

OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

01/07/2020

NSW Office for Health and Medical Research





Executive Summary

This report includes strategic and site level performance and compliance metrics that are collected by the Office for Health and Medical Research (OHMR) from NSW Public Health Organisations (PHOs) on studies authorised between 1st of July 2018 and 30th of June 2020. The performance of NSW PHOs on health and medical research are reported twice a year, each covering a 6-month period.

This report examines the progress undertaken since the program was rolled out on the 1st of July 2016. The relevant information for the ethics and governance applications has been exported from Australian Research Ethics Database (AU-RED) for applications prior to 2019, and Research Ethics and Governance Information System (REGIS) from 2018.

The report compares the change in performance in 8 consecutive reporting periods:

- Period 1: covers from 1 June 2016 to 31 December 2016 (6 months)
- Period 2: covers from 1 January 2017 to 30 June 2017 (6 months)
- Period 3: covers from 1 July 2017 to 31 December 2017 (6 months)
- Period 4: covers from 1 January 2018 to 30 June 2018 (6 months) *
- Period 5: covers from 1 July 2018 to 31 December 2018 (6 months) *
- Period 6: covers from 1 January 2019 to 30 June 2019 (6 months) *
- Period 7: covers from 1 July 2019 to 31 December 2019 (6 months)
- Period 8: covers from 1 January 2020 to 30 June 2020 (6 months)

Overall Performance Environment:

REGIS is the online platform used to manage ethics and governance applications for all NSW Public Health Organisation. The soft-launch introduction of REGIS into research offices in April 2018 meant that all PHOs were processing ethics and governance applications in two systems (REGIS and AU RED) during Periods 4-6 (* asterisked above) of the reporting period. A proportion of the data collected during those periods accounts for the data retrieved from both AU RED and REGIS. OHMR has undertaken data validation activities to accurately represent research ethics and governance performance on this platform. During Periods 7-8, all applications were processed entirely through REGIS. Period 8 is also directly impacted by the COVID-19 pandemic. These events have had an impact on research office performance. More information on the impacts of COVID-19 on research in NSW can be found in Appendix B of this report.



Ethics Review Timelines of Human Research in NSW PHOs

METRIC 3: NSW HREC Submission Closing Date to NSW HREC Approval (using administrative clock)

NSW State Benchmark:

- In 2017/18 financial year, the benchmark for reviewing human research studies for NSW PHO HRECs was 60 calendar days.
- The new benchmark from the 2018/19 financial year is for reviewing human research studies for NSW PHO HRECs within 45 calendar days.

All studies (greater than low risk) approved by the HREC with a final Decision Notification date between 1st of July 2018 and 30th of June 2020.

Selection Criteria Summary:

Study Type- "All", Current Decision- "Approved", Final Decision Notification Date- "within the period"

Summary for Metric 3:

Ethics review performance of NSW HRECs according to the <45-day benchmark for studies approved between 01/07/2018 and 30/06/2020 are shown in the comparison table with two periods of the former (<60 days) benchmark (Table 1).

In NSW, 2875 studies (greater than low risk pathway) were approved by an HREC with a final written Decision Notification Date (final clock stop date) between 01/07/2018 and 30/06/2020. Of these applications, 830 (29%) were classified as clinical trials (Table 2).

Table 1: The 45 calendar days benchmark for review and approval of human research ethics applications (greater than low risk) is applied to the dataset between 01/07/2018 – 30/06/2020. The overall performance of NSW HRECs are represented in colour coding: **Highly Performing** (≥95), **Underperforming** (95> x ≥75) and **Not Performing** (<75).

LHD Abbreviation	ETHICS Approval (All Research Types) <45 days										
	Application Volume				Performance						
	Total # of applications				% Reviewed <60 days		% Reviewed <45 days				
	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020	Jul 2019 Dec 2019	Jan 2020 Jun 2020	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020	
SLHD-RPA	78	65	47	66	94%	98%	96%	91%	87%	95%	
HNELHD	52	55	67	46	100%	89%	87%	62%	93%	83%	
SWSLHD	35	41	44	41	95%	90%	71%	63%	86%	76%	
WSLHD	34	27	19	38	37%	32%	59%	85%	16%	13%	
BLLBRRY	NA	1	32	37	97%	100%	NA	100%	88%	97%	
SVHN	36	42	24	31	100%	90%	97%	93%	96%	71%	
SLHD-Concord	22	22	18	29	94%	100%	91%	91%	61%	93%	
CINSW	34	19	33	26	100%	92%	65%	95%	82%	92%	
SESLHD	30	38	33	22	33%	9%	53%	32%	21%	5%	
NSLHD	0	10	11	19	73%	89%	0%	60%	36%	79%	
SCHN	35	24	22	17	95%	100%	100%	71%	73%	100%	
ISLHD	16	13	3	17	100%	71%	81%	85%	100%	24%	
NBMLHD	9	9	14	11	93%	73%	11%	33%	64%	45%	
WNSWLHD	3	4	7	4	100%	100%	67%	25%	100%	100%	
NNSWLHD	3	0	7	2	86%	50%	33%	NA	43%	50%	
JHFMHN	1	3	2	1	100%	0%	100%	67%	100%	0%	
TOTAL	388	373	383	407	88%	82%	80%	73%	74%	72%	

Table 2: The performance of NSW HRECs in reviewing and approving clinical trials (greater than low risk) between 01/07/2018 and 30/06/2020. The review timelines are calculated using an administrative clock (calendar days). The overall performance of the NSW HRECs are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

LHD Abbreviation	ETHICS Approval (Clinical Trials) <45 days									
	Application Volume				Performance					
	Total # of applications				% Reviewed <60 days		% Reviewed <45 days			
	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020	Jul 2019 Dec 2019	Jan 2020 Jun 2020	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020
BLLBRRY	NA	1	31	37	97%	100%	NA	100%	87%	97%
SLHD-RPA	25	25	21	19	100%	95%	96%	92%	100%	95%
SWSLHD	6	11	13	16	92%	88%	67%	36%	85%	75%
WSLHD	7	11	8	15	38%	20%	57%	91%	13%	7%
SLHD-Concord	9	5	4	10	100%	100%	78%	80%	25%	90%
SESLHD	4	3	8	10	25%	20%	25%	33%	13%	10%
HNELHD	11	13	12	9	100%	44%	55%	62%	92%	44%
SVHN	25	23	12	8	100%	100%	96%	87%	100%	88%
NSLHD	0	1	3	5	100%	80%	0%	100%	0%	80%
SCHN	10	8	11	4	100%	100%	100%	75%	91%	100%
NBMLHD	2	2	3	3	67%	67%	0%	50%	33%	67%
ISLHD	4	1	1	1	100%	100%	100%	100%	100%	0%
CINSW	0	0	4	0	100%	NA	NA	NA	75%	NA
WNSWLHD	0	0	0	0	NA	NA	NA	NA	NA	NA
NNSWLHD	0	0	0	0	NA	NA	NA	NA	NA	NA
JHFMHN	0	1	0	0	NA	NA	NA	0%	NA	NA
TOTAL	103	105	131	137	89%	78%	81%	76%	76%	72%



Site-specific Authorisation (SSA) Timelines of Human Research Projects in NSW PHOs

METRIC 4: Date Valid SSA Application Received by the RGO to Site Authorisation

NSW State Benchmark:

- In 2017/18 financial year, the benchmark for site authorisation of human research studies in NSW PHOs was 30 calendar days.
- The new benchmark for studies approved from the 2018/19 financial year is 15 calendar days.

