



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 – HSO 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 HSO 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.¹
- **Historical Turnaround Time Data:** Page 2 of the report is a graphical representation of the HSO's turnaround times for the current fiscal year and previous fiscal years. The HSO is proud to demonstrate a drastic reduction in turnaround times since July 2012, largely due to an increase in resources and improvements to the IRB submission process.
- **Throughput:** Page 3 is accounting graphic representation of throughput, an internal metric which compares the number of items submitted to the HSO 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 received and completed.
- **Total Protocols:** Page 4 offers an 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:

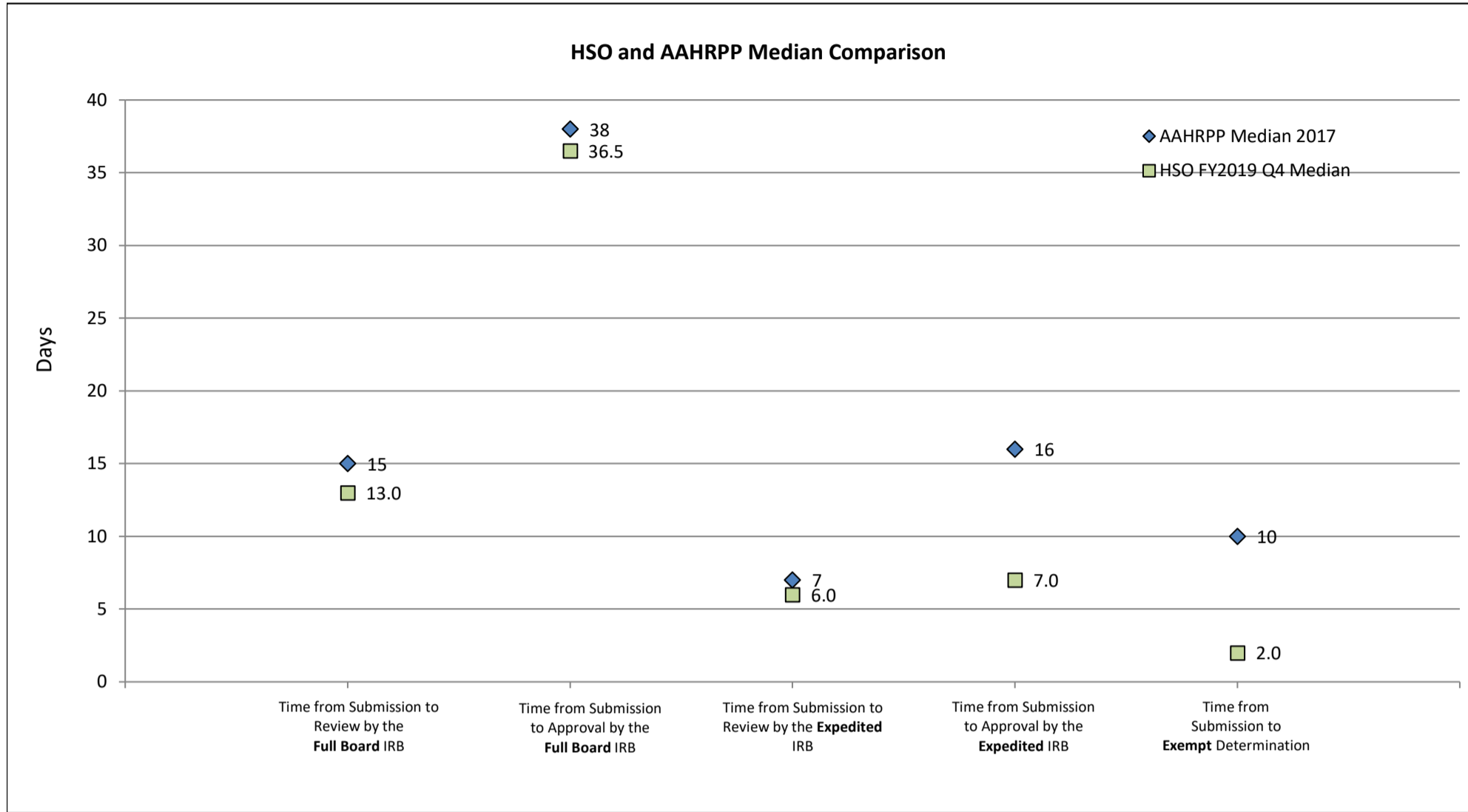
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

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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¹ From 2011 to 2013, AAHRPP collected mean turnaround time from accredited institutions. Beginning in 2014, AAHRPP transitioned from mean to median turnaround times. Median turnaround time is now the only turnaround time metric published by AAHRPP. Beginning in July 2015 (Fiscal Year 2016, Q1), both AAHRPP and IU turnaround times reported are median numbers rather than mean, except where noted otherwise.

