



## 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:

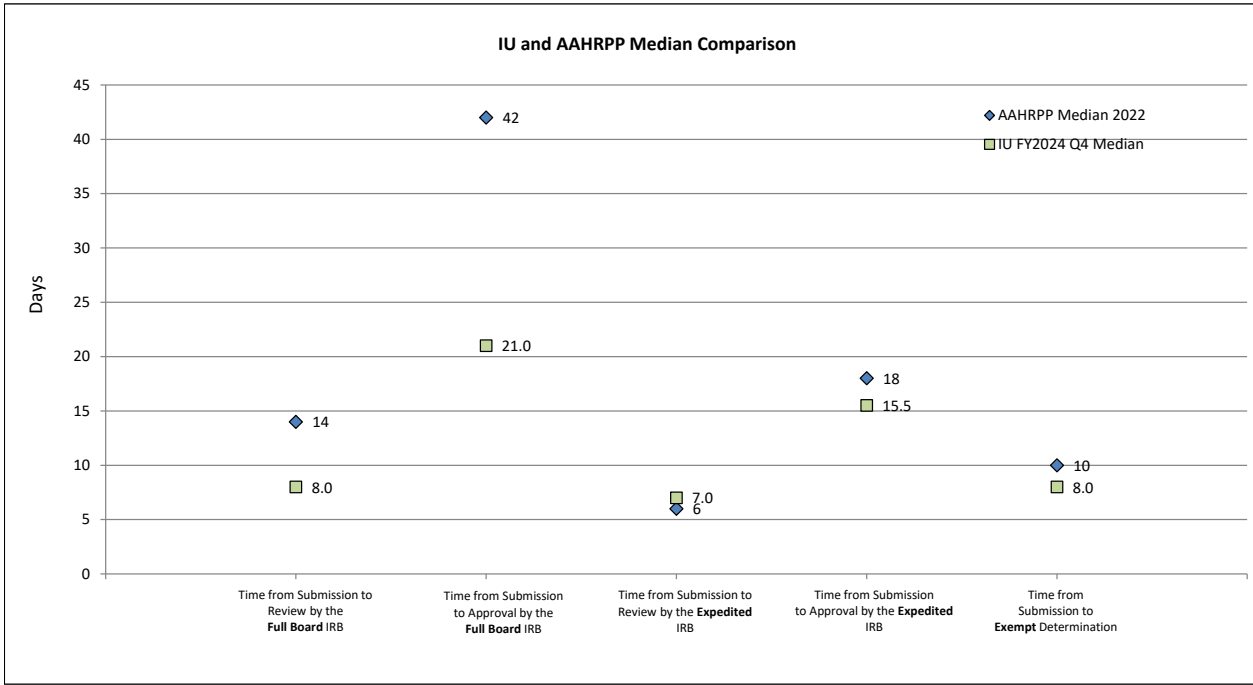
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

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.

John Baumann, PhD  
Associate Vice President for Research Compliance  
Indiana University  
(317) 278-7830  
[baumannj@iu.edu](mailto:baumannj@iu.edu)

