



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.

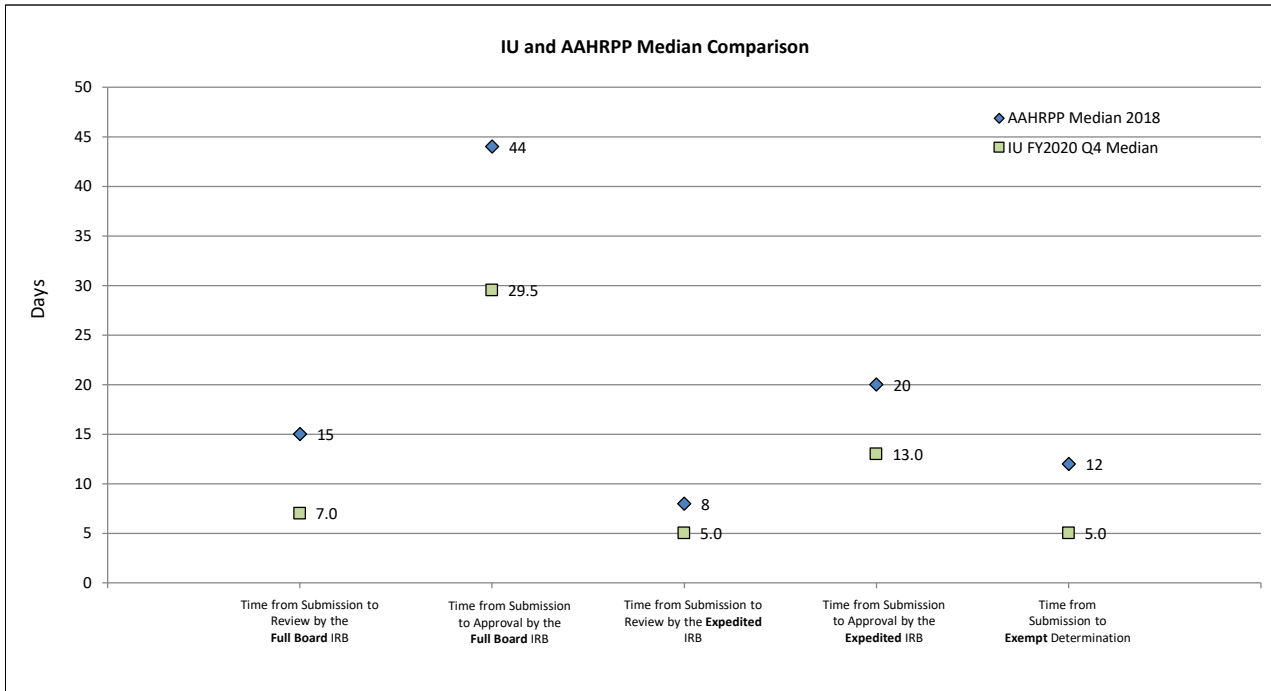
Please note that IU quarters are based on a fiscal year beginning July 1 and ending June 30. As such, quarters refer the following dates:

- 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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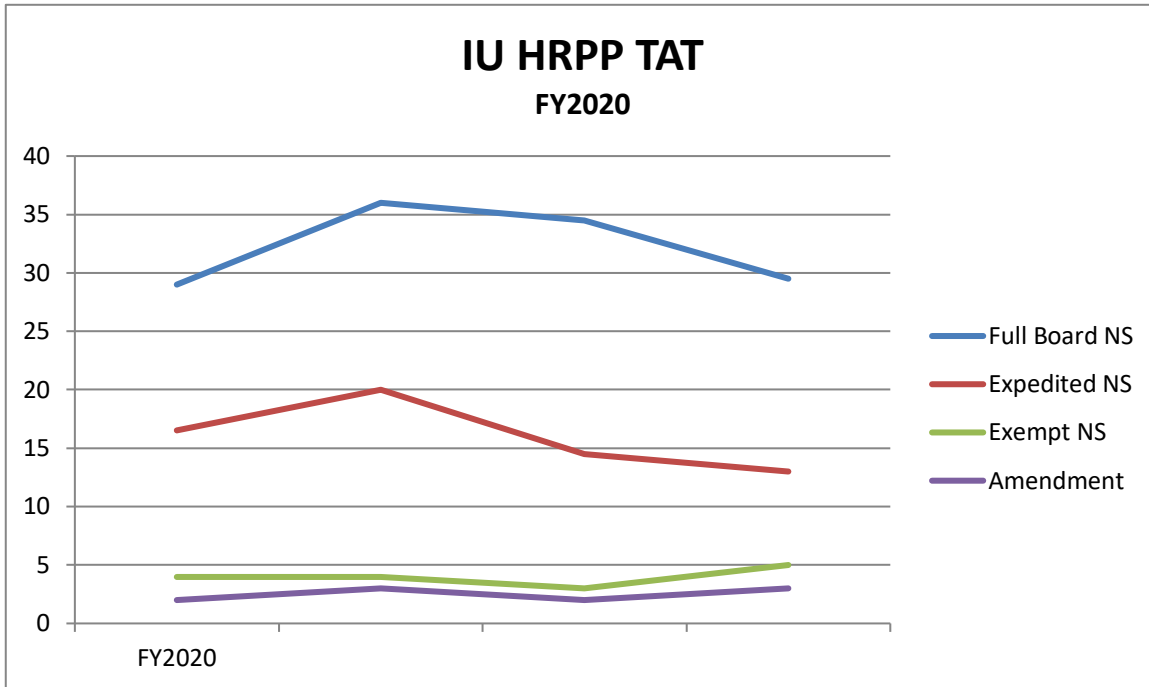
New Study Approval Comparison: IU vs. AAHRPP - FY2020 Q4					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2018	15	44	8	20	12
IU FY2020 Q4 Median	7.0	29.5	5.0	13.0	5.0



Notes:

1. AAHRPP metrics for academic institutions released 2019, based on 2018 annual report data.
2. Full Board N = 42; Expedited N = 129; Exempt N = 522
3. Means in order of the chart: Full Board - 7, 42; Expedited - 5, 20; Exempt - 9

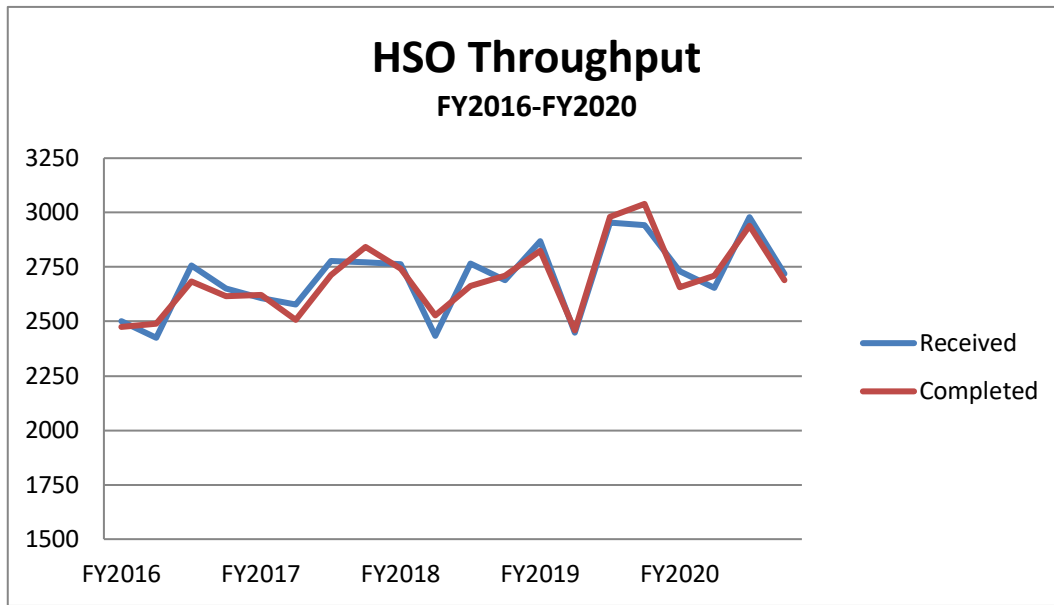
IU Turnaround Times (TAT) - FY2020 Q4							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1060	5.8	11.5	3	232	0	232
Exempt Protocols	522	9.3	16.8	5	154	0	154
Expedited Protocols	129	20.3	21.9	13	126	0	126
Full Board Protocols	42	42.0	44.6	29.5	228	0	228
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	72	14.5	22.0	7	138	0	138
Full Board Protocols	42	42.0	44.6	29.5	228	0	228
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	744	5.4	10.4	3	232	0	232
Exempt Protocols	279	7.9	13.9	6	146	0	146
Expedited Protocols	78	16.6	15.6	11	85	0	85
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	243	4.6	8.8	2	82	0	82
Exempt Protocols	243	10.8	19.6	5	154	0	154
Expedited Protocols	51	26.0	28.3	15	126	0	126