New Study Approval Comparison: HSO vs. AAHRPP - FY2019 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 2017	15	38	7	16	10
HSO FY2019 Q4 Median	13.0	36.5	6.0	7.0	2.0

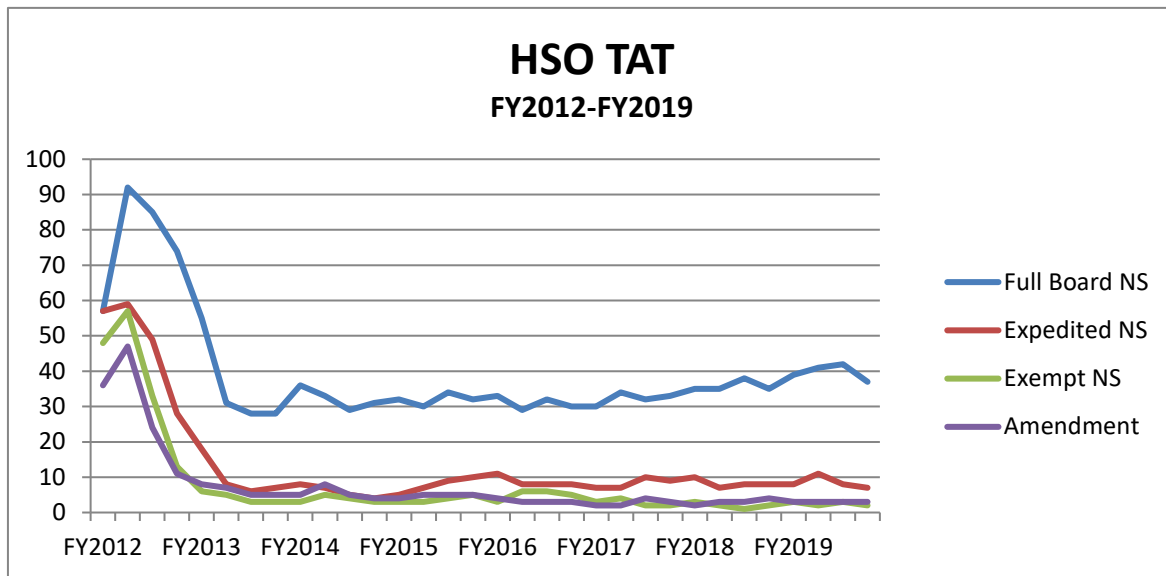


Notes:

1. AAHRPP metrics released 2018, based on 2017 annual report data.
2. Time from Submission Complete to Review by Expedited Procedure is measured from the Screener Complete Date.
3. Full Board N = 46; Expedited N = 123; Exempt N = 471
4. Means in order of the chart: Full Board - 16, 35; Expedited - 9, 11; Exempt - 4

HSO Quarterly Report
Fiscal Year 2019, Fourth Quarter

HSO Turnaround Times (TAT) - FY2019 Q4							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1138	5.5	8.9	3	89	0	89
Exempt Protocols	471	3.8	5.1	2	71	0	71
Expedited Protocols	123	9.9	9.8	7	48	0	48
Full Board Protocols	46	35.0	20.7	36.5	84	1	85
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	58	29.2	19.2	24.5	84	5	89
Full Board Protocols	46	35.0	20.7	36.5	84	1	85
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	845	4.6	6.0	3	61	0	61
Exempt Protocols	213	4.5	6.2	3	71	0	71
Expedited Protocols	54	10.9	10.4	7.5	48	0	48
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	235	2.9	3.7	1	28	0	28
Exempt Protocols	258	3.3	3.8	2	19	0	19
Expedited Protocols	69	9.2	9.3	7	39	0	39

