OHMR Research Ethics and Governance Metrics Program Update



Metrics Activity Report for State and NSW PHOs

09/05/2018

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 1st of July 2016 and 31st of March 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^{st} of July 2016. The relevant information for the ethics and governance applications has been exported from Australian Research Ethics Database (AU-