
Full Board Protocols	2	1	-1	N/A
<b>Total</b>	<b>929</b>	<b>880</b>	<b>-49</b>	<b>5.3%</b>

NOTE: Total for All HSO includes Reliance items which are not separately listed in Team sections



Year	Quarter	Received	Completed	Difference
FY2016	Q1	2500	2474	-26
	Q2	2425	2490	66
	Q3	2757	2685	-72
	Q4	2652	2615	-37
FY2017	Q1	2606	2622	16
	Q2	2578	2506	-72
	Q3	2777	2713	-64
	Q4	2772	2842	70
FY2018	Q1	2763	2741	-22
	Q2	2433	2528	95
	Q3	2765	2664	-101
	Q4	2691	2709	18
FY2019	Q1	2869	2824	-45
	Q2	2448	2459	11
	Q3	2953	2980	27
	Q4	2942	3040	98
FY2020	Q1	2732	2656	-76
	Q2	2655	2710	55
	Q3	2979	2940	-39
	Q4	2719	2690	-29
FY2021	Q1	2802	2739	-63
	Q2	2397	2603	206
	Q3	2750	2707	-43
	Q4	2863	2818	-45
FY2022	Q1	3063	2982	-81
	Q2	2665	2659	-6
	Q3	<b>3102</b>	<b>3094</b>	<b>-8</b>

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<b>HSO Total Protocols</b>						
	FY2022 Q3	FY2022 Q2	FY2022 Q1	FY2021 Q4	FY2021 Q3	FY2021 Q2
Exempt (approved in the last year: 4.1.2021 to 3.31.2022)	1832	1821	1857	1762	1943	1978
Expedited	2917	2837	2830	2793	2777	2787
Full Board	928	944	939	975	996	1079
<b>AAHRPP Total</b>	<b>5677</b>	<b>5602</b>	<b>5626</b>	<b>5530</b>	<b>5716</b>	<b>5844</b>
Reliance	861	826	804	783	772	735
Emergency Use	0	0	0	0	0	1
Humanitarian Use Devices (HUD)	22	20	20	17	20	22
Not Human Subjects Research	265	280	N/A	N/A	N/A	306
<b>Miscellaneous Total</b>	<b>1148</b>	<b>1126</b>	<b>824</b>	<b>800</b>	<b>792</b>	<b>1064</b>
<b>All HSO Total</b>	<b>6825</b>	<b>6728</b>	<b>6450</b>	<b>6330</b>	<b>6508</b>	<b>6908</b>

NOTES:

1. Reliance includes: IU protocols deferred to external IRBs for review.
2. Emergency Use is a quarterly count rather than a running total as these submissions are not considered "Active".
3. Not Human Subjects Research includes Applications for Not Human Subjects research approved since 1/19/2021 (implementation of Quali Protocols). In prior quarters, NHSR approvals in the prior year were counted.