

# OHMR Research Ethics and Governance Metrics Program Update



## Metrics Activity Report for State and NSW PHOs

01/08/2018

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 1<sup>st</sup> of July 2016 and 30<sup>th</sup> of June 2018. The performance of NSW PHOs on health and medical research are reported 6 monthly each financial year.

This report examines the progress undertaken since the program was rolled out on the 1<sup>st</sup> of July 2016. The relevant information for the ethics and governance applications has been exported from Australian Research Ethics Database (AU-RED) on the 16<sup>th</sup> and 18<sup>th</sup> of July 2018 respectively.

The report compares the change in performance in 4 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)\*

\* Research Ethics and Governance Information System (REGIS) has been soft-launched in Period 4. A small proportion of applications were processed in this system. OHMR is currently taking data validation activities to accurately represent research ethics and governance performance on this platform.

The performance thresholds and illustrations of measurement calculations were provided in the [Metrics manual](#).



## 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 (excluding LNR) approved by the HREC with a final written notification date (final clock stop date) between 1<sup>st</sup> of July 2016 and 30<sup>th</sup> of June 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, 1797 studies (excluding LNR) were approved by an HREC with a final written notification date (final clock stop date) between 01/07/2016 and 30/06/2018 (Table 1). Of these ethics applications, 478 (27%) were classified as clinical trials (Table 2). There is a noticeable improvement in state wide ethics review timelines.

**Table 1: AURED Dataset- The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving human research ethics applications (excluding LNRs) between 01/07/2016 and 30/06/2018.** 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 4. The overall performance of the NSW HRECs are represented in colour coding: **Highly Performing** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

LHD Abbreviation	Research Ethics Approval Activity in 16/17 and 17/18 FY							
	Application Volume				Performance			
	Total # of applications				% Reviewed under 60 days			
	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4
SLHD-RPAH	108	74	102	79	61%	78%	96%	96%
SESLHD	38	46	37	44	53%	57%	65%	57%
HNE	63	52	56	43	100%	100%	96%	95%
SCHN	28	27	38	41	100%	100%	100%	100%
SVH	40	52	37	35	98%	100%	100%	100%
WSLHD	35	29	40	35	91%	86%	95%	69%
CINSW	19	24	24	35	68%	79%	83%	60%
SWSLHD	43	39	34	28	88%	90%	100%	96%
SLHD-Concord	26	30	16	19	65%	87%	75%	89%
WGONG	10	5	19	16	90%	80%	95%	100%
NSLHD	45	37	34	15	98%	86%	62%	47%
NEPEAN	8	10	9	12	50%	60%	100%	92%
WNSWLHD	11	11	13	9	91%	91%	100%	100%
JH&FMHN	5	2	1	3	100%	100%	100%	67%
NNNSWLHD/MNCLHD	1	0	3	1	0%	NA	100%	0%
RRCS	1	0	0	0	100%	NA	NA	NA
<b>Total</b>	<b>481</b>	<b>438</b>	<b>463</b>	<b>415</b>	<b>81%</b>	<b>85%</b>	<b>91%</b>	<b>85%</b>

**Table 2: AU-RED Dataset- The performance of NSW Human Research Ethics Committees (HRECs) in reviewing and approving clinical trials (excluding LNRs) between 01/07/2016 and 31/03/2018.** 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 4. The overall performance of the NSW HRECs are represented in colour coding: **Highly Performing** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

Clinical Trial Ethics Approval Activity in 16/17 and 17/18 FY								
LHD Abbreviation	Application Volume				Performance			
	Total # of applications				% Reviewed under 60 days			
	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4
SLHD-RPAH	36	20	35	34	25%	40%	94%	100%
SVH	20	26	21	21	100%	100%	100%	100%
WSLHD	8	7	12	12	88%	86%	100%	58%
SCHN	11	9	17	11	100%	100%	100%	100%
SLHD-Concord	8	12	6	11	75%	75%	50%	100%
HNE	15	10	7	9	100%	100%	100%	89%
NSLHD	19	16	17	8	95%	88%	76%	50%
WGONG	0	1	0	3	NA	100%	NA	100%
SESLHD	3	4	4	3	67%	75%	25%	100%
JH&FMHN	0	0	0	2	NA	NA	NA	50%
NEPEAN	1	0	1	1	100%	NA	100%	100%
SWSLHD	8	3	5	1	88%	33%	100%	100%
CINSW	0	0	0	0	NA	NA	NA	NA
WNSWLHD	0	0	0	0	NA	NA	NA	NA
NNSWLHD/MNCLHD	0	0	0	0	NA	NA	NA	NA
RRCS	0	0	0	0	NA	NA	NA	NA
<b>Total</b>	<b>129</b>	<b>108</b>	<b>125</b>	<b>116</b>	<b>74%</b>	<b>81%</b>	<b>90%</b>	<b>91%</b>