All studies (greater than low risk) authorised with a final SSA Decision Notification Date between 1st of July 2018 and 30th of June 2020.

Selection Criteria Summary:

Study Type- "All", Current Decision- "Authorised", "Authorised with conditions" or "Further information response authorised", Final Decision Notification Date - "within the period"

Summary for Metric 4:

SSA review performance of NSW PHOs according to the <15 day benchmark for studies authorised between 01/07/2018 and 30/06/2020 are shown in the comparison table (Table 3).

In NSW, 5798 studies (greater than low risk) were authorised in NSW PHOs with a final SSA decision letter provided to the site principal investigator (final clock stop date) between 01/07/2018 and 30/06/2020. Of these site authorisation applications, 2394 (41%) were classified as clinical trials (Table 4). There is a noticeable decline in state-wide site authorisation timelines in the latest reporting periods.

Table 3: The new benchmark (15 calendar days) for site authorisation of human research applications (greater than low risks) is applied to the dataset between 01/07/2018 – 30/06/2020. The overall performance of the NSW public health organisations (sites) are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

LHD Abbreviation	SSA Approval (All Research Types) <15 days										
	Application Volume				Performance						
	Total # of applications				% Authorised < 30 days		% Authorised < 15 days				
	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jan 2020 Jun 2020	Jul 2019 Dec 2109	Jan 2020 Jun 2020	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jan 2020 Jun 2020	
SESLHD	127	59	68	103	69%	73%	55%	42%	43%	59%	
SWSLHD	131	95	86	85	92%	100%	82%	81%	88%	87%	
HNELHD	134	75	126	82	87%	71%	63%	49%	56%	44%	
WSLHD	114	108	99	76	94%	86%	71%	77%	58%	41%	
SLHD-RPA	100	99	63	69	90%	94%	100%	95%	73%	72%	
SVHN	69	39	42	51	88%	90%	81%	77%	67%	69%	
SCHN	76	59	58	47	76%	91%	63%	83%	33%	51%	
NSLHD	NA	7	30	41	13%	44%	NA	71%	10%	29%	
SLHD-Concord	50	43	38	37	87%	100%	96%	100%	63%	86%	
NBMLHD	38	41	26	37	69%	65%	61%	51%	27%	32%	
CCLHD	23	7	22	27	27%	15%	61%	57%	9%	11%	
ISLHD	44	18	20	21	90%	95%	55%	39%	65%	48%	
MNCLHD	2	6	19	12	53%	58%	0%	33%	16%	50%	
WNSWLHD	27	12	10	12	90%	100%	96%	100%	70%	100%	
ASNSW	0	0	0	8	NA	63%	NA	NA	NA	50%	
NNSWLHD	12	6	26	7	81%	57%	75%	50%	38%	29%	
NSWHPH	NA	NA	1	7	100%	71%	NA	NA	0%	57%	
MLHD	8	5	8	5	75%	100%	25%	40%	25%	80%	
JHFMHN	5	2	4	0	75%	NA	100%	100%	75%	NA	
SNSWLHD	8	1	3	0	67%	NA	63%	100%	67%	NA	
NNSWLHD/MNCLHD	34	22	NA	NA	NA	NA	62%	64%	NA	NA	
Total	1002	704	749	727	80%	80%	72%	73%	54%	57%	

Table 4: The performance of NSW PHOs in authorising clinical trial applications (greater than low risk) between 01/01/2017 and 30/06/2020. The review timelines are calculated using an administrative clock (presented in calendar days). The overall performance of the NSW sites are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

	SSA Approval (Clinical Trials) <15 days									
	Application Volume				Performance					
	Total # of applications				% Authorised <30 days		% Authorised < 15 days			
LHD Abbreviation	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jan 2020 Jun 2020	Jul 2019 Dec 2109	Jan 2020 Jun 2020	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jan 2020 Jun 2020
SWSLHD	42	30	41	37	88%	100%	93%	77%	85%	81%
WSLHD	46	55	79	37	94%	89%	76%	75%	56%	38%
SESLHD	40	26	44	36	70%	69%	75%	35%	43%	58%
HNELHD	41	26	49	33	84%	64%	56%	38%	39%	33%
SLHD-RPA	32	39	32	30	91%	97%	100%	90%	69%	60%
SVHN	41	24	32	30	88%	90%	85%	75%	69%	70%
SCHN	23	18	26	23	88%	100%	65%	89%	42%	61%
SLHD-Concord	27	13	21	21	86%	100%	100%	100%	57%	76%
NSLHD	NA	1	17	19	18%	21%	NA	100%	12%	21%
NBMLHD	14	14	13	14	69%	57%	64%	64%	15%	21%
CCLHD	9	3	13	11	31%	0%	78%	67%	8%	0%
ISLHD	16	3	11	11	82%	100%	44%	67%	73%	64%
WNSWLHD	8	1	6	4	83%	100%	100%	100%	67%	100%
MNCLHD	1	1	12	3	58%	100%	0%	100%	25%	67%
ASNSW	0	0	0	2	NA	50%	NA	NA	NA	50%
NNSWLHD	0	2	15	2	93%	100%	NA	50%	27%	50%
NSWHPTH	NA	NA	0	0	NA	NA	NA	NA	NA	NA
MLHD	1	1	0	0	NA	NA	0%	0%	NA	NA
JHFMHN	3	0	1	0	100%	NA	100%	NA	100%	NA
SNSWLHD	0	0	1	0	0%	NA	NA	NA	0%	NA
NNSWLHD/MNCLHD	15	8	NA	NA	NA	NA	67%	63%	NA	NA
Total	359	265	413	313	80%	80%	78%	71%	51%	53%

A list of NSW PHOs names and abbreviations that review and/or authorise human research studies:

Human Research Ethics Committee/ Research Governance Office Names	Abbreviation used in the tables	Ethics	Site
Ambulance Service of NSW	ASNSW		Yes
Bellberry	BLLBRRY	Yes	
Central Coast LHD	CCLHD		Yes
The Cancer Council NSW	CCNSW		
NSW Population & Health Services Research Ethics Committee	CINSW	Yes	
Greater Western LHD	WNSWLHD	Yes	Yes
Hammond Care	HCARE		Yes
Hunter New England LHD	HNELHD	Yes	Yes
Justice Health & Forensic Mental Health Network	JHFMHN	Yes	Yes
Mid North Coast LHD	MNCLHD		Yes
Murrumbidgee LHD	MLHD		Yes
Northern NSW LHD	NNSWLHD	Yes	Yes
Nepean Blue Mountains LHD	NBMLHD	Yes	Yes
Northern Sydney LHD	NSLHD	Yes	Yes
NSW Health Pathology	NSWHPTH		Yes
Royal Rehabilitation Centre Sydney HREC	RRCS	Yes	
Sydney Children's Hospitals Network	SCHN	Yes	Yes
South Eastern Sydney LHD	SESLHD	Yes	Yes
Sydney LHD (Concord Zone)	SLHD – Concord	Yes	Yes
Sydney LHD (RPAH Zone)	SLHD – RPA	Yes	Yes
Southern NSW LHD	SNSWLHD		Yes
St Vincent's Hospital	SVHN	Yes	Yes
South Western Sydney LHD	SWSLHD	Yes	Yes
Illawarra Shoalhaven LHD (joint committee with University of Wollongong)	ISLHD	Yes	Yes
Western Sydney LHD	WSLHD	Yes	Yes

Note: Research Ethics and Governance Reform grant was not provided to the institutions shown in grey (CCNSW, HCARE and RRCS).

