

OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

1/11/2019

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 2018. 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)*

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 and governance KPI targets from 60 days to 45 days (KS5301 – “Metric 3”) and 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 the Periods 4-5 of the reporting period. A small proportion of the data (~10%) collected during those periods accounts for the data retrieved from REGIS. OHMR has undertaken data validation activities to accurately represent research ethics and governance performance on this platform.

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 for 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 2018.

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:

In NSW, 2188 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 31/12/2018 (Table 1). Of these ethics applications, 583 (27%) were classified as clinical trials (Table 2). There is a noticeable improvement in state wide ethics review timelines.

Table 1: 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 31/12/2018. 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 5. The overall performance of the NSW HRECs are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

ETHICS Approval (All Research Types)										
LHD Abbreviation	Application Volume					Performance				
	Total # of applications					% Reviewed under 60 days				
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 1	Period 2	Period 3	Period 4	Period 5
SLHD-RPA	108	74	102	79	78	61%	78%	96%	96%	97%
HNELHD	63	52	56	43	58	100%	100%	96%	95%	95%
SVHN	40	52	37	35	39	98%	100%	100%	100%	100%
SCHN	28	27	38	41	35	100%	100%	100%	100%	100%
SWSLHD	43	39	34	28	35	88%	90%	100%	96%	80%
WSLHD	35	29	40	35	34	91%	86%	95%	69%	97%
CINSW	19	24	24	35	34	68%	79%	83%	60%	79%
SESLHD	38	46	37	44	30	53%	57%	65%	57%	73%
SLHD-Concord	26	30	16	19	23	65%	87%	75%	89%	100%
ISLHD	10	5	19	16	16	90%	80%	95%	100%	94%
NBMLHD	8	10	9	12	9	50%	60%	100%	92%	67%
WNSWLHD	11	11	13	9	3	91%	91%	100%	100%	67%
NNSWLHD/MNCLHD	1	0	3	1	2	0%	NA	100%	0%	100%
JH&FMHN	5	2	1	3	1	100%	100%	100%	67%	100%
NSLHD	45	37	34	15	0	98%	86%	62%	47%	NA
RRCS	1	0	0	0	0	100%	NA	NA	NA	NA
Total	481	438	463	415	401	81%	85%	91%	85%	91%

Table 2: The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving clinical trials (greater than low risk) between 01/07/2016 and 31/12/2018. The review timelines are calculated using an administrative clock (presented in calendar days). The committee names are sorted by descending order of total CT applications approved followed by descending order of committee's performance in Period 5. The overall performance of the NSW HRECs are represented in colour coding: **Highly Performing** (≥ 95), **Underperforming** ($95 > x \geq 75$) and **Not Performing** (< 75).

ETHICS Approval (Clinical Trials)										
LHD Abbreviation	Application Volume					Performance				
	Total # of applications					% Reviewed under 60 days				
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 1	Period 2	Period 3	Period 4	Period 5
SVHN	20	26	21	21	27	100%	100%	100%	100%	100%
SLHD-RPA	36	20	35	34	25	25%	40%	94%	100%	96%
HNELHD	15	10	7	9	14	100%	100%	100%	89%	86%
SCHN	11	9	17	11	10	100%	100%	100%	100%	100%
SLHD-Concord	8	12	6	11	9	75%	75%	50%	100%	100%
WSLHD	8	7	12	12	7	88%	86%	100%	58%	100%
SWSLHD	8	3	5	1	6	88%	33%	100%	100%	67%
ISLHD	0	1	0	3	4	NA	100%	NA	100%	100%
SESLHD	3	4	4	3	4	67%	75%	25%	100%	75%
NBMLHD	1	0	1	1	2	100%	NA	100%	100%	100%
NSLHD	19	16	17	8	0	95%	88%	76%	50%	NA
JHFMHN	0	0	0	2	0	NA	NA	NA	50%	NA
CINSW	0	0	0	0	0	NA	NA	NA	NA	NA
WNSWLHD	0	0	0	0	0	NA	NA	NA	NA	NA
NNSWLHD/MNCLHD	0	0	0	0	0	NA	NA	NA	NA	NA
RRCS	0	0	0	0	0	NA	NA	NA	NA	NA
Total	129	108	125	116	110	74%	81%	90%	91%	94%



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 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 2018.

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:

In NSW, 4543 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 31/12/2018 (Table 3). Of these site authorisation applications, 1765(39%) were classified as clinical trials (Table 4). There is a noticeable improvement in state wide site authorisation timelines.

