



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:

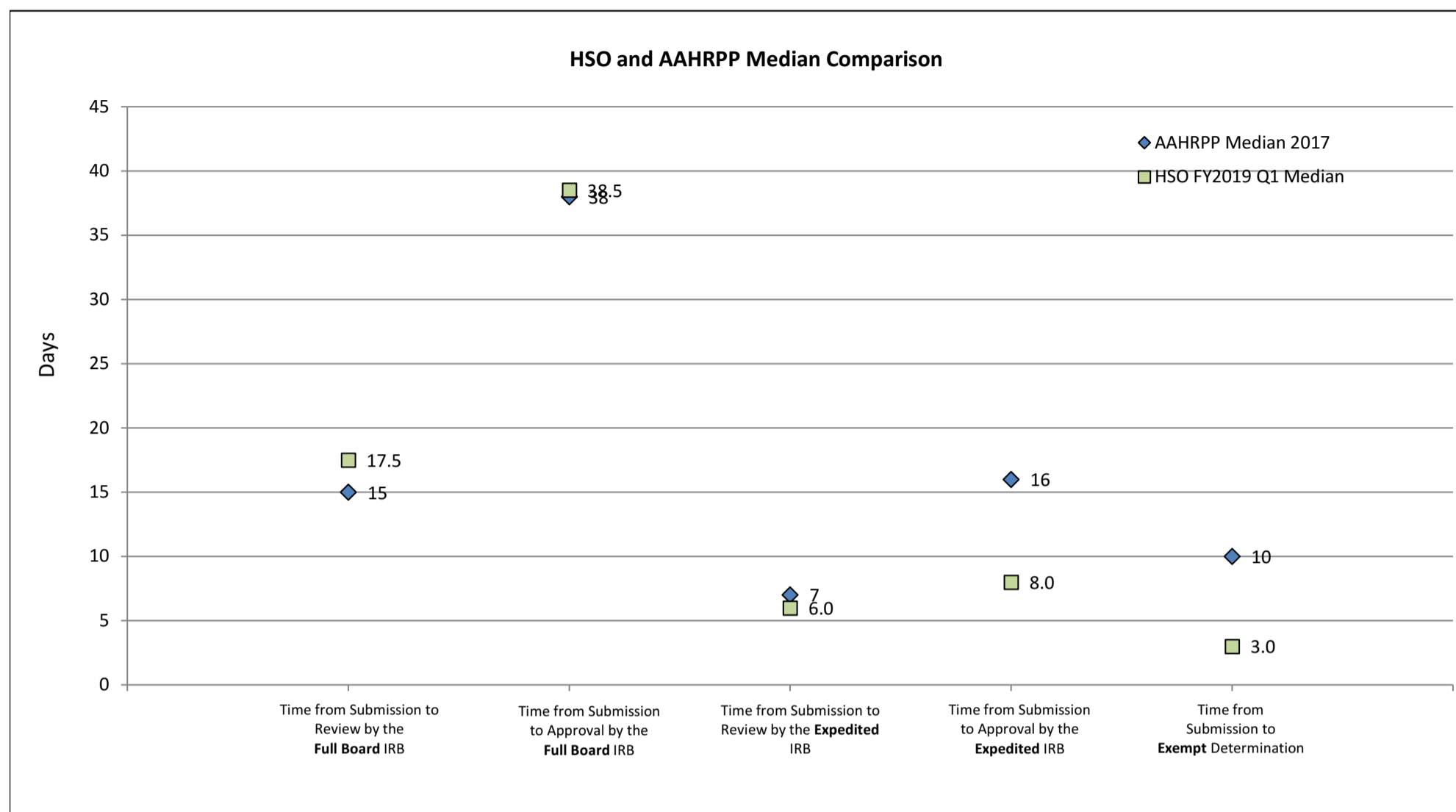
- Q1: July 1 – September 30
- Q2: October 1 – December 31
- Q3: January 1 – March 31
- Q4: April 1 – June 30

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.