Appendix A

NSW Approvals for Ethics and Governance over the lifetime of the Metrics Program

Table 5: The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving human research ethics applications (greater than low risk) between 01/01/2017 and 30/06/2020 using the 60 day benchmark. The review timelines are calculated using an administrative clock (presented in calendar days). The committee names are sorted by descending order of total applications approved followed by descending order of committee's performance in Period 8. The overall performance of the NSW HRECs is represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

LHD Abbreviation	ETHICS Approval (All Research Types)																
	Application Volume									Performance							
	Total # of applications									% Reviewed under 60 days							
	Jul 2016 Dec 2016	Jan 2017 Jun 2017	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020		Jul 2016 Dec 2016	Jan 2017 Jun 2017	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020
SLHD-RPA	108	74	102	79	78	65	47	66		61%	78%	96%	96%	97%	95%	94%	98%
HNELHD	63	52	56	43	58	55	67	46		100%	100%	96%	95%	95%	75%	100%	89%
SWSLHD	43	39	34	28	35	41	44	41		88%	90%	100%	96%	80%	83%	95%	90%
WSLHD	35	29	40	35	34	27	19	38		91%	86%	95%	69%	97%	93%	37%	32%
BLLBRRY	0	0	0	0	0	1	32	37		100%	NA	NA	NA	NA	100%	97%	100%
SVHN	40	52	37	35	39	41	24	31		98%	100%	100%	100%	100%	100%	100%	90%
SLHD-Concord	26	30	16	19	23	22	18	29		65%	87%	75%	89%	100%	100%	94%	100%
CINSW	19	24	24	35	34	19	33	26		68%	79%	83%	60%	79%	100%	100%	92%
SESLHD	38	46	37	44	30	38	33	22		53%	57%	65%	57%	73%	58%	33%	9%
NSLHD	45	37	34	15	0	10	11	19		98%	86%	62%	47%	NA	100%	73%	89%
SCHN	28	27	38	41	35	24	22	17		100%	100%	100%	100%	100%	100%	95%	100%
ISLHD	10	5	19	16	16	13	3	17		90%	80%	95%	100%	94%	92%	100%	71%
NBMLHD	8	10	9	12	9	9	14	11		50%	60%	100%	92%	67%	33%	93%	73%
WNSWLHD	11	11	13	9	3	4	7	4		91%	91%	100%	100%	67%	75%	100%	100%
NNSWLHD	1	0	3	1	2	0	7	2		0%	NA	100%	0%	100%	NA	86%	50%
JH&FMHN	5	2	1	3	1	3	2	1		100%	100%	100%	67%	100%	67%	100%	0%
RRCS	1	0	0	0	0	0	0	0		100%	NA						
	481	438	463	415	397	372	383	407		81%	85%	91%	85%	91%	87%	88%	82%

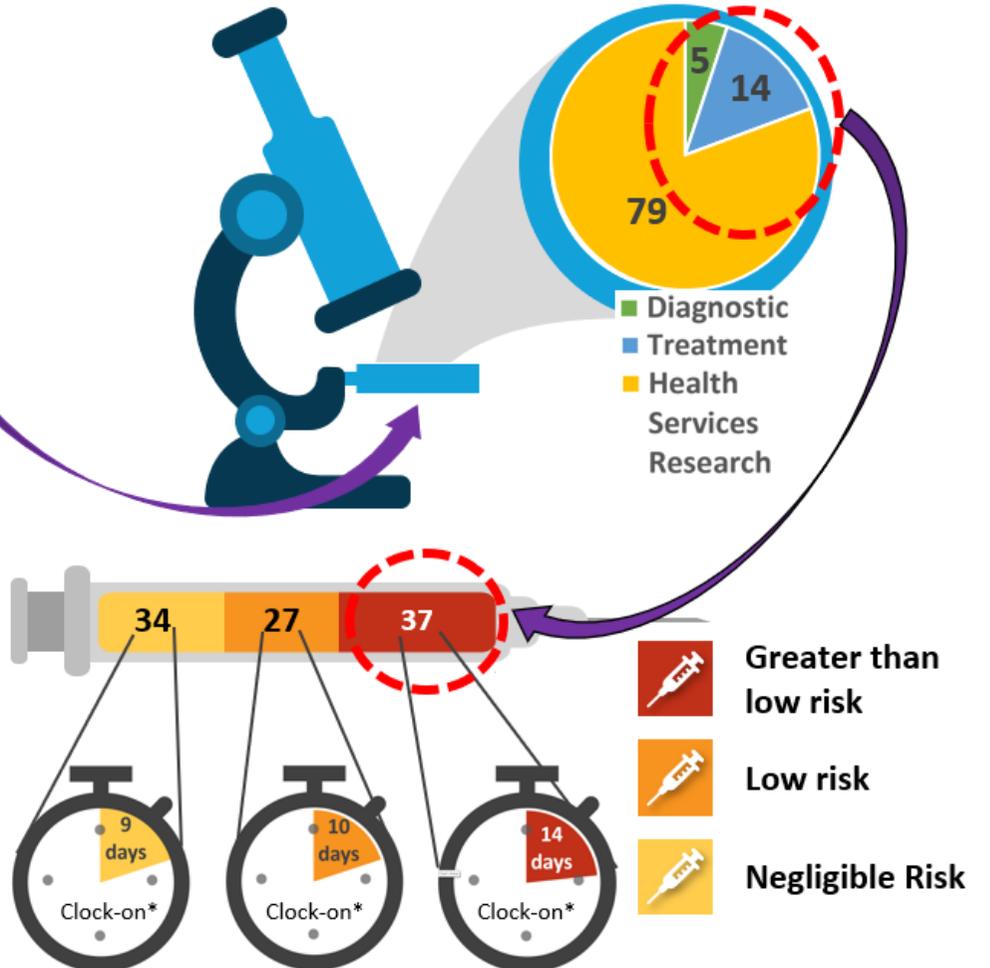
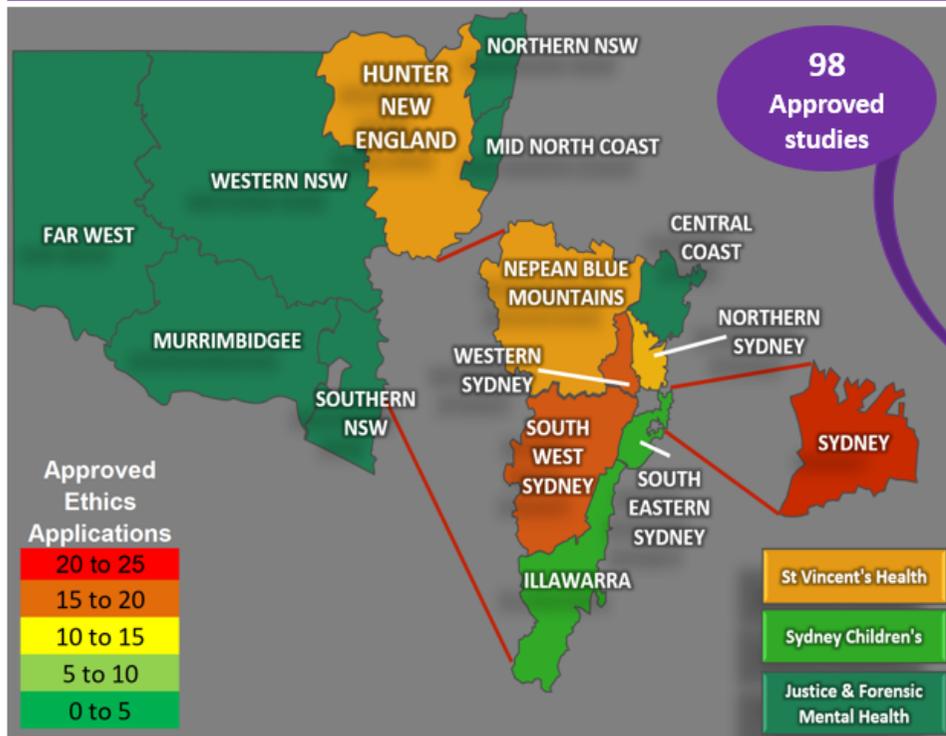
Table 6: The performance of NSW PHOs in authorising human research applications (greater than low risk) between 01/01/2017 and 30/06/2020 using the 30 day benchmark. The review timelines are calculated using an administrative clock (presented in calendar days). Sites are sorted by descending order of total applications authorised followed by descending order of site's performance in Period 8. The overall performance of the NSW sites are represented in colour coding: **Highly Performing** (≥95), **Underperforming** (95 > x ≥75) and **Not Performing** (<75).

