



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:

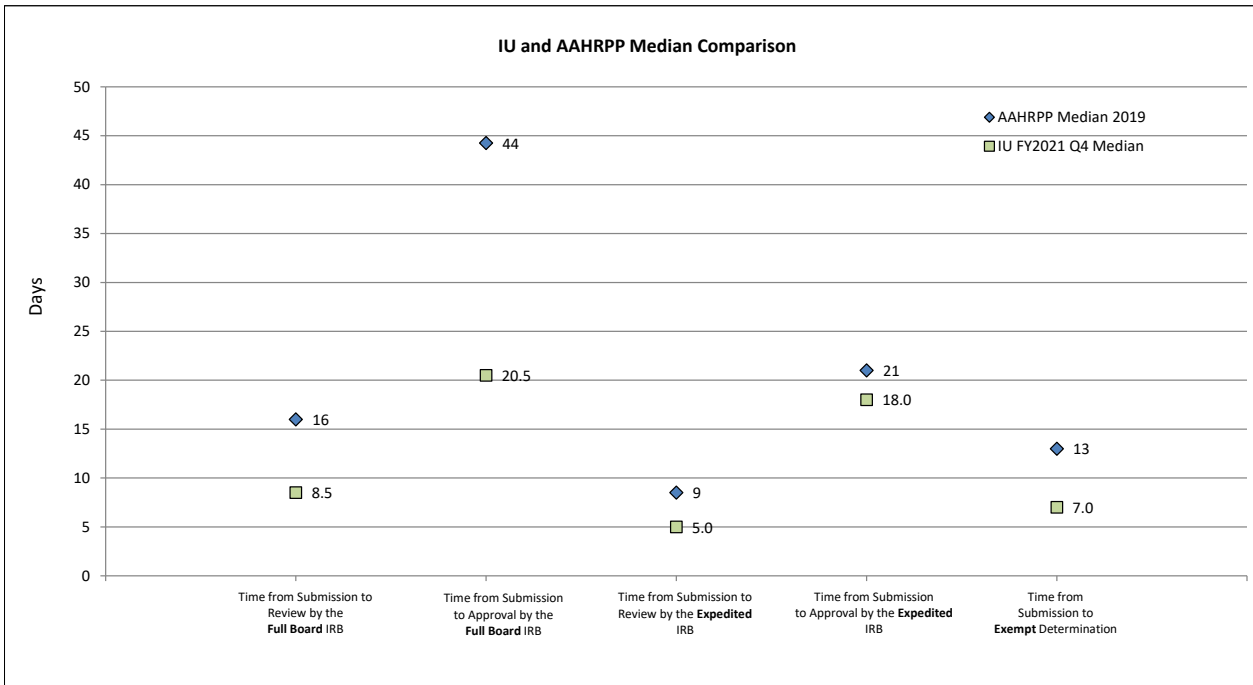
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

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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IU HRPP Quarterly Report
Fiscal Year 2021 Q4