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

Throughput - FY2020 Q4				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1130	1100	-30	2.7%
Closeouts	118	116	-2	1.7%
Continuing Reviews	189	182	-7	3.7%
Continuing Reviews with Amendments	80	79	-1	1.3%
General Info (FYI)	92	106	14	-15.2%
Not Human Subjects Protocols	88	86	-2	2.3%
Exempt Protocols	547	549	2	-0.4%
Expedited Protocols	161	152	-9	5.6%
Full Board Protocols	38	51	13	-34.2%
Reliance Team	276	269	-7	2.5%
Total	2719	2690	-29	1.1%
Full Board Team				
Amendments	80	77	-3	3.8%
Continuing Reviews	48	47	-1	2.1%
Continuing Reviews with Amendments	43	42	-1	2.3%
General Info (FYI)	92	106	14	-15.2%
Full Board Protocols	38	51	13	-34.2%
Total	301	323	22	-7.3%
Biomedical Team				
Amendments	786	770	-16	2.0%
Closeouts	92	90	-2	2.2%
Continuing Reviews	131	126	-5	3.8%
Continuing Reviews with Amendments	37	36	-1	2.7%
Not Human Subjects Protocols	64	59	-5	7.8%
Exempt Protocols	298	287	-11	3.7%
Expedited Protocols	95	85	-10	10.5%
Total	1503	1453	-50	3.3%
Social/Behavioral/Educational Team				
Amendments	264	253	-11	4.2%
Closeouts	26	26	0	0.0%
Continuing Reviews	10	9	-1	10.0%
Continuing Reviews with Amendments	0	1	1	#DIV/0!
Not Human Subjects Protocols	24	27	3	-12.5%
Exempt Protocols	249	262	13	-5.2%
Expedited Protocols	66	67	1	-1.5%
Total	639	645	6	-0.9%

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

HRPP Quarterly Report
Fiscal Year 2020 Q4

HSP Total Protocols						
	FY2020 Q4	FY2020 Q3	FY2020 Q2	FY2020 Q1	FY2019 Q4	FY2019 Q3
Exempt (approved in the last year: 7.1.2019 - 6.30.2020)	1847	1794	1817	1827	1861	1816
Expedited	2675	2686	2665	2712	2780	2914
Full Board	1030	1108	1127	1136	1141	1148
AAHRPP Total	5552	5588	5609	5675	5782	5878
Deferrals	694	723	695	657	606	568
Emergency Use	8	7	7	7	6	6
Humanitarian Use Devices (HUD)	21	20	20	22	21	20
Not Human Subjects Research	303	293	289	271	279	265
Miscellaneous Total	1026	1043	1011	957	912	859
All HSP Total	6578	6631	6620	6632	6694	6737

NOTES:

1. Deferrals include: IU protocols deferred to NCI CIRB, WIRB, or other external IRB.
2. Not Human Subjects Research includes Applications for Not Human Subjects research and Applications for Non-Research Student Projects approved in the last year.