LHD Abbreviation	SSA Approval (All Research Types)																
	Application Volume									Performance							
	Total # of applications									% authorised under 30 days							
	Jul 2016 Dec 2016	Jan 2017 Jun 2017	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020	Jul 2016 Dec 2016	Jan 2017 Jun 2017	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jan 2020 Jun 2020	
SESLHD	98	100	90	78	127	59	68	103	97%	93%	99%	96%	88%	71%	69%	73%	
SWSLHD	106	102	103	87	131	95	86	85	16%	36%	77%	91%	92%	88%	92%	100%	
HNELHD	106	93	107	73	134	75	126	82	94%	87%	95%	89%	84%	77%	87%	71%	
WSLHD	115	91	150	134	114	108	99	76	97%	76%	70%	87%	90%	97%	94%	86%	
SLHD-RPA	120	101	91	100	100	99	63	69	96%	98%	98%	100%	100%	100%	90%	94%	
SVHN	52	68	80	66	69	39	42	51	96%	85%	99%	100%	97%	95%	88%	90%	
SCHN	61	55	68	66	76	59	58	47	97%	100%	100%	73%	88%	97%	76%	91%	
NSLHD	72	51	67	22	0	7	30	41	83%	88%	70%	32%	NA	71%	13%	44%	
SLHD-Concord	57	52	45	36	50	43	38	37	56%	62%	71%	75%	100%	100%	87%	100%	
NBMLHD	39	35	34	41	38	41	26	37	90%	89%	97%	100%	87%	68%	69%	65%	
CCLHD	12	16	16	14	23	7	22	27	100%	100%	94%	100%	91%	71%	27%	15%	
ISLHD	24	18	28	33	44	18	20	21	100%	94%	100%	97%	80%	83%	90%	95%	
MNCLHD	NA	NA	NA	NA	2	6	19	12	NA	NA	NA	NA	50%	50%	53%	58%	
WNSWLHD	17	14	29	25	27	12	10	12	100%	100%	100%	100%	100%	100%	90%	100%	
ASNSW	1	0	0	0	0	0	0	8	100%	NA	NA	NA	NA	NA	NA	63%	
NNSWLHD	29	20	46	28	46	28	26	7	66%	70%	85%	82%	80%	79%	81%	57%	
NSWHPH	NA	NA	NA	NA	NA	NA	1	7	NA	NA	NA	NA	NA	NA	100%	71%	
MLHD	5	10	8	13	8	5	8	5	100%	80%	88%	100%	88%	80%	75%	100%	
JHFMHN	1	3	1	2	5	2	4	0	0%	67%	100%	100%	100%	100%	75%	NA	
SNSWLHD	3	3	1	1	8	1	3	0	100%	100%	100%	100%	88%	100%	67%	NA	
HCARE	1	1	5	0	0	0	0	0	100%	100%	100%	NA	NA	NA	NA	NA	
RRCS	0	1	0	0	0	0	0	0	NA	NA	NA	NA	NA	NA	NA	NA	
	919	834	969	819	1002	704	749	727	82%	81%	88%	90%	90%	88%	80%	80%	

Appendix B

Impact of COVID-19 on Research in PHOs in NSW

ETHICS - NSW LHD Map of the 98 approved COVID-19 ethics applications



*Clock-on refers to the average time taken by HREC and research office from submission closing date to approval (excludes researcher time).

**The data is collected between 1st Jan 2020 and 30th Jun 2020

***NSW State Benchmark for ethics review time is 45 days.

Performance of NSW HRECs in Ethics Review Timelines

ETHICS	Approved (1006)							
	COVID19 (98)				Non-COVID19 (908)			
	Clock On* Mean	Clock On* Median	Clock Off** Mean	Clock Off** Median	Clock On* Mean	Clock On* Median	Clock Off** Mean	Clock Off** Median
Greater than low risk	14	12	28	29	42	33	108	91
Low Risk	10	7	19	13	31	24	79	61
Negligible risk	9	8	14	15	25	19	61	43



Clock-on

The data is collected between 1st Jan 2020 and 30th Jun 2020

***Clock-on** refers to the administrative clock that measures the average time taken by HREC and research office from submission closing date to approval (excludes researcher time).

****Clock-off** refers to the administrative clock that measures the average total time taken from submission to approval.

Comparison of the performance of NSW HRECs in Ethics Review between 1st Jan 2019 – 30th Jun 2020

Period 8: Jan'20 – Jun'20

Period 7: Jul'19 – Dec'19

Period 6: Jan'19 – Jun'19

Key Message:

Prioritising COVID studies resulted with a small but meaningful increase in the median ethics review time for non-COVID studies. When compared against the past 2 periods, this increase is not significant. However, there is been a dramatic increase in the magnitude of the outliers for non-COVID studies in this period, which will cause significant delay in study start-up times.