Table 3: The performance of NSW PHOs in authorising human research applications (greater than low risks) between 01/07/2016 and 30/06/2018. 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 5. 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 (All Research Types)										
LHD Abbreviation	Application Volume					Performance				
	Total # of applications					% authorised under 30 days				
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 1	Period 2	Period 3	Period 4	Period 5
HNELHD	106	93	107	73	134	94%	87%	95%	89%	84%
SWSLHD	106	102	103	87	131	16%	36%	77%	91%	92%
SESLHD	98	100	90	78	127	97%	93%	99%	96%	88%
WSLHD	115	91	150	134	114	97%	76%	70%	87%	90%
SLHD-RPA	120	101	91	100	100	96%	98%	98%	100%	100%
SCHN	61	55	68	66	76	97%	100%	100%	73%	88%
SVHN	52	68	80	66	69	96%	85%	99%	100%	97%
SLHD-Concord	57	52	45	36	50	56%	62%	71%	75%	100%
NNSWLHD/MNCLHD	29	20	46	28	48	66%	70%	85%	82%	80%
ISLHD	24	18	28	33	44	100%	94%	100%	97%	80%
NBMLHD	39	35	34	41	38	90%	89%	97%	100%	87%
WNSWLHD	17	14	29	25	27	100%	100%	100%	100%	100%
CCLHD	12	16	16	14	23	100%	100%	94%	100%	91%
MLHD	5	10	8	13	8	100%	80%	88%	100%	88%
SNSWLHD	3	3	1	1	8	100%	100%	100%	100%	88%
JH&FMHN	1	3	1	2	5	0%	67%	100%	100%	100%
NSLHD	72	51	67	22	0	83%	88%	70%	32%	NA
ASNSW	1	0	0	0	0	100%	NA	NA	NA	NA
HCARE	1	1	5	0	0	100%	100%	100%	NA	NA
RRCS	0	1	0	0	0	NA	NA	NA	NA	NA
TOTAL	919	834	107	73	134	82%	81%	88%	90%	90%

Table 4: The performance of NSW PHOs in authorising clinical trial applications (greater than low risks) between 01/07/2016 and 30/06/2018. 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 CT applications authorised followed by descending order of site's performance in Period 5. 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)										
LHD Abbreviation	Application Volume					Performance				
	Total # of applications					% authorised under 30 days				
	Period 1	Period 2	Period 3	Period 4	Period 5	Period 1	Period 2	Period 3	Period 4	Period 5
WSLHD	46	43	67	63	46	93%	72%	76%	90%	93%
SWSLHD	39	32	37	31	42	21%	69%	89%	90%	98%
SVHN	23	34	52	37	41	96%	85%	98%	100%	100%
HNELHD	40	35	39	27	41	92%	80%	95%	89%	85%
SESLHD	41	30	36	24	40	100%	90%	100%	96%	90%
SLHD-RPA	43	30	36	28	32	91%	97%	94%	100%	100%
SLHD-Concord	18	23	24	26	27	39%	35%	50%	77%	100%
SCHN	23	19	33	31	23	100%	100%	100%	84%	91%
ISLHD	8	5	10	6	16	100%	100%	100%	100%	69%
NNSWLHD/MNCLHD	17	12	23	8	15	65%	75%	83%	88%	93%
NBMLHD	15	10	10	11	14	100%	70%	100%	100%	93%
CCLHD	6	12	7	5	9	100%	100%	86%	100%	100%
WNSWLHD	4	2	4	6	8	100%	100%	100%	100%	100%
JHFMHN	0	1	0	0	3	NA	100%	NA	NA	100%
MLHD	1	2	0	0	1	100%	50%	NA	NA	100%
NSLHD	35	26	33	14	0	83%	88%	67%	43%	NA
HCARE	0	1	2	0	0	NA	100%	100%	NA	NA
ASNSW	0	0	0	0	0	NA	NA	NA	NA	NA
RRCS	0	0	0	0	0	NA	NA	NA	NA	NA
SNSWLHD	0	0	0	0	0	NA	NA	NA	NA	NA
TOTAL	359	317	413	317	349	82%	80%	87%	90%	93%



The proposed 2018/19 financial year Ethics Benchmark is simulated in 2017/18 dataset:

Table 5: The proposed new benchmark for review and approval of human research ethics applications (greater than low risks) – 45 calendar days – is applied to 2017/18 financial year dataset. 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		
	Period 3	Period 4	Period 5	Period 3	Period 4	Period 5	Period 3	Period 4	Period 5
SLHD-RPA	102	79	78	96%	96%	97%	81%	89%	96%
HNELHD	56	43	58	96%	95%	95%	93%	88%	88%
SVHN	37	35	39	100%	100%	100%	86%	91%	97%
SCHN	38	41	35	100%	100%	100%	92%	100%	100%
SWSLHD	34	28	35	100%	96%	80%	91%	86%	71%
CINSW	24	35	34	83%	60%	79%	54%	34%	65%
WSLHD	40	35	34	95%	69%	97%	55%	23%	59%
SESLHD	37	44	30	65%	57%	73%	30%	34%	53%
SLHD-Concord	16	19	23	75%	89%	100%	56%	47%	91%
ISLHD	19	16	16	95%	100%	94%	84%	94%	81%
NBMLHD	9	12	9	100%	92%	67%	44%	33%	11%
WNSWLHD	13	9	3	100%	100%	67%	46%	67%	67%
NNSWLHD/MNCLHD	3	1	2	100%	0%	100%	67%	0%	0%
JHFMHN	1	3	1	100%	67%	100%	100%	67%	100%
NSLHD	34	15	0	62%	47%	NA	21%	20%	NA
RRCS	0	0	0	NA	NA	NA	NA	NA	NA
Total	463	415	401	91%	85%	91%	70%	67%	80%



Proposed 2018/19 financial year Site Authorisation Benchmark simulated in 2017/18 dataset:

Table 6: The new benchmark for site authorisation of human research applications (greater than low risks) – 15 calendar days – is applied to 2017/18 financial year dataset. 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).

	SSA Approval (All Research Types) <15 days								
	Application Volume			Performance					
	Total # of applications			% authorised under 30 days			% authorised under 15 days		
LHD Abbreviation	Period 3	Period 4	Period 5	Period 3	Period 4	Period 5	Period 3	Period 4	Period 5
HNELHD	107	73	134	99%	96%	84%	78%	56%	63%
SWSLHD	103	87	131	77%	91%	92%	28%	44%	82%
SESLHD	90	78	127	70%	87%	88%	44%	65%	55%
WSLHD	150	134	114	98%	100%	90%	81%	89%	71%
SLHD-RPA	91	100	100	95%	89%	100%	65%	64%	100%
SCHN	68	66	76	100%	73%	88%	93%	44%	63%
SVHN	80	66	69	99%	100%	97%	86%	94%	81%
SLHD-Concord	45	36	50	71%	75%	100%	31%	36%	96%
NNSWLHD/MNCLHD	46	28	48	100%	97%	80%	79%	70%	63%
ISLHD	28	33	44	85%	82%	80%	61%	54%	55%
NBMLHD	34	41	38	97%	100%	87%	65%	80%	61%
WNSWLHD	29	25	27	100%	100%	100%	90%	100%	96%
CCLHD	16	14	23	94%	100%	91%	75%	100%	61%
MLHD	8	13	8	88%	100%	88%	63%	62%	25%
SNSWLHD	1	1	8	100%	100%	88%	100%	100%	63%
JH&FMHN	1	2	5	100%	100%	100%	100%	100%	100%
NSLHD	67	22	0	70%	32%	NA	39%	18%	NA
ASNSW	0	0	0	100%	NA	NA	100%	NA	NA
HCARE	5	0	0	NA	NA	NA	NA	NA	NA
RRCs	0	0	0	NA	NA	NA	NA	NA	NA
TOTAL	107	73	134	88%	90%	90%	62%	65%	72%

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	AU-RED Code
Ambulance Service of NSW	ASNSW		Yes	ASNSW
Central Coast LHD	CCLHD		Yes	CCLHD
The Cancer Council NSW	CCNSW			CCNSW
NSW Population & Health Services Research Ethics Committee	CINSW	Yes		CIPHS
Greater Western LHD	WNSWLHD	Yes	Yes	GWABS
Hammond Care	HCARE		Yes	HCARE
Hunter New England LHD	HNELHD	Yes	Yes	HNE
Justice Health & Forensic Mental Health Network	JHFMHN	Yes	Yes	JH
Murrumbidgee LHD	MLHD		Yes	MLHD
Northern NSW LHD	NNSWLHD/MNCLHD	Yes	Yes	NCC
Nepean Blue Mountains LHD	NBMLHD	Yes	Yes	NEPEAN
Northern Sydney LHD	NSLHD	Yes	Yes	HAWKE
Royal Rehabilitation Centre Sydney HREC	RRCS	Yes		RRCS
Sydney Children's Hospitals Network	SCHN	Yes	Yes	SCHN
South Eastern Sydney LHD	SESLHD	Yes	Yes	POWH
Sydney LHD (Concord Zone)	SLHD – CCD	Yes	Yes	CRGH
Sydney LHD (RPAH Zone)	SLHD – RPA	Yes	Yes	RPAH
Southern NSW LHD	SNSWLHD		Yes	SNSWLHD
St Vincent's Hospital	SVHN	Yes	Yes	SVH
South Western Sydney LHD	SWSLHD	Yes	Yes	LPOOL
Illawarra Shoalhaven LHD (joint committee with University of Wollongong)	ISLHD	Yes	Yes	WGONG
Western Sydney LHD	WSLHD	Yes	Yes	WMEAD

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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