



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:

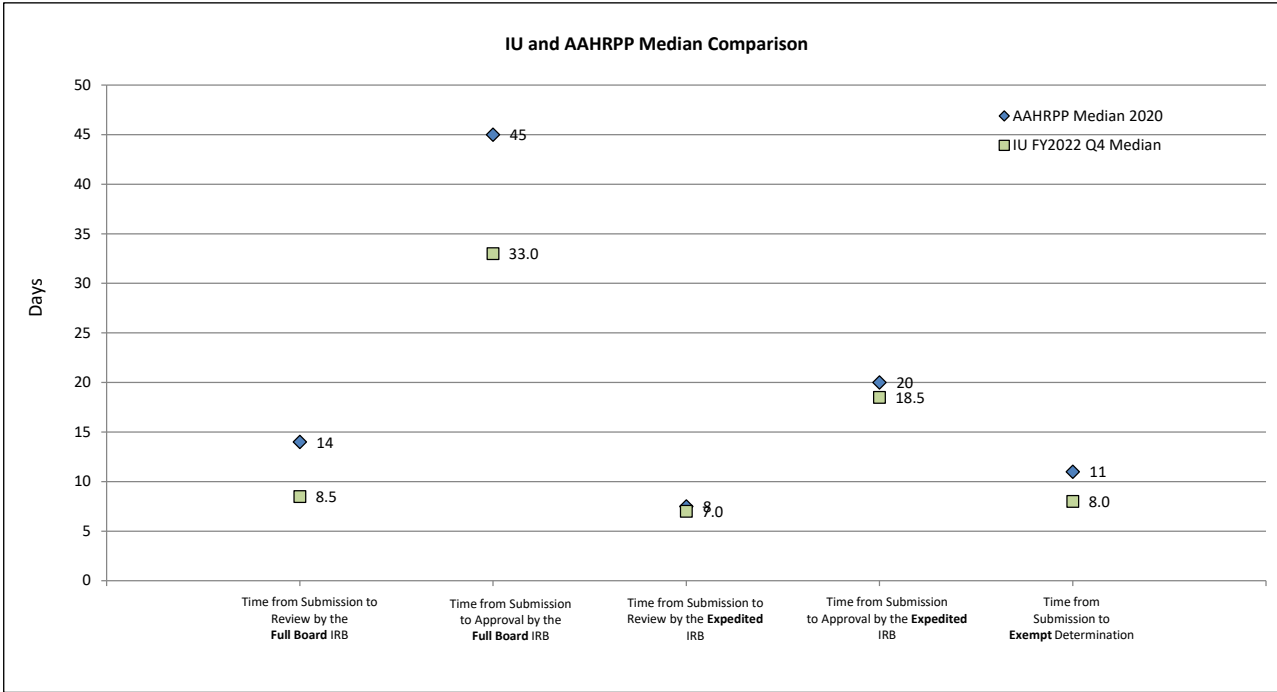
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

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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HRPP Quarterly Report
Fiscal Year 2022, Quarter 4