The figures shows the “clock-on” data

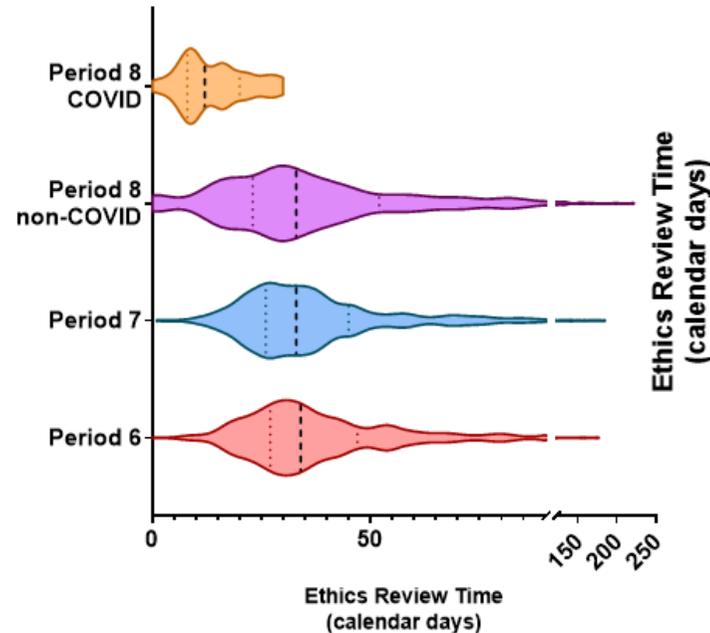


Figure 1 - Violin plot of NSW HRECs' ethics review performance illustrates the boxplot (median) distribution of the entire dataset with density points. The data points are the approval times of all **greater than low risk** ethics applications.

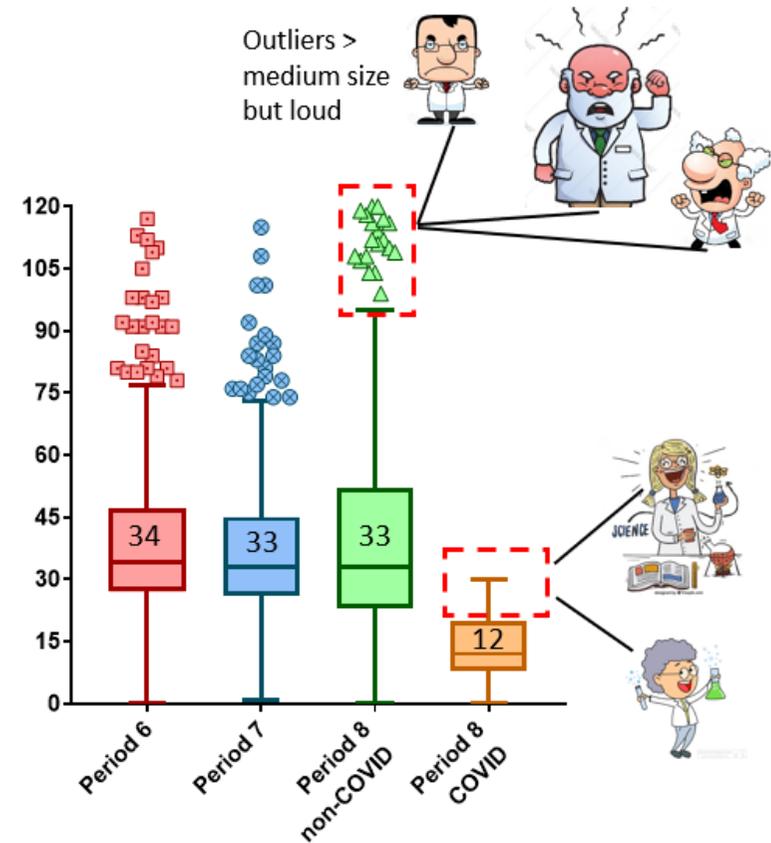
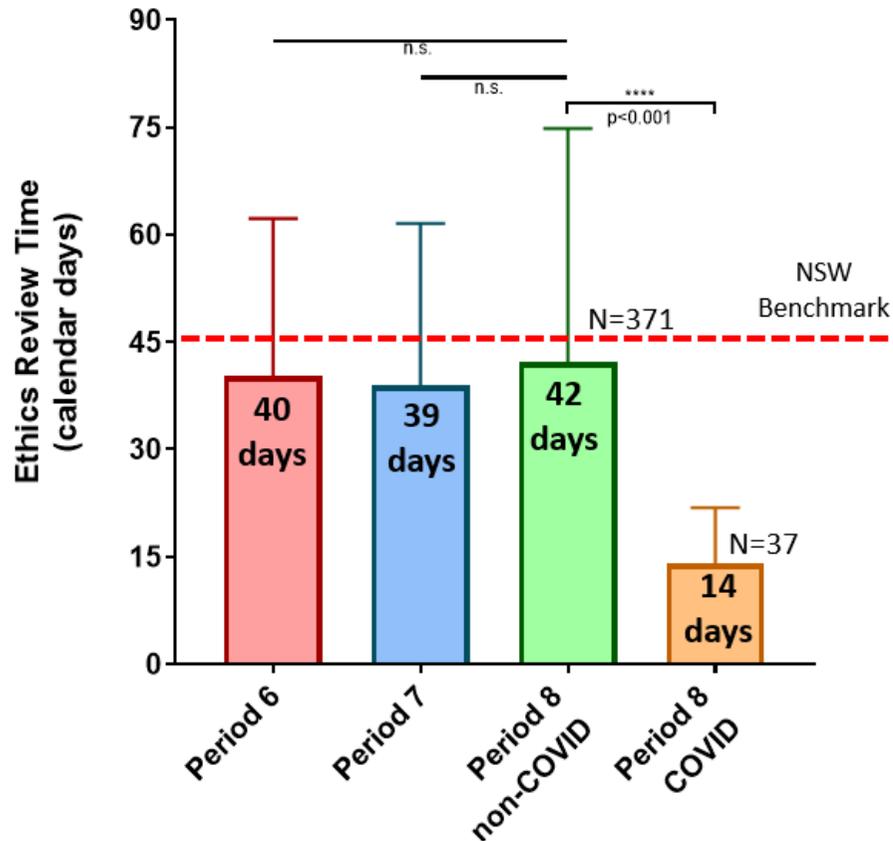


Figure 2 – Boxplot (median) illustration of all **greater than low risk ethics** applications across 3 different time periods. Multiple comparisons were corrected using with Tukey's test (**outliers**).

Impact of prioritizing COVID19 applications on the non-COVID19 HREC review time



Period 8: Jan'20 – Jun'20
 Period 7: Jul'19 – Dec'19
 Period 6: Jan'19 – Jun'19

Key Message:

Mean HREC review time (14days) for COVID19 studies showed a phenomenal success for both research office and researchers. However, this result, which only accounts for 9% of total HREC applications, came at the cost of significantly increasing HREC review times for non-COVID studies, which accounts 91% of the total # of HREC applications.