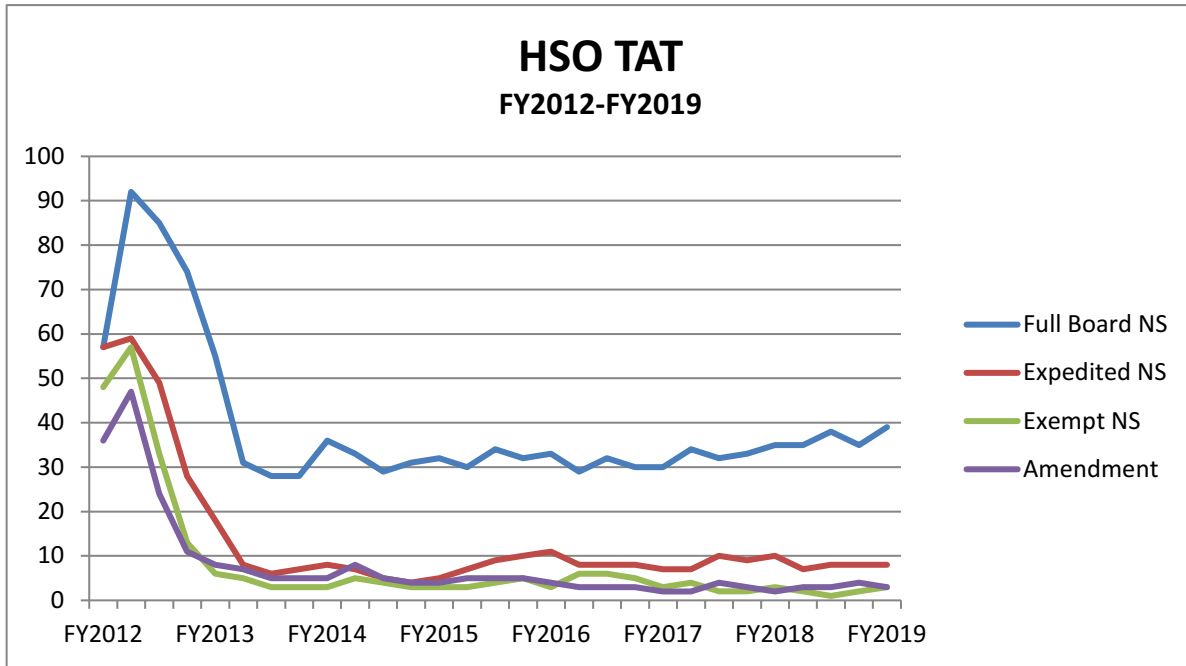
New Study Approval Comparison: HSO vs. AAHRPP - FY2019 Q1					
	Time from Submission Complete to Review by the Convened IRB	Time from Submission Complete to Approval by the Convened IRB	Time from Submission Complete to Review by the Expedited Procedure	Time from Submission Complete to Approval by the Expedited Procedure	Time from Submission Complete to Exempt Determination
AAHRPP Median 2017	15	38	7	16	10
HSO FY2019 Q1 Median	17.5	38.5	6.0	8.0	3.0



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 = 64; Expedited N = 134; Exempt N = 416
4. Means in order of the chart: Full Board - 21, 38; Expedited - 10, 15; Exempt - 4

HSO Turnaround Times (TAT) - FY2019 Q1							
All HSO							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	1105	6.7	10.9	3	84	0	84
Exempt Protocols	416	4.4	5.7	3	43	0	43
Expedited Protocols	134	14.9	18.0	8	131	0	131
Full Board Protocols	64	38.4	23.0	38.5	104	0	104
Full Board Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	52	31.8	20.6	29	84	0	84
Full Board Protocols	64	38.4	23.0	38.5	104	0	104
Biomedical Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	817	6.2	9.3	3	78	0	78
Exempt Protocols	190	5.4	7.0	3	43	0	43
Expedited Protocols	60	22.6	22.5	18.5	131	0	131
SBE Team							
Item	Volume	Mean TAT (Calendar Days)	Standard Deviation	Median TAT (Calendar Days)	Range	Min	Max
Amendments	236	2.9	4.2	1	35	0	35
Exempt Protocols	226	3.5	4.2	2	22	0	22
Expedited Protocols	74	8.6	9.6	6	41	0	41