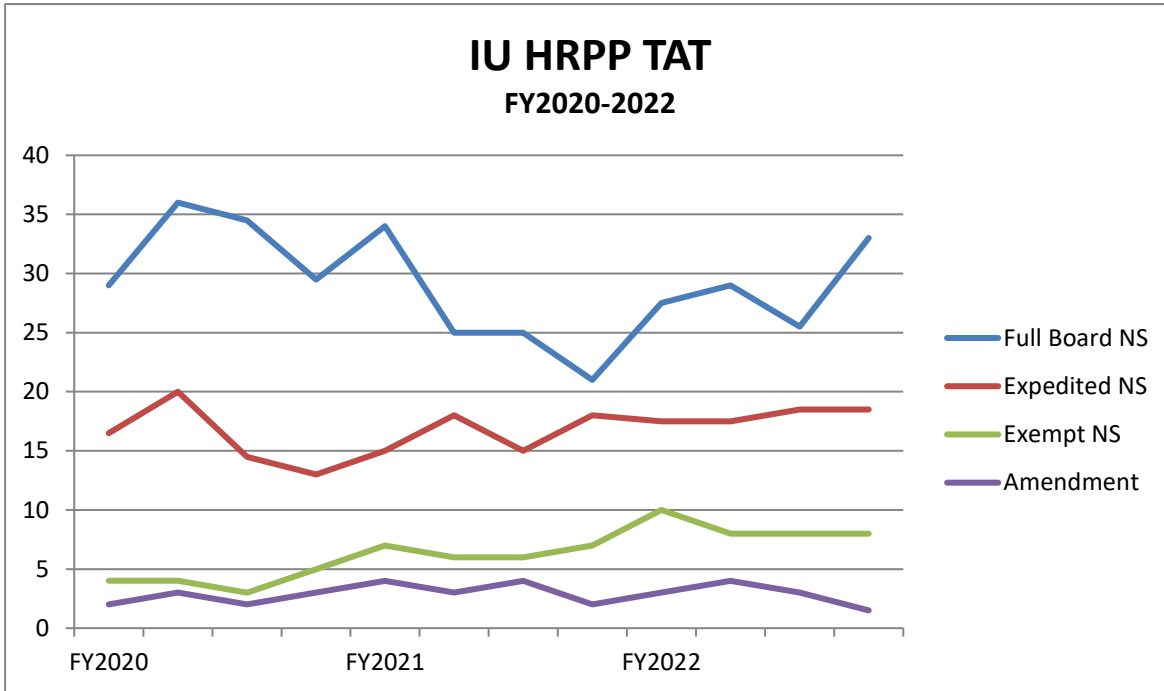
New Study Approval Comparison: IU vs. AAHRPP - FY2022 Q4					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2020	14	45	8	20	11
IU FY2022 Q4 Median	8.5	33.0	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 = 40; Expedited N = 116; Exempt N = 457
3. Means in order of the chart: Full Board - 10, 42; Expedited - 6, 22; Exempt - 14

IU Turnaround Times (TAT) - FY2022 Q4							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1226	5.3	8.9	1.5	84	0	84
Exempt Protocols	457	13.6	13.7	8	105	0	105
Expedited Protocols	116	22.4	18.0	18.5	100	0	100
Full Board Protocols	40	42.1	39.5	33	181	1	182
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	327	6.6	11.8	1	69	0	69
Full Board Protocols	40	42.1	39.5	33	181	1	182
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	603	4.3	7.4	1	84	0	84
Exempt Protocols	216	10.4	8.7	7	56	0	56
Expedited Protocols	47	18.1	17.6	14	100	0	100
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	296	5.9	7.7	3	46	0	46
Exempt Protocols	241	16.5	16.5	11	105	0	105
Expedited Protocols	69	25.3	17.9	23	91	0	91