Figure 3 – Mean performance of NSW HRECs ethics review times (greater than low risk studies) across the past 3 periods with standard deviation.

The figures shows the “clock-on” data

Comparison of NSW HRECs' Ethics review performance for COVID and non-COVID studies

ETH - COVID vs non-COVID

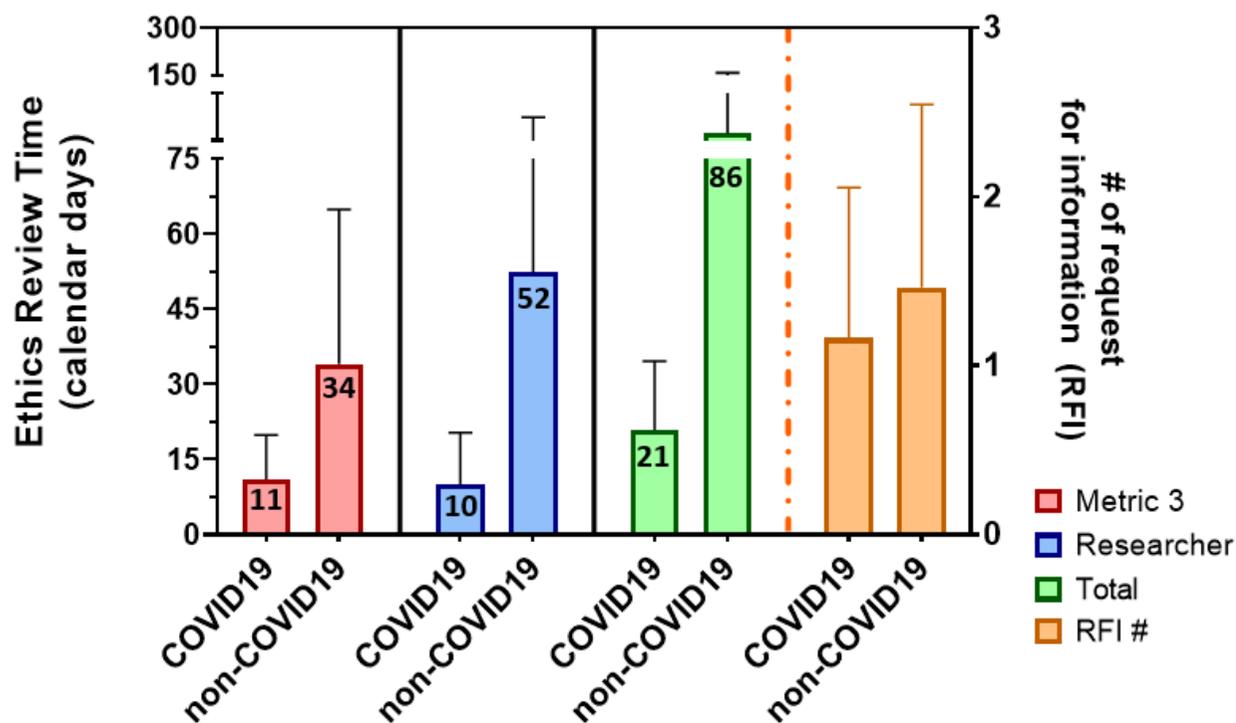


Figure 4 – Comparative **mean** performance of NSW HRECs ethics review times (**all risk types**) between 1 Jan – 30 Jun 2020

The figures shows the data, which is collected between 1st Jan - 30th Jun 2020

Key Message:

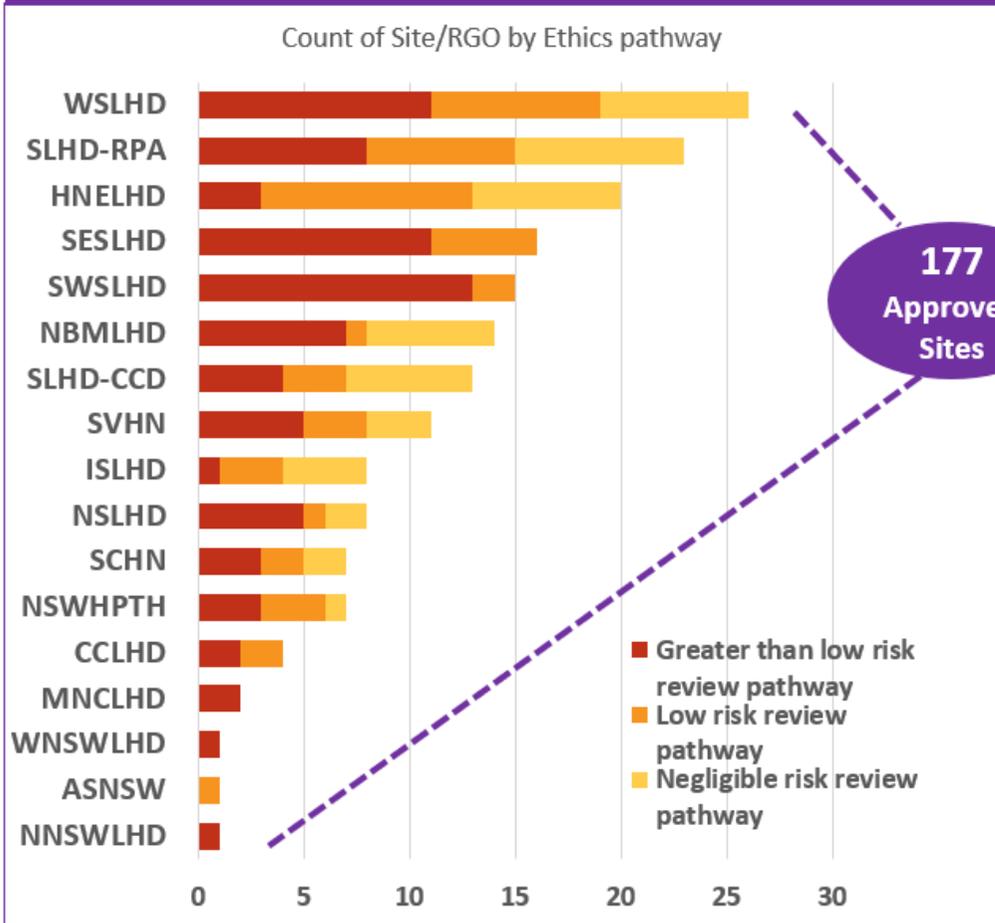
Overall, NSW HRECs are reviewing COVID-19 studies (including **all 3 risk levels**) at a phenomenal rate of **21 days** (mean, clock-off), compared to **86 days** for **non-COVID-19** studies (mean, clock-off). Apart from prioritising the COVID-19 applications, this dramatic difference in HREC review times can be partially explained by the reduction in RFI* count.

