

OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

03/02/2020

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 2016 and 31st of December 2019. The performance of NSW PHOs on health and medical research are generally reported 6 monthly each financial year.

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) and Research Ethics and Governance Information System (REGIS).

The report compares the change in performance in 5 consecutive reporting periods:

- Period 1: covers from 1 July 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 (6months) *
- Period 7: covers from 1 July 2019 to 31 December 2019 (6months)

Overall Performance Environment:

This report is the first since public health organisations (PHOs) have been using the Research Ethics and Governance Information System (REGIS) platform for the management of their ethics and governance applications. Due to the challenging nature of the state-wide introduction of the product, it is the first report in twelve months.

It is also the first report since the recalibration of the ethics KPI target from 60 days to 45 days (KS5301 – “Metric 3”) and the governance KPI target from 30 days to 15 days (KS5302 – “Metric 4”) on 1 July 2018.

Introduction of REGIS:

The soft-launch introduction of the REGIS workflow management system into research offices in April 2018 has 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 Period 7, all applications were processed entirely through REGIS.

OHMR acknowledges that this environment has created a burden on research office staff, which likely has adversely affected these performance metrics.



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 2018/19 financial year is 45 calendar days.

All studies (greater than low risk) approved by the HREC with a final written notification date (final clock stop date) between 1st of July 2016 and 31st of December 2019.

Selection Criteria Summary:

Study Type- "All", Current Decision- "Approved", Final clock stop date- "within the period"
*Clock start and stop dates for the review process are included.

Summary for Metric 3:

Ethics review performance of NSW HRECs according to new (<45 day) and old (<60 days) benchmarks between 01/07/2017 and 31/12/2019 is shown in the comparison table (Table 1). In NSW, 2950 studies (greater than low risk pathway) were approved by an HREC with a final written notification date (final clock stop date) between 01/07/2016 and 31/12/2019 (Table 2). Of these ethics applications, 822 (28%) were classified as clinical trials (Table 3).

Table 1: The new benchmark (45 calendar days) for review and approval of human research ethics applications (greater than low risk) is applied to the dataset between 01/07/2017 – 31/12/2019. The overall performance of NSW HRECs are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) 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 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2019
HNELHD	56	43	58	55	67	96%	95%	95%	75%	100%	93%	88%	88%	60%	93%
SLHD-RPA	102	79	78	65	47	96%	96%	97%	95%	94%	81%	89%	96%	91%	87%
SWSLHD	34	28	35	41	44	100%	96%	80%	83%	95%	91%	86%	71%	63%	86%
SESLHD	37	44	30	38	33	65%	57%	73%	58%	33%	30%	34%	53%	32%	21%
CINSW	24	35	34	19	33	83%	60%	79%	100%	100%	54%	34%	65%	95%	82%
BLLBRRY	0	0	0	1	32	NA	NA	NA	100%	97%	NA	NA	NA	100%	88%
SVHN	37	35	39	41	24	100%	100%	100%	100%	100%	86%	91%	97%	93%	96%
SCHN	38	41	35	24	22	100%	100%	100%	100%	95%	92%	100%	100%	71%	73%
WSLHD	40	35	34	27	19	95%	69%	97%	93%	37%	55%	23%	59%	85%	16%
SLHD-Concord	16	19	23	22	18	75%	89%	100%	100%	94%	56%	47%	91%	86%	61%
NBMLHD	9	12	9	9	14	100%	92%	67%	33%	93%	44%	33%	11%	33%	64%
NSLHD	34	15	0	10	11	62%	47%	NA	100%	73%	21%	20%	NA	60%	36%
WNSWLHD	13	9	3	4	7	100%	100%	67%	75%	100%	46%	67%	67%	50%	100%
NNSWLHD	3	1	2	0	7	100%	0%	100%	NA	86%	67%	0%	0%	NA	43%
ISLHD	19	16	16	13	3	95%	100%	94%	92%	100%	84%	94%	81%	85%	100%
JHFMHN	1	3	1	3	2	100%	67%	100%	67%	100%	100%	67%	100%	67%	100%
Total	463	415	397	372	383	91%	85%	91%	86%	88%	70%	67%	80%	73%	74%