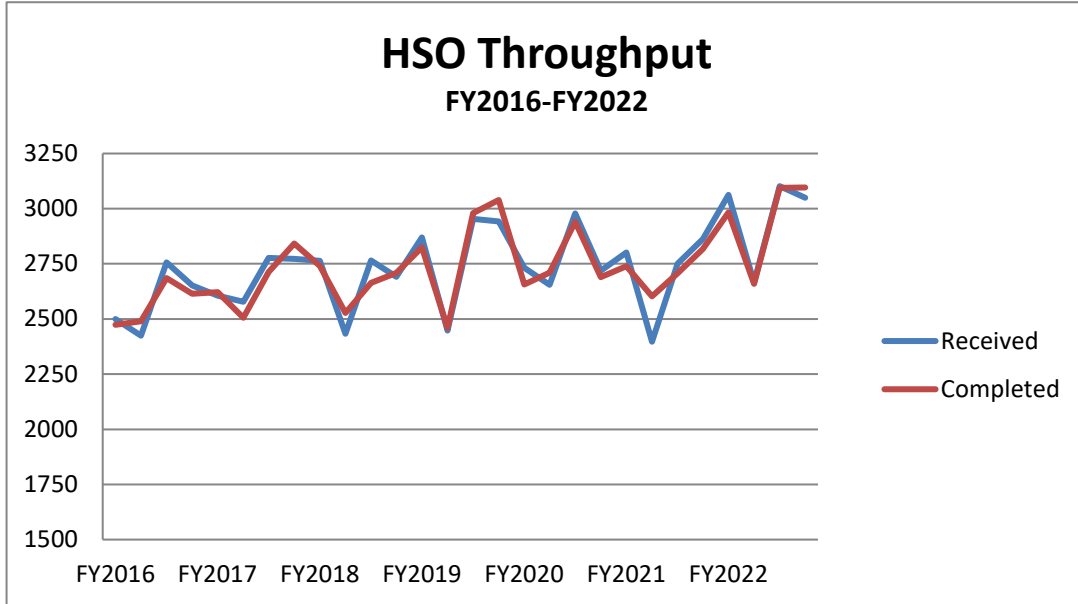


Year	Quarter	Full Board NS	Expedited NS	Exempt NS	Amendment
FY2020	Q1	29	16.5	4	2
	Q2	36	20	4	3
	Q3	34.5	14.5	3	2
	Q4	29.5	13	5	3
FY2021	Q1	34	15	7	4
	Q2	25	18	6	3
	Q3	25	15	6	4
	Q4	21	18	7	2
FY2022	Q1	27.5	17.5	10	3
	Q2	29	17.5	8	4
	Q3	25.5	18.5	8	3
	Q4	33	18.5	8	1.5

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Throughput - FY2022 Q4				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1252	1266	14	-1.1%
Closeouts	287	286	-1	0.3%
Continuing Reviews	201	238	37	-18.4%
General Info (FYI)	90	76	-14	15.6%
Not Human Subjects Protocols	51	48	-3	5.9%
Exempt Protocols	495	495	0	0.0%
Expedited Protocols	129	136	7	-5.4%
Full Board Protocols	49	48	-1	2.0%
Reliance Team	496	503	7	-1.4%
Total	3050	3096	46	-1.5%
Greater than Minimal Risk Team				
Amendments	319	332	13	-4.1%
Closeouts	40	40	0	0.0%
Continuing Reviews	136	158	22	-16.2%
General Info (FYI)	90	76	-14	15.6%
Full Board Protocols	23	30	7	-30.4%
Total	608	636	28	-4.6%
Biomedical Team				
Amendments	622	615	-7	1.1%
Closeouts	108	106	-2	1.9%
Continuing Reviews	58	72	14	-24.1%
Not Human Subjects Protocols	29	27	-2	6.9%
Exempt Protocols	239	226	-13	5.4%
Expedited Protocols	56	53	-3	5.4%
Full Board Protocols	22	16	-6	27.3%
Total	1134	1115	-19	1.7%
Social/Behavioral/Educational Team				
Amendments	311	319	8	-2.6%
Closeouts	139	140	1	-0.7%
Continuing Reviews	7	8	1	-14.3%
Not Human Subjects Protocols	22	21	-1	4.5%
Exempt Protocols	256	269	13	-5.1%
Expedited Protocols	73	83	10	-13.7%
Full Board Protocols	4	2	-2	N/A
Total	812	842	30	-3.7%

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	3102	3094	-8

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Q4	3050	3096	46
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HSO Total Protocols						
	FY2022 Q4	FY2022 Q3	FY2022 Q2	FY2022 Q1	FY2021 Q4	FY2021 Q3
Exempt (approved in the last year: 7.1.2021 to 6.30.2022)	1815	1832	1821	1857	1762	1943
Expedited	2896	2917	2837	2830	2793	2777
Full Board	926	928	944	939	975	996
AAHRPP Total	5637	5677	5602	5626	5530	5716
Reliance	881	861	826	804	783	772
Emergency Use	1	0	0	0	0	0
Humanitarian Use Devices (HUD)	21	22	20	20	17	20
Not Human Subjects Research	249	265	280	N/A	N/A	N/A
Miscellaneous Total	1152	1148	1126	824	800	792
All HSO Total	6789	6825	6728	6450	6330	6508

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 in the last year. In some prior quarters, NHSR approvals were not counted.