- Metric 3 refers to clock-on time

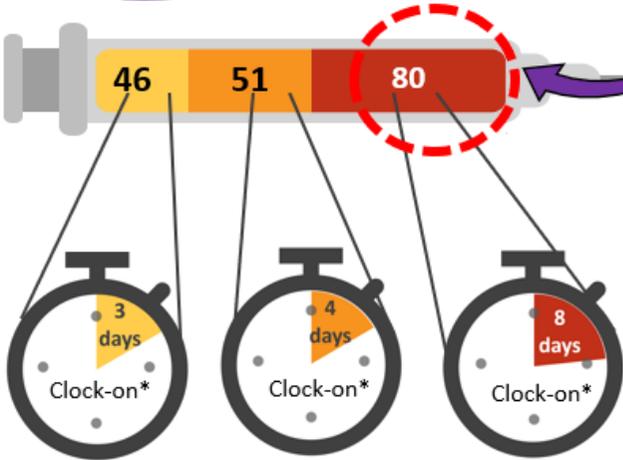
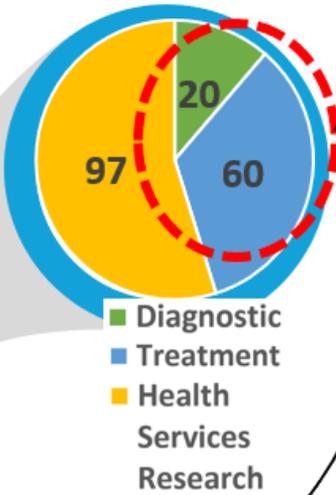
- Total refers to clock-off time

*RFI refers to request for information, which measures how many times an application went back and forth between researcher and research office.

GOVERNANCE – NSW Site breakdown of 177 approved COVID-19 site-specific applications



177 Approved Sites



- Greater than low risk
- Low risk
- Negligible Risk

*Clock-on refers to the average time taken by the research office from submission to approval
 **The data is collected between 1st Jan 2020 and 30th Jun 2020

NSW State Benchmark is 15 days.

Performance of NSW Sites in SSA Review Timelines

SSA	Approved (1404)							
	COVID19 (177)				Non-COVID19 (1227)			
	Clock On* Mean	Clock On* Median	Clock Off** Mean	Clock Off** Median	Clock On* Mean	Clock On* Median	Clock Off** Mean	Clock Off** Median
Greater than low risk	8	6	22	21	22	13	84	59
Low Risk	4	2	18	10	20	7	77	54
Negligible risk	3	2	17	14	12	5	53	36

The data is collected between 1st Jan 2020 and 30th Jun 2020

***Clock-on** refers to the administrative clock that measures the time taken by HREC and research office from submission closing date to approval (excludes researcher time).

****Clock-off** refers to the administrative clock that measures the total time taken from submission to approval.



Clock-on

Comparison of the performance of NSW sites in SSA Review between 1st Jan 2019 – 30th Jun 2020

Period 8: Jan'20 – Jun'20

Period 7: Jul'19 – Dec'19

Period 6: Jan'19 – Jun'19

Key Message:

The median processing time for COVID-19 SSAs (clock-on: 6 days) were less than half the time it takes to process non-COVID-19 SSAs (clock-off: 13 days) with the exception of 4 outliers. While prioritising COVID studies did not lead to any significant negative impact for SSA, the overall SSA processing times were very low and efforts to improve governance went unrealized.

The figures shows the “clock-on” data

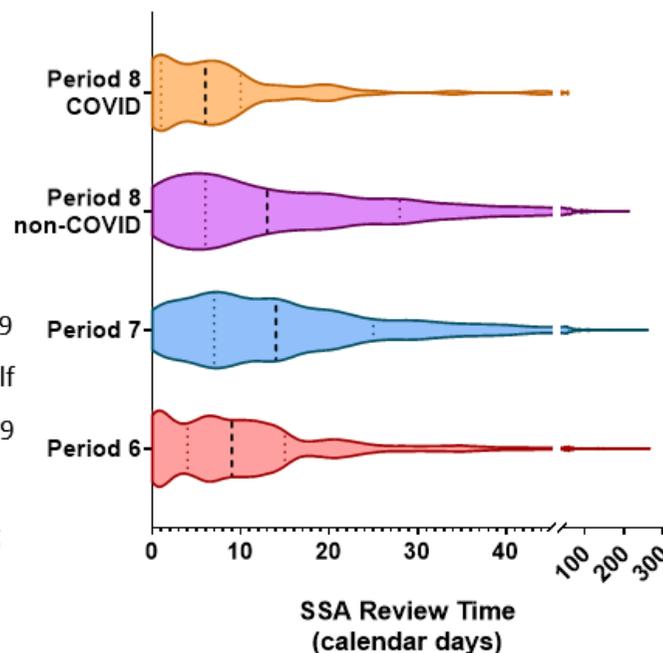


Figure 5 - Violin plot of NSW sites' SSA review performance illustrates the boxplot (**median**) distribution of the entire dataset with **density** points. The data points are the approval times of all **greater than low risk** SSA applications.

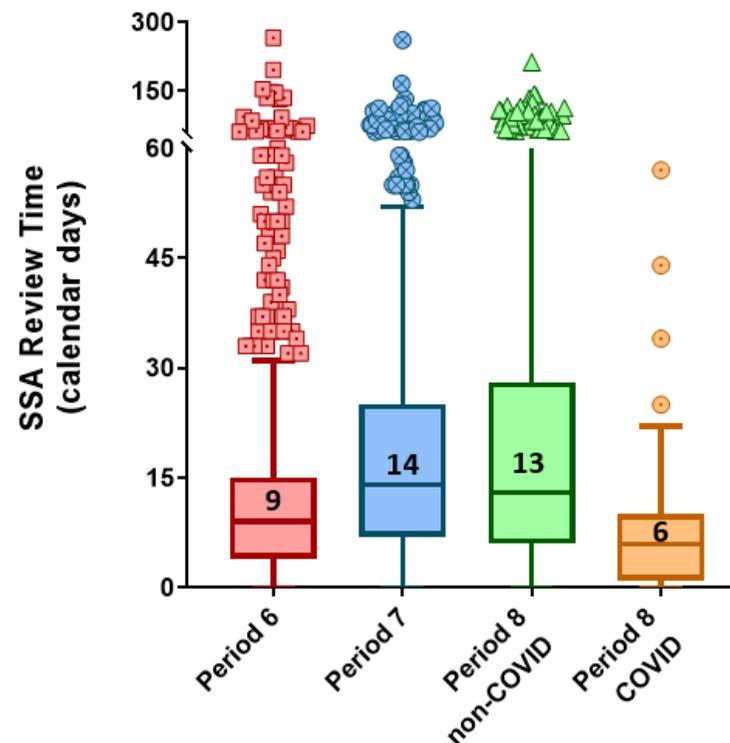


Figure 6 – Boxplot (**median**) illustration of all **greater than low risk** SSA applications across 3 different time periods. Multiple comparisons were corrected using with Tukey's test (**outliers**).