Table 2: The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving human research ethics applications (greater than low risk) between 01/07/2016 and 31/12/2019. 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 7. 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 (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	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	
HNELHD	63	52	56	43	58	55	67	100%	100%	96%	95%	95%	75%	100%	
SLHD-RPA	108	74	102	79	78	65	47	61%	78%	96%	96%	97%	95%	94%	
SWSLHD	43	39	34	28	35	41	44	88%	90%	100%	96%	80%	83%	95%	
SESLHD	38	46	37	44	30	38	33	53%	57%	65%	57%	73%	58%	33%	
CINSW	19	24	24	35	34	19	33	68%	79%	83%	60%	79%	100%	100%	
BLBRRY	1	0	0	0	0	1	32	100%	NA	NA	NA	NA	100%	97%	
SVHN	40	52	37	35	39	41	24	98%	100%	100%	100%	100%	100%	100%	
SCHN	28	27	38	41	35	24	22	100%	100%	100%	100%	100%	100%	95%	
WSLHD	35	29	40	35	34	27	19	91%	86%	95%	69%	97%	93%	37%	
SLHD-Concord	26	30	16	19	23	22	18	65%	87%	75%	89%	100%	100%	94%	
NBMLHD	8	10	9	12	9	9	14	50%	60%	100%	92%	67%	33%	93%	
NSLHD	45	37	34	15	0	10	11	98%	86%	62%	47%	NA	100%	73%	
WNSWLHD	11	11	13	9	3	4	7	91%	91%	100%	100%	67%	75%	100%	
NNSWLHD	1	0	3	1	2	0	7	0%	NA	100%	0%	100%	NA	86%	
ISLHD	10	5	19	16	16	13	3	90%	80%	95%	100%	94%	92%	100%	
JH&FMHN	5	2	1	3	1	3	2	100%	100%	100%	67%	100%	67%	100%	
Total	482	438	463	415	397	372	383	81%	85%	91%	85%	91%	86%	88%	

Table 3: The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving clinical trials (greater than low risk) between 01/07/2016 and 31/12/2019. The review timelines are calculated using an administrative clock (presented in calendar days). The committee names are sorted by descending order of total clinical trial applications approved followed by descending order of committee's performance in Period 7. 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)														
	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	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	
BLLBRRY	0	0	0	0	0	1	31	NA	NA	NA	NA	NA	100%	97%	
SLHD-RPA	36	20	35	34	25	13	21	25%	40%	94%	100%	96%	96%	100%	
SWSLHD	8	3	5	1	6	0	13	88%	33%	100%	100%	67%	73%	92%	
SVHN	20	26	21	21	27	25	12	100%	100%	100%	100%	100%	100%	100%	
HNELHD	15	10	7	9	14	23	12	100%	100%	100%	89%	86%	69%	100%	
SCHN	11	9	17	11	10	8	11	100%	100%	100%	100%	100%	100%	100%	
WSLHD	8	7	12	12	7	11	8	88%	86%	100%	58%	100%	91%	38%	
SESLHD	3	4	4	3	4	5	8	67%	75%	25%	100%	75%	67%	25%	
SLHD-Concord	8	12	6	11	9	11	4	75%	75%	50%	100%	100%	NA	100%	
CINSW	0	0	0	0	0	0	4	NA	NA	NA	NA	NA	NA	100%	
NSLHD	19	16	17	8	0	2	3	95%	88%	76%	50%	NA	100%	100%	
NBMLHD	1	0	1	1	2	1	3	100%	NA	100%	100%	100%	50%	67%	
ISLHD	0	1	0	3	4	3	1	NA	100%	NA	100%	100%	100%	100%	
WNSWLHD	0	0	0	0	0	1	0	NA	NA	NA	NA	NA	NA	NA	
NNSWLHD	0	0	0	0	0	1	0	NA	NA	NA	NA	NA	NA	NA	
JHFMHN	0	0	0	2	0	0	0	NA	NA	NA	50%	NA	0%	NA	
Total	129	108	125	116	108	105	131	74%	81%	90%	91%	94%	89%	89%	



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 from 2018/19 financial year is 15 calendar days.

All studies (greater than low risk) authorised with a final SSA decision letter between 1st of July 2016 and 31st of December 2019.