IU HRPP Quarterly Report  
Fiscal Year 2024, Quarter 4

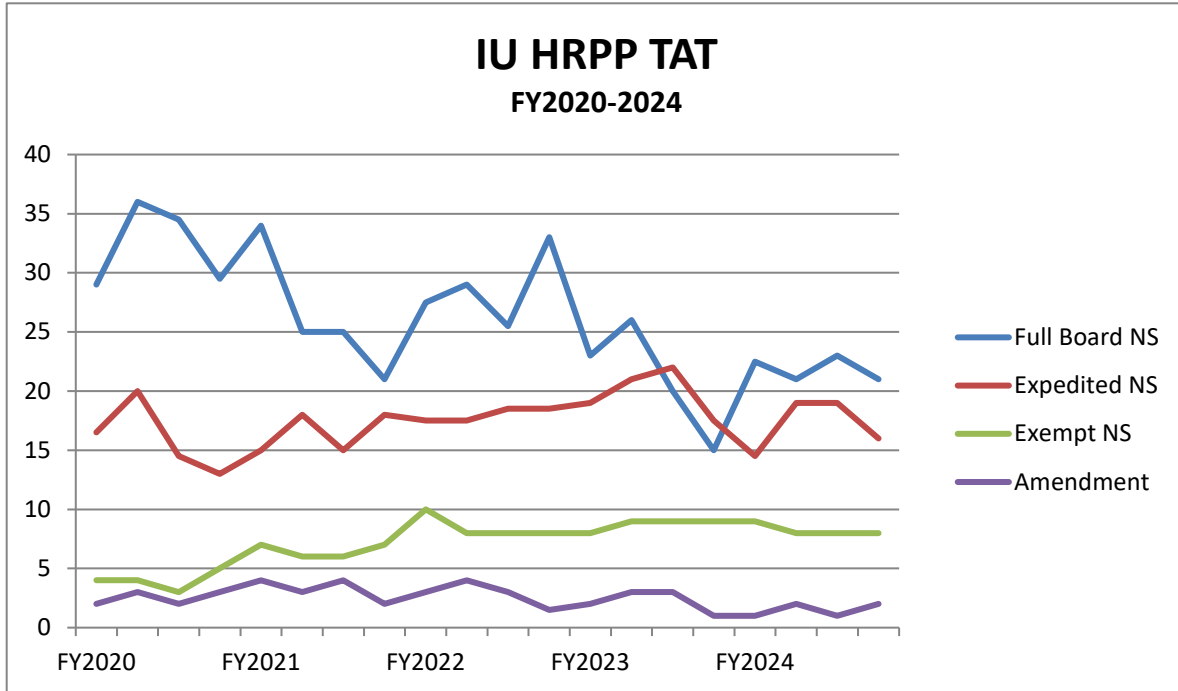
New Study Approval Comparison: IU vs. AAHRPP - FY2024 Q4					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2022	14	42	6	18	10
IU FY2024 Q4 Median	8.0	21.0	7.0	15.5	8.0



Notes:

1. AAHRPP metrics for academic institutions released 2023, based on 2022 annual report data.
2. Full Board N = 35; Expedited N = 134; Exempt N = 525
3. Means in order of the chart: Full Board - 10, 35; Expedited - 7, 22; Exempt - 13

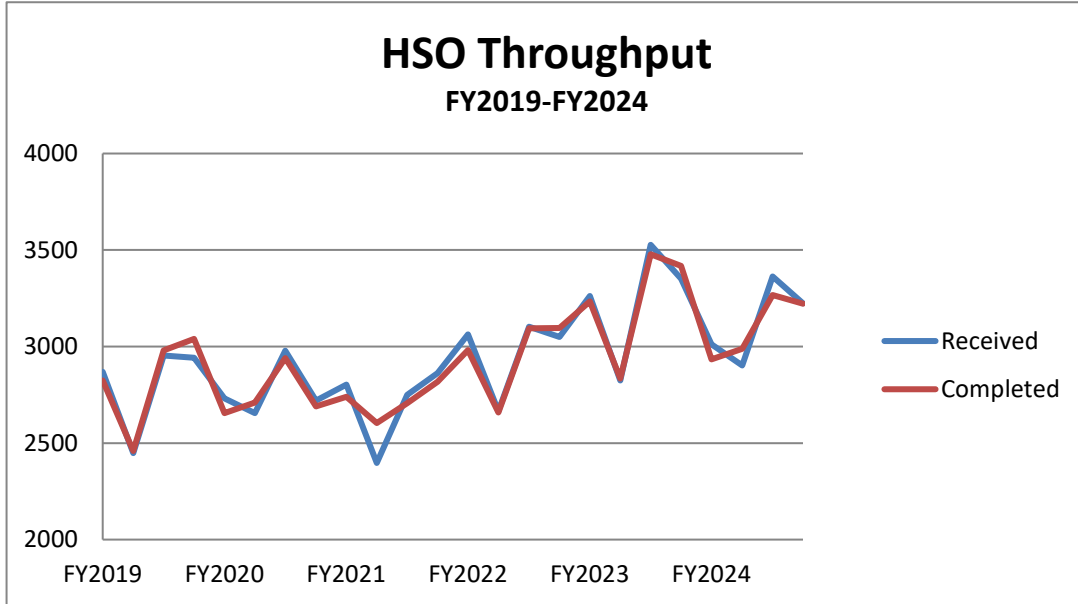
IU Turnaround Times (TAT) - FY2024 Q4							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1269	5.3	8.3	2	78	0	78
Exempt Protocols	525	13.3	12.8	8	99	0	99
Expedited Protocols	134	21.8	19.4	15.5	119	0	119
Full Board Protocols	35	34.6	30.0	21	98	2	100
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	266	6.6	10.7	0	65	0	65
Full Board Protocols	35	34.6	30.0	21	98	2	100
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	693	4.6	7.4	2	78	0	78
Exempt Protocols	241	9.9	8.3	7	52	0	52
Expedited Protocols	71	17.5	13.6	13	62	0	62
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	310	5.9	7.6	4	48	0	48
Exempt Protocols	284	16.2	15.0	11	99	0	99
Expedited Protocols	63	26.7	23.5	19	119	0	119