Impact of prioritizing COVID19 applications on the non-COVID19 SSA review time

Key Message:

Mean SSA review times presents a clear proof of prioritisation of COVID studies by NSW sites. As a result, COVID site applications were processed ~3 times faster than non-COVID studies (8 days VS 22 days). While this doesn't significantly change the mean SSA review time for non-COVID studies (no significant difference between Period 7 and 8), significant efforts taken to improve governance in the past few years remain to be unrealised. In fact, mean SSA review time was recorded above NSW benchmark (15 days) in both Period 7 & 8 - twice in a row.

Period 8: Jan'20 – Jun'20
Period 7: Jul'19 – Dec'19
Period 6: Jan'19 – Jun'19

SSA Review Time (calendar days)

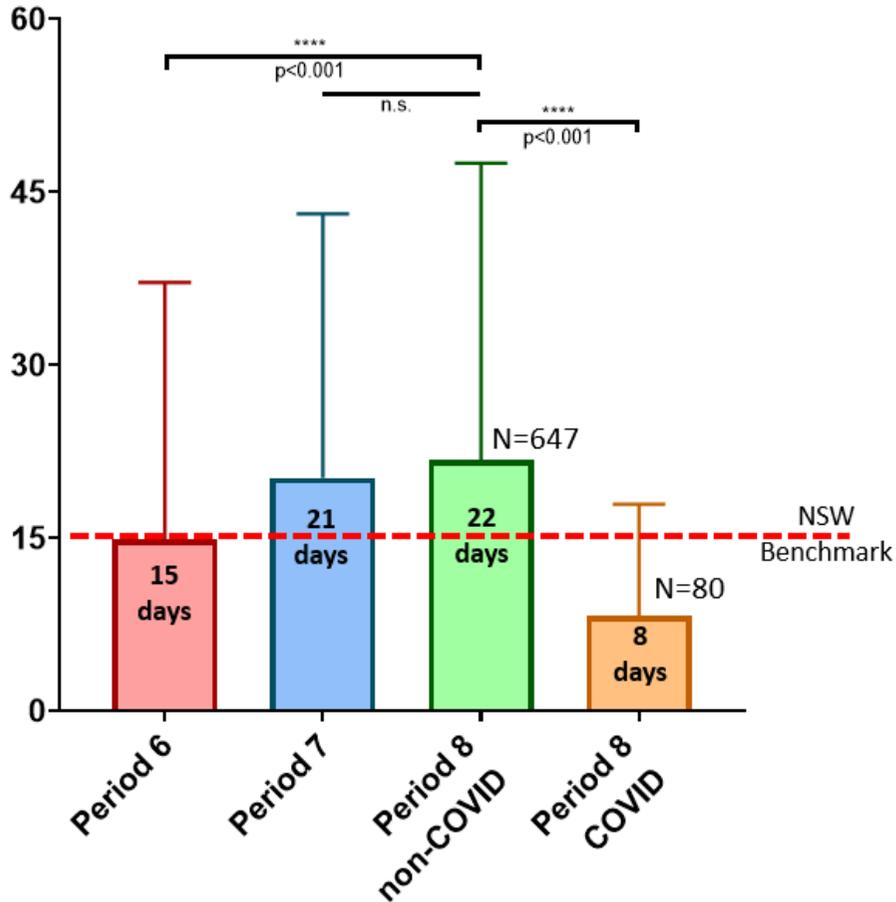


Figure 7 – Mean performance of NSW sites SSA review times (greater than low risk studies) with standard deviation between Period 6-8.

The figures shows the “clock-on” data

Comparison of NSW HRECs' Ethics review performance for COVID and non-COVID studies

SSA - COVID vs non-COVID

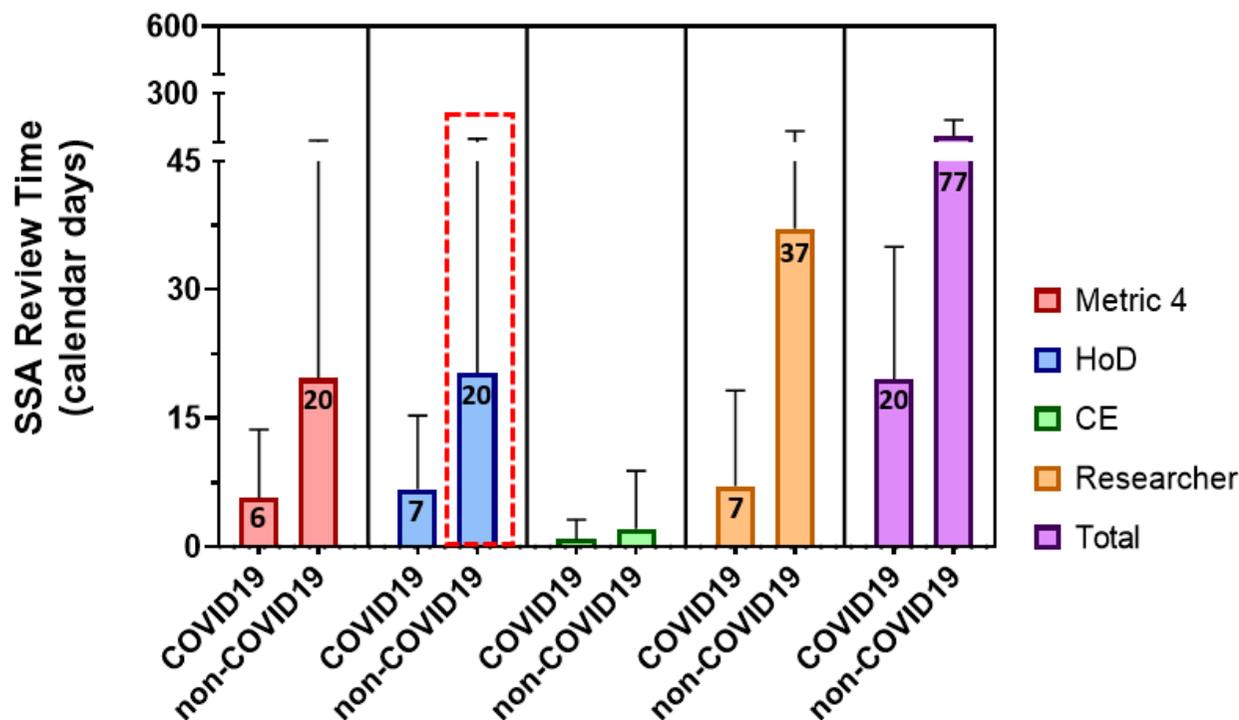


Figure 8 – Comparative **mean** performance of NSW sites SSA review times (**all risk types**)

- The figures shows the data, which is collected between 1st Jan-30th Jun 2020

Key message:

Overall, NSW site applications for COVID-19 studies were processed (including **all 3 risk levels**) at a hitherto unseen **rate of 20 days (mean total, clock-off)**, ~4 times faster than **non-COVID-19 studies (77days, clock-off)**. The data illustrates that this success is an orchestrated effort by the research office, HoD and researchers combined.

- Metric 4 refers to “clock-on” time
- HOD refers to HoD of department review time
- CE refers to Chief Executive review time
- Total refers to “clock-off” time



For more information

This report has been prepared by the Research Ethics and Governance Unit in Office for Health and Medical Research.

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