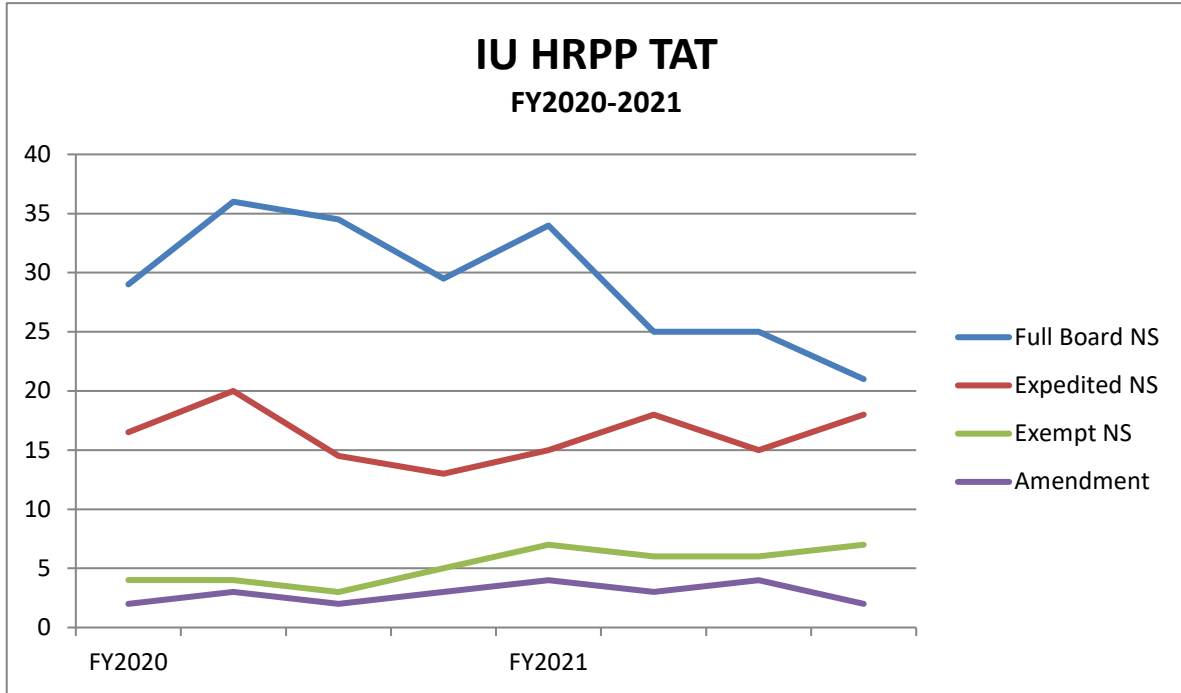
New Study Approval Comparison: IU vs. AAHRPP - FY2021 Q4					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2019	16	44	9	21	13
IU FY2021 Q4 Median	8.5	20.5	5.0	18.0	7.0



Notes:

1. AAHRPP metrics for academic institutions released 2020, based on 2019 annual report data.
2. Full Board N = 34; Expedited N = 107; Exempt N = 478
3. Means in order of the chart: Full Board - 10, 30; Expedited - 5, 23; Exempt - 10

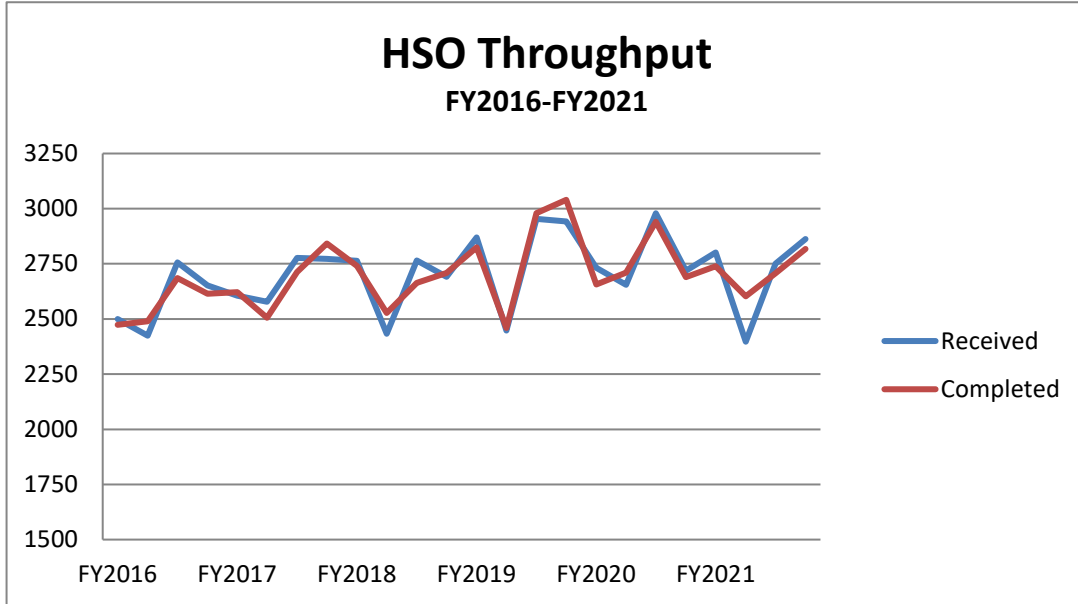
IU Turnaround Times (TAT) - FY2021 Q4							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1232	5.1	8.2	2	91	0	91
Exempt Protocols	478	10.0	9.5	7	69	0	69
Expedited Protocols	107	23.4	21.1	18	114	0	114
Full Board Protocols	34	30.1	30.6	20.5	163	3	166
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	390	5.8	9.8	2	91	0	91
Full Board Protocols	34	30.1	30.6	20.5	163	3	166
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	575	4.3	6.6	2	77	0	77
Exempt Protocols	196	7.1	6.5	6	36	0	36
Expedited Protocols	63	17.7	17.4	12	95	0	95
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	267	6.0	8.6	4	71	0	71
Exempt Protocols	282	12.0	10.7	8	69	0	69
Expedited Protocols	44	31.5	23.4	22	111	3	114