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
FY2023	Q1	23	19	8	2
	Q2	26	21	9	3
	Q3	20	22	9	3
	Q4	15	17.5	9	1
FY2024	Q1	22.5	14.5	9	1
	Q2	21	19	8	2
	Q3	23	19	8	1
	<b>Q4</b>	<b>21</b>	<b>16</b>	<b>8</b>	<b>2</b>

Throughput - FY2024 Q4				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1336	1307	-29	2.2%
Closeouts	282	282	0	0.0%
Continuing Reviews	201	190	-11	5.5%
General Info (FYI)	90	81	-9	10.0%
Not Human Subjects Protocols	71	66	-5	7.0%
Exempt Protocols	557	575	18	-3.2%
Expedited Protocols	126	150	24	-19.0%
Full Board Protocols	46	54	8	-17.4%
Reliance Team	515	517	2	-0.4%
<b>Total</b>	<b>3224</b>	<b>3222</b>	<b>-2</b>	<b>0.1%</b>
Greater than Minimal Risk Team				
Amendments	277	271	-6	2.2%
Closeouts	24	23	-1	4.2%
Continuing Reviews	118	108	-10	8.5%
General Info (FYI)	90	81	-9	10.0%
Full Board Protocols	27	30	3	-11.1%
<b>Total</b>	<b>536</b>	<b>513</b>	<b>-23</b>	<b>4.3%</b>
Biomedical Team				
Amendments	718	709	-9	1.3%
Closeouts	145	146	1	-0.7%
Continuing Reviews	71	69	-2	2.8%
Not Human Subjects Protocols	55	50	-5	9.1%
Exempt Protocols	262	252	-10	3.8%
Expedited Protocols	72	79	7	-9.7%
Full Board Protocols	19	23	4	-21.1%
<b>Total</b>	<b>1342</b>	<b>1328</b>	<b>-14</b>	<b>1.0%</b>
Social/Behavioral/Educational Team				
Amendments	341	327	-14	4.1%
Closeouts	113	113	0	0.0%
Continuing Reviews	12	13	1	-8.3%
Not Human Subjects Protocols	16	16	0	0.0%
Exempt Protocols	295	323	28	-9.5%
Expedited Protocols	54	71	17	-31.5%
Full Board Protocols	0	1	1	#DIV/0!
<b>Total</b>	<b>831</b>	<b>864</b>	<b>33</b>	<b>-4.0%</b>

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



Year	Quarter	Received	Completed	Difference
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
	Q4	3050	3096	46
FY2023	Q1	3262	3234	-28
	Q2	2824	2834	10
	Q3	3527	3478	-49
	Q4	3352	3418	66
FY2024	Q1	3011	2933	-78
	Q2	2902	2989	87
	Q3	3363	3267	-96
	Q4	3224	3222	-2

IU HRPP Quarterly Report  
Fiscal Year 2024, Quarter 4

<b>Total Human Subjects Protocols</b>						
	FY2024 Q4	FY2024 Q3	FY2024 Q2	FY2024 Q1	FY2023 Q4	FY2023 Q3
Exempt	1827	1758	1816	1778	1861	1883
Expedited	3106	3083	3039	3017	2963	2989
Full Board	827	835	860	880	889	908
Reliance	982	961	940	931	914	914
Humanitarian Use Devices (HUD)	22	22	21	21	21	22
<b>Active Studies</b>	<b>6764</b>	<b>6659</b>	<b>6676</b>	<b>6627</b>	<b>6648</b>	<b>6716</b>
Emergency Use	0	0	0	0	0	0
Not Human Subjects Research	248	249	222	253	249	246
<b>Total Protocols</b>	<b>7012</b>	<b>6908</b>	<b>6898</b>	<b>6880</b>	<b>6897</b>	<b>6962</b>

NOTES:

1. Exempt and Not Human Subjects Research counts include Exemptions and Not Human Subjects Research determinations in the prior year period (07.01.2023 through 06.30.2024).
2. Reliance includes active protocols which have been deferred to an external IRB for review.
3. Emergency Use is a quarterly count rather than a running total as these submissions are not considered "Active".