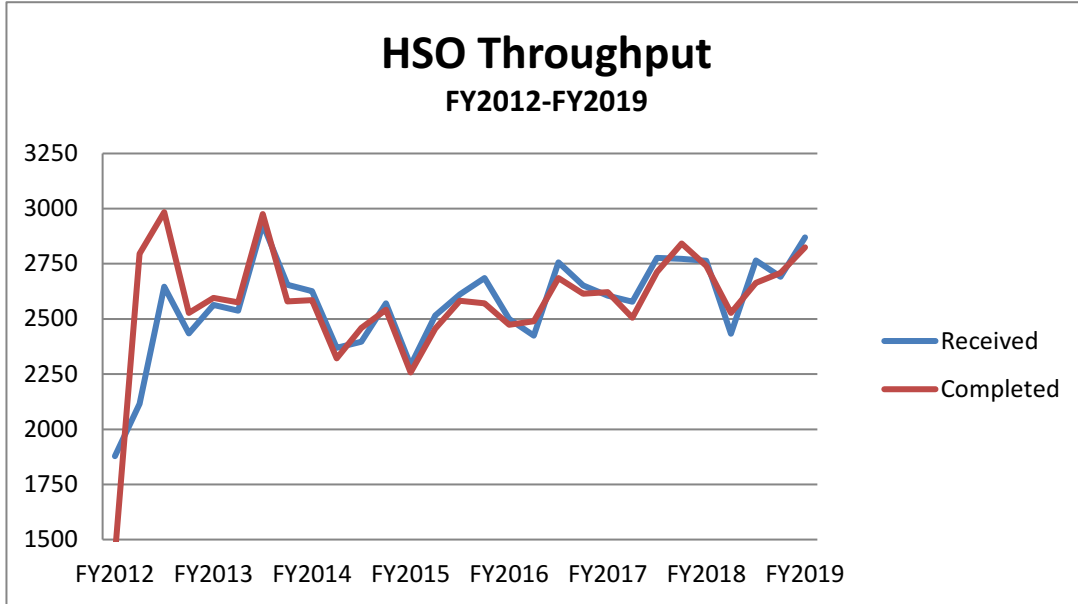


Year	Quarter	Full Board NS	Expedited NS	Exempt NS	Amendment
FY2012	Q1	57	57	48	36
	Q2	92	59	57	47
	Q3	85	49	33	24
	Q4	74	28	13	11
FY2013	Q1	55	18	6	8
	Q2	31	8	5	7
	Q3	28	6	3	5
	Q4	28	7	3	5
FY2014	Q1	36	8	3	5
	Q2	33	7	5	8
	Q3	29	5	4	5
	Q4	31	4	3	4
FY2015	Q1	32	5	3	4
	Q2	30	7	3	5
	Q3	34	9	4	5
	Q4	32	10	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

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FY2019 Quarter 1

Throughput - FY2019 Q1				
Item	No Submitted	No. Completed	Throughput	% Backlogged
All HSO				
Amendments	1163	1138	-25	2.1%
Closeouts	175	173	-2	1.1%
Continuing Reviews	349	393	44	-12.6%
Continuing Reviews with Amendments	181	178	-3	1.7%
General Info (FYI)	93	82	-11	11.8%
Not Human Subjects Protocols	73	75	2	-2.7%
Exempt Protocols	472	442	-30	6.4%
Expedited Protocols	158	142	-16	10.1%
Full Board Protocols	70	67	-3	4.3%
Reliance Team	135	134	-1	0.7%
Total	2869	2824	-45	1.6%
Full Board Team				
Amendments	56	53	-3	5.4%
Continuing Reviews	43	53	10	-23.3%
Continuing Reviews with Amendments	73	73	0	0.0%
General Info (FYI)	93	82	-11	11.8%
Full Board Protocols	70	67	-3	4.3%
Total	335	328	-7	2.1%
Biomedical Team				
Amendments	839	834	-5	0.6%
Closeouts	143	141	-2	1.4%
Continuing Reviews	238	265	27	-11.3%
Continuing Reviews with Amendments	79	77	-2	2.5%
Not Human Subjects Protocols	42	45	3	-7.1%
Exempt Protocols	196	197	1	-0.5%
Expedited Protocols	75	62	-13	17.3%
Total	1612	1621	9	-0.6%
Social/Behavioral/Educational Team				
Amendments	268	251	-17	6.3%
Closeouts	32	32	0	0.0%
Continuing Reviews	68	75	7	-10.3%
Continuing Reviews with Amendments	29	28	-1	3.4%
Not Human Subjects Protocols	31	30	-1	3.2%
Exempt Protocols	276	245	-31	11.2%
Expedited Protocols	83	80	-3	3.6%
Total	787	741	-46	5.8%

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

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HSO Total Protocols						
	FY2019 Q1	FY2018 Q4	FY2018 Q3	FY2018 Q2	FY2018 Q1	FY2017 Q4
Exempt (approved in the last year: 10.1.2017 - 9.30.2018)	1562	1455	1388	1352	1330	1337
Expedited	3038	3112	3120	3100	3051	3003
Full Board	1181	1169	1130	1148	1172	1184
AAHRPP Total	5781	5736	5638	5600	5553	5524
Deferrals	558	567	557	529	498	437
Emergency Use	6	6	6	5	5	5
Humanitarian Use Devices (HUD)	23	24	24	22	21	20
Not Human Subjects Research	255	221	218	194	194	187
Miscellaneous Total	842	818	805	750	718	649
All HSO Total	6623	6554	6443	6350	6271	6173

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.