## Site Authorisation 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 (excluding LNR) authorised with a final SSA decision letter between 1<sup>st</sup> of July 2016 and 30<sup>th</sup> of June 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, 3541 studies (excluding LNR) 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 30/06/2018 (Table 3). Of these site authorisation applications, 1406 (40%) were classified as clinical trials (Table 4). There is a noticeable improvement in state wide site authorisation timelines.

**Table 3: AU-RED Dataset- The performance of NSW PHOs in authorising human research applications (excluding LNRs) 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 4. The overall performance of the NSW sites are represented in colour coding: **Highly Performing** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

	Research Authorisation Activity in 16/17 and 17/18 FY							
	Application Volume				Performance			
	Total # of applications				% authorised under 30 days			
	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4
WSLHD	115	91	150	134	97%	76%	70%	87%
SLHD-RPAH	120	101	91	100	96%	98%	98%	100%
SWSLHD	106	102	103	87	16%	36%	77%	91%
SESLHD	98	100	90	78	97%	93%	99%	96%
HNE	106	93	107	73	94%	87%	95%	89%
SVH	52	68	80	66	96%	85%	99%	100%
SCHN	61	55	68	66	97%	100%	100%	73%
NEPEAN	39	35	34	41	90%	89%	97%	100%
SLHD-Concord	57	52	45	36	56%	62%	71%	75%
WGONG	24	18	28	33	100%	94%	100%	97%
NNSWLHD/MNCLHD	29	20	46	28	66%	70%	85%	82%
WNSWLHD	17	14	29	25	100%	100%	100%	100%
NSLHD	72	51	67	22	83%	88%	70%	32%
CCLHD	12	16	16	14	100%	100%	94%	100%
MLHD	5	10	8	13	100%	80%	88%	100%
JH&FMHN	1	3	1	2	0%	67%	100%	100%
SNSWLHD	3	3	1	1	100%	100%	100%	100%
ASNSW	1	0	0	0	100%	NA	NA	NA
HCARE	1	1	5	0	100%	100%	100%	NA
RRCS	0	1	0	0	NA	NA	NA	NA
<b>TOTAL</b>	<b>919</b>	<b>834</b>	<b>969</b>	<b>819</b>	<b>82%</b>	<b>81%</b>	<b>88%</b>	<b>90%</b>

**Table 4: AU-RED Dataset- The performance of NSW PHOs in authorising clinical trial applications (excluding LNRs) 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 4. The overall performance of the NSW sites are represented in colour coding: **Highly Performing** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

LHD Abbreviation	Clinical Trial Authorisation Activity in 16/17 and 17/18 FY							
	Application Volume				Performance			
	Total # of applications				% authorised under 30 days			
	Period 1	Period 2	Period 3	Period 4	Period 1	Period 2	Period 3	Period 4
WSLHD	46	43	67	63	93%	72%	76%	90%
SVH	23	34	52	37	96%	85%	98%	100%
SWSLHD	39	32	37	31	21%	69%	89%	90%
SCHN	23	19	33	31	100%	100%	100%	84%
SLHD-RPAH	43	30	36	28	91%	97%	94%	100%
HNE	40	35	39	27	92%	80%	95%	89%
SLHD-Concord	18	23	24	26	39%	35%	50%	77%
SESLHD	41	30	36	24	100%	90%	100%	96%
NSLHD	35	26	33	14	83%	88%	67%	43%
NEPEAN	15	10	10	11	100%	70%	100%	100%
NNSWLHD/MNCLHD	17	12	23	8	65%	75%	83%	88%
WNSWLHD	4	2	4	6	100%	100%	100%	100%
WGONG	8	5	10	6	100%	100%	100%	100%
CCLHD	6	12	7	5	100%	100%	86%	100%
JH&FMHN	0	1	0	0	NA	100%	NA	NA
MLHD	1	2	0	0	100%	50%	NA	NA
HCARE	0	1	2	0	NA	100%	100%	NA
ASNSW	0	0	0	0	NA	NA	NA	NA
RRCS	0	0	0	0	NA	NA	NA	NA
SNSWLHD	0	0	0	0	NA	NA	NA	NA
<b>TOTAL</b>	<b>359</b>	<b>317</b>	<b>413</b>	<b>317</b>	<b>82%</b>	<b>80%</b>	<b>87%</b>	<b>90%</b>