Selection Criteria Summary:

Study Type- "All", Current Decision- "Authorised", "Authorised with conditions" or "Further information response authorised", Final clock stop date- "within the period"
*Clock start and stop dates for the review process are included.

Summary for Metric 4:

SSA review performance of NSW PHOs according to new (<15 day) and old (<30 days) benchmarks between 01/07/2017 and 31/12/2019 is shown in the comparison table (Table 3). In NSW, 5989 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 01/07/2016 and 31/12/2019 (Table 3). Of these site authorisation applications, 2440 (41%) were classified as clinical trials (Table 4). There is a noticeable decline in state wide site authorisation timelines in the latest reporting period.

Table 4: The new benchmark (15 calendar days) for site authorisation of human research applications (greater than low risks) is applied to the dataset between 01/07/2017 – 31/12/2019. 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 under 30 days					% authorised under 15 days				
	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109	Jul 2017 Dec 2017	Jan 2018 Jun 2018	Jul 2018 Dec 2018	Jan 2019 Jun 2019	Jul 2019 Dec 2109
HNELHD	107	73	134	75	126	95%	89%	84%	77%	87%	65%	64%	63%	49%	56%
WSLHD	150	134	114	108	99	70%	87%	90%	97%	94%	44%	65%	71%	77%	58%
SWSLHD	103	87	131	95	86	77%	91%	92%	88%	92%	28%	44%	82%	81%	88%
SESLHD	90	78	127	59	68	99%	96%	88%	71%	69%	78%	56%	55%	42%	43%
SLHD-RPA	91	100	100	99	63	98%	100%	100%	100%	90%	81%	89%	100%	95%	73%
SCHN	68	66	76	59	58	100%	73%	88%	97%	76%	93%	44%	63%	83%	33%
SVHN	80	66	69	39	42	99%	100%	97%	95%	88%	86%	94%	81%	77%	67%
SLHD-Concord	45	36	50	43	38	71%	75%	100%	100%	87%	31%	36%	96%	100%	63%
NSLHD	67	22	0	7	30	70%	32%	NA	71%	13%	39%	18%	NA	71%	10%
NBMLHD	34	41	38	41	26	97%	100%	87%	68%	69%	65%	80%	61%	51%	27%
NNSWLHD	46	28	46	28	26	85%	82%	80%	79%	81%	61%	54%	63%	61%	38%
CCLHD	16	14	23	7	22	94%	100%	91%	71%	27%	75%	100%	61%	57%	9%
ISLHD	28	33	44	18	20	100%	97%	80%	83%	90%	79%	70%	55%	39%	65%
MNCLHD	0	0	2	6	19	NA	NA	50%	50%	53%	NA	NA	NA	33%	16%
WNSWLHD	29	25	27	12	10	100%	100%	100%	100%	90%	90%	100%	96%	100%	70%
MLHD	8	13	8	5	8	88%	100%	88%	80%	75%	63%	62%	25%	40%	25%
JHFMHN	1	2	5	2	4	100%	100%	100%	100%	75%	100%	100%	100%	100%	75%
SNSWLHD	1	1	8	1	3	100%	100%	88%	100%	67%	100%	100%	63%	100%	67%
ASNSW	0	0	0	0	1	NA	NA	NA	NA	100%	NA	NA	NA	NA	0%
TOTAL	964	819	1002	704	749	88%	90%	90%	88%	80%	62%	65%	72%	73%	54%