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

Throughput - FY2021 Q4				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1260	1268	8	-0.6%
Closeouts	167	165	-2	1.2%
Continuing Reviews	228	206	-22	9.6%
Continuing Reviews with Amendments	27	36	9	-33.3%
General Info (FYI)	77	87	10	-13.0%
Not Human Subjects Protocols	52	59	7	-13.5%
Exempt Protocols	549	511	-38	6.9%
Expedited Protocols	130	117	-13	10.0%
Full Board Protocols	32	38	6	-18.8%
Reliance Team	341	331	-10	2.9%
Total	2863	2818	-45	1.6%
Greater than Minimal Risk Team				
Amendments	381	399	18	-4.7%
Closeouts	47	44	-3	6.4%
Continuing Reviews	152	145	-7	4.6%
Continuing Reviews with Amendments	19	28	9	-47.4%
General Info (FYI)	77	87	10	-13.0%
Full Board Protocols	19	29	10	-52.6%
Total	695	732	37	-5.3%
Biomedical Team				
Amendments	604	587	-17	2.8%
Closeouts	81	84	3	-3.7%
Continuing Reviews	71	59	-12	16.9%
Continuing Reviews with Amendments	8	8	0	0.0%
Not Human Subjects Protocols	33	39	6	-18.2%
Exempt Protocols	232	204	-28	12.1%
Expedited Protocols	80	68	-12	15.0%
Full Board Protocols	10	8	-2	20.0%
Total	1119	1057	-62	5.5%
Social/Behavioral/Educational Team				
Amendments	275	282	7	-2.5%
Closeouts	39	37	-2	5.1%
Continuing Reviews	5	2	-3	60.0%
Continuing Reviews with Amendments	0	0	0	N/A
Not Human Subjects Protocols	19	20	1	-5.3%
Exempt Protocols	317	307	-10	3.2%
Expedited Protocols	50	49	-1	2.0%
Full Board Protocols	3	1	-2	66.7%
Total	708	698	-10	1.4%

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

IU HRPP Quarterly Report
Fiscal Year 2021 Q4

HSO Total Protocols						
	FY2021 Q4	FY2021 Q3	FY2021 Q2	FY2021 Q1	FY2020 Q4	FY2020 Q3
Exempt (approved in the last year: 7.1.2020 to 6.30.2021)	1762	1943	1978	1858	1847	1794
Expedited	2742	2777	2787	2752	2675	2686
Full Board	1013	996	1079	1076	1030	1108
AAHRPP Total	5517	5716	5844	5686	5552	5588
Reliance	845	772	735	712	694	723
Emergency Use	0	0	1	0	1	0
Humanitarian Use Devices (HUD)	22	20	22	22	21	20
Not Human Subjects Research	159	238	306	312	303	293
Miscellaneous Total	1026	1030	1064	1046	1019	1036
All HSO Total	6543	6746	6908	6732	6571	6624

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.