## 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 (excluding LNRs) – 45 calendar days – is applied to 2017/18 financial year dataset. The overall performance of NSW HRECs are represented in colour coding: **Highly Performing** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

LHD Abbreviation	Research Ethics Approval Activity in 17/18 FY- under 45 days					
	Application Volume		Performance			
	Total # of applications		% Reviewed under 60 days		% Reviewed under 45 days* (New Benchmark Simulation)	
	Period 3	Period 4	Period 3	Period 4	Period 3	Period 4
SCHN	38	41	100%	100%	92%	100%
WGONG	19	16	95%	100%	84%	94%
SVH	37	35	100%	100%	86%	91%
SLHD-RPAH	102	79	96%	96%	81%	89%
HNE	56	43	96%	95%	93%	88%
SWSLHD	34	28	100%	96%	91%	86%
WNSWLHD	13	9	100%	100%	46%	67%
JH&FMHN	1	3	100%	67%	100%	67%
SLHD-Concord	16	19	75%	89%	56%	47%
CINSW	24	35	83%	60%	54%	34%
SESLHD	37	44	65%	57%	30%	34%
NEPEAN	9	12	100%	92%	44%	33%
WSLHD	40	35	95%	69%	55%	23%
NSLHD	34	15	62%	47%	21%	20%
NNNSWLHD/MNCLHD	3	1	100%	0%	67%	0%
RRCS	0	0	NA	NA	NA	NA
<b>Total</b>	<b>463</b>	<b>415</b>	<b>91%</b>	<b>85%</b>	<b>70%</b>	<b>67%</b>



## 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 (excluding LNRs) – 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** ( $\geq 95$ ), **Underperforming** ( $95 > x \geq 75$ ) and **Not Performing** ( $< 75$ ).

	Research Authorisation Activity in 2017/18 FY- under 15 days					
	Application Volume		Performance			
	Total # of applications		% authorised under 30 days		% authorised under 15 days* (New Benchmark Simulation)	
	Period 3	Period 4	Period 3	Period 4	Period 3	Period 4
CCLHD	16	14	94%	100%	75%	100%
WNSWLHD	29	25	100%	100%	90%	100%
JH&FMHN	1	2	100%	100%	100%	100%
SNSWLHD	1	1	100%	100%	100%	100%
SVH	80	66	99%	100%	86%	94%
SLHD-RPAH	91	100	98%	100%	81%	89%
NEPEAN	34	41	97%	100%	65%	80%
WGONG	28	33	100%	97%	79%	70%
WSLHD	150	134	70%	87%	44%	65%
HNE	107	73	95%	89%	65%	64%
MLHD	8	13	88%	100%	63%	62%
SESLHD	90	78	99%	96%	78%	56%
NNSWLHD/MNCLHD	46	28	85%	82%	61%	54%
SCHN	68	66	100%	73%	93%	44%
SWSLHD	103	87	77%	91%	28%	44%
SLHD-Concord	45	36	71%	75%	31%	36%
NSLHD	67	22	70%	32%	39%	18%
HCARE	5	0	100%	NA	100%	NA
ASNSW	0	0	NA	NA	NA	NA
RRCS	0	0	NA	NA	NA	NA
<b>TOTAL</b>	<b>969</b>	<b>819</b>	<b>88%</b>	<b>90%</b>	<b>62%</b>	<b>65%</b>

## 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	CI-NSW	Yes		CIPHS
Greater Western LHD	WNSWLHD	Yes	Yes	GWABS
Hammond Care	HCARE		Yes	HCARE
Hunter New England LHD	HNE	Yes	Yes	HNE
Justice Health & Forensic Mental Health Network	JH&FMHN	Yes	Yes	JH
Murrumbidgee LHD	MLHD		Yes	MLHD
Northern NSW LHD	NNSWLHD/MNCLHD	Yes	Yes	NCC
Nepean Blue Mountains LHD	NEPEAN	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 - Concord	Yes	Yes	CRGH
Sydney LHD (RPAH Zone)	SLHD - RPAH	Yes	Yes	RPAH
Southern NSW LHD	SNSWLHD		Yes	SNSWLHD
St Vincent's Hospital	SVH	Yes	Yes	SVH
South Western Sydney LHD	SWSLHD	Yes	Yes	LPOOL
Illawarra Shoalhaven LHD (joint committee with University of Wollongong)	WGONG	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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