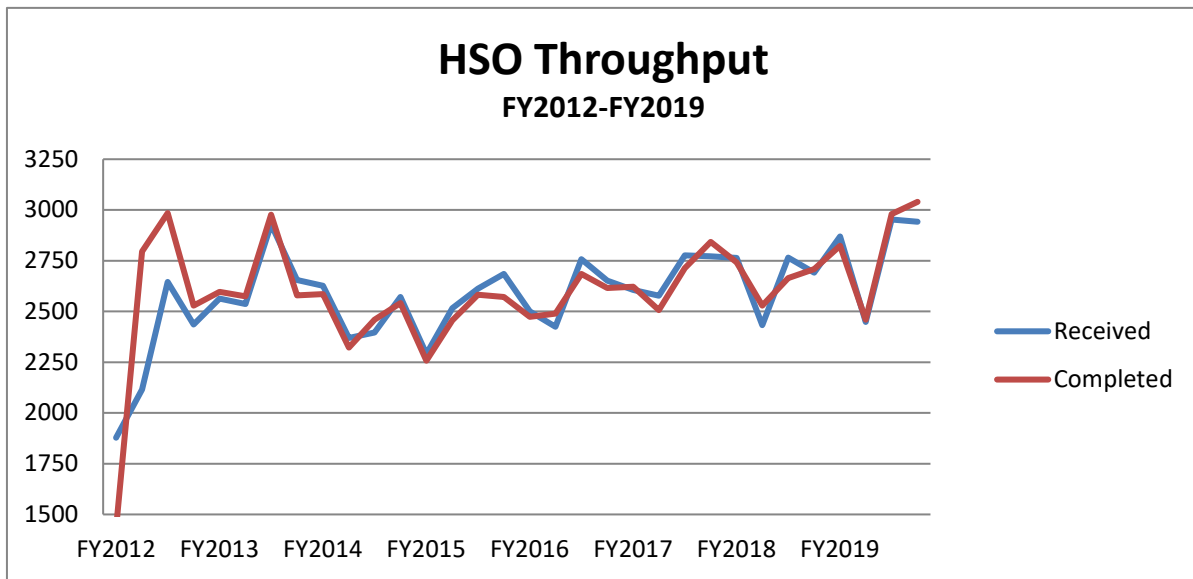


Year	Quarter	Full Board NS	Expedited NS	Exempt NS	Amendment
FY2012	Q1	57	57	48	36
	Q2	92	59	57	47
	Q3	85	49	33	24
	Q4	74	28	13	11
FY2013	Q1	55	18	6	8
	Q2	31	8	5	7
	Q3	28	6	3	5
	Q4	28	7	3	5
FY2014	Q1	36	8	3	5
	Q2	33	7	5	8
	Q3	29	5	4	5
	Q4	31	4	3	4
FY2015	Q1	32	5	3	4
	Q2	30	7	3	5
	Q3	34	9	4	5
	Q4	32	10	5	5
FY2016	Q1	33	11	3	4
	Q2	29	8	6	3
	Q3	32	8	6	3
	Q4	30	8	5	3
FY2017	Q1	30	7	3	2
	Q2	34	7	4	2
	Q3	32	10	2	4
	Q4	33	9	2	3
FY2018	Q1	35	10	3	2
	Q2	35	7	2	3
	Q3	38	8	1	3
	Q4	35	8	2	4
FY2019	Q1	39	8	3	3
	Q2	41	11	2	3
	Q3	42	8	3	3
	Q4	37	7	2	3

HSO Quarterly Report
Fiscal Year 2019, Fourth Quarter

Throughput - FY2019 Q4				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1132	1161	29	-2.6%
Closeouts	207	196	-11	5.3%
Continuing Reviews	256	255	-1	0.4%
Continuing Reviews with Amendments	243	258	15	-6.2%
General Info (FYI)	117	129	12	-10.3%
Not Human Subjects Protocols	74	72	-2	2.7%
Exempt Protocols	467	515	48	-10.3%
Expedited Protocols	131	136	5	-3.8%
Full Board Protocols	48	55	7	-14.6%
Reliance Team	267	263	-4	1.5%
Total	2942	3040	98	-3.3%
Full Board Team				
Amendments	53	59	6	-11.3%
Continuing Reviews	24	19	-5	20.8%
Continuing Reviews with Amendments	81	88	7	-8.6%
General Info (FYI)	117	129	12	-10.3%
Full Board Protocols	48	55	7	-14.6%
Total	323	350	27	-8.4%
Biomedical Team				
Amendments	848	850	2	-0.2%
Closeouts	169	158	-11	6.5%
Continuing Reviews	166	177	11	-6.6%
Continuing Reviews with Amendments	128	131	3	-2.3%
Not Human Subjects Protocols	51	49	-2	3.9%
Exempt Protocols	205	216	11	-5.4%
Expedited Protocols	62	56	-6	9.7%
Total	1629	1637	8	-0.5%
Social/Behavioral/Educational Team				
Amendments	231	252	21	-9.1%
Closeouts	38	38	0	0.0%
Continuing Reviews	66	59	-7	10.6%
Continuing Reviews with Amendments	34	39	5	-14.7%
Not Human Subjects Protocols	23	23	0	0.0%
Exempt Protocols	262	299	37	-14.1%
Expedited Protocols	69	80	11	-15.9%
Total	723	790	67	-9.3%

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



Year	Quarter	Received	Completed	Difference
FY2012	Q1	1878	1431	-447
	Q2	2116	2796	680
	Q3	2646	2984	338
	Q4	2435	2528	93
FY2013	Q1	2563	2596	33
	Q2	2537	2575	38
	Q3	2930	2976	46
	Q4	2655	2580	-75
FY2014	Q1	2626	2586	-40
	Q2	2369	2322	-47
	Q3	2397	2459	62
	Q4	2571	2542	-29
FY2015	Q1	2290	2258	-32
	Q2	2516	2456	-60
	Q3	2612	2582	-30
	Q4	2685	2571	-114
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

HSO Quarterly Report
Fiscal Year 2019, Fourth Quarter

HSO Total Protocols						
	FY2019 Q4	FY2019 Q3	FY2019 Q2	FY2019 Q1	FY2018 Q4	FY2018 Q3
Exempt (approved in the last year: 7.1.2018 - 6.30.2019)	1861	1816	1677	1562	1455	1388
Expedited	2780	2914	3015	3038	3112	3120
Full Board	1141	1148	1161	1181	1169	1130
AAHRPP Total	5782	5878	5853	5781	5736	5638
Deferrals	606	568	541	558	567	557
Emergency Use	6	6	6	6	6	6
Humanitarian Use Devices (HUD)	21	20	22	23	24	24
Not Human Subjects Research	279	265	273	255	221	218
Miscellaneous Total	912	859	842	842	818	805
All HSO Total	6694	6737	6695	6623	6554	6443

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.