Table 5: The performance of NSW PHOs in authorising human research applications (greater than low risk) between 01/07/2016 and 31/12/2019. The review timelines are calculated using an administrative clock (presented in calendar days). The public health organisations (sites) are sorted by descending order of total applications authorised followed by descending order of site's performance in Period 7. The overall performance of the NSW 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)													
	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	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
HNELHD	106	93	107	73	134	75	126	94%	87%	95%	89%	84%	77%	87%
WSLHD	115	91	150	134	114	108	99	97%	76%	70%	87%	90%	97%	94%
SWSLHD	106	102	103	87	131	95	86	16%	36%	77%	91%	92%	88%	92%
SESLHD	98	100	90	78	127	59	68	97%	93%	99%	96%	88%	71%	69%
SLHD-RPA	120	101	91	100	100	99	63	96%	98%	98%	100%	100%	100%	90%
SCHN	61	55	68	66	76	59	58	97%	100%	100%	73%	88%	97%	76%
SVHN	52	68	80	66	69	39	42	96%	85%	99%	100%	97%	95%	88%
SLHD-Concord	57	52	45	36	50	43	38	56%	62%	71%	75%	100%	100%	87%
NSLHD	72	51	67	22	0	7	30	83%	88%	70%	32%	NA	71%	13%
NBMLHD	39	35	34	41	38	41	26	90%	89%	97%	100%	87%	68%	69%
NNSWLHD	29	20	46	28	46	28	26	66%	70%	85%	82%	80%	79%	81%
CCLHD	12	16	16	14	23	7	22	100%	100%	94%	100%	91%	71%	27%
ISLHD	24	18	28	33	44	18	20	100%	94%	100%	97%	80%	83%	90%
MNCLHD	0	1	0	0	2	6	19	NA	NA	NA	NA	50%	50%	53%
WNSWLHD	17	14	29	25	27	12	10	100%	100%	100%	100%	100%	100%	90%
MLHD	5	10	8	13	8	5	8	100%	80%	88%	100%	88%	80%	75%
JHFMHN	1	3	1	2	5	2	4	0%	67%	100%	100%	100%	100%	75%
SNSWLHD	3	3	1	1	8	1	3	100%	100%	100%	100%	88%	100%	67%
ASNSW	1	0	0	0	0	0	1	100%	NA	NA	NA	NA	NA	100%
TOTAL	918	833	964	819	1002	704	749	82%	81%	88%	90%	90%	88%	80%

Table 6: The performance of NSW PHOs in authorising clinical trial applications (greater than low risk) between 01/07/2016 and 31/12/2019. The review timelines are calculated using an administrative clock (presented in calendar days). The public health organisations (sites) are sorted by descending order of total clinical trial applications authorised followed by descending order of site's performance in Period 7. The overall performance of the NSW sites are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

LHD Abbreviation	SSA Approval (Clinical Trials)													
	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 2109	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 2109
WSLHD	46	43	67	63	46	55	79	93%	72%	76%	90%	93%	96%	94%
HNELHD	40	35	39	27	41	26	49	92%	80%	95%	89%	85%	81%	84%
SESLHD	41	30	36	24	40	26	44	100%	90%	100%	96%	90%	62%	70%
SWSLHD	39	32	37	31	42	30	41	21%	69%	89%	90%	98%	90%	88%
SLHD-RPA	43	30	36	28	32	39	32	91%	97%	94%	100%	100%	100%	91%
SVHN	23	34	52	37	41	24	32	96%	85%	98%	100%	100%	100%	88%
SCHN	23	19	33	31	23	18	26	100%	100%	100%	84%	91%	94%	88%
SLHD-Concord	18	23	24	26	27	13	21	39%	35%	50%	77%	100%	100%	86%
NSLHD	35	26	33	14	0	1	17	83%	88%	67%	43%	NA	100%	18%
NNSWLHD	17	12	23	8	15	10	15	65%	75%	83%	88%	93%	80%	93%
CCLHD	6	12	7	5	9	3	13	100%	100%	86%	100%	100%	67%	31%
NBMLHD	15	10	10	11	14	14	13	100%	70%	100%	100%	93%	86%	69%
MNCLHD	0	0	0	0	1	1	12	NA	NA	NA	NA	0%	100%	58%
ISLHD	8	5	10	6	16	3	11	100%	100%	100%	100%	69%	100%	82%
WNSWLHD	4	2	4	6	8	1	6	100%	100%	100%	100%	100%	100%	83%
JHFMHN	0	1	0	0	3	0	1	NA	100%	NA	NA	100%	NA	100%
SNSWLHD	0	0	0	0	0	0	1	NA	NA	NA	NA	NA	NA	0%
MLHD	1	2	0	0	1	1	0	100%	50%	NA	NA	100%	100%	NA
ASNSW	0	0	0	0	0	0	0	NA	NA	NA	NA	NA	NA	NA
TOTAL	359	316	411	317	359	265	413	82%	80%	87%	90%	93%	90%	80%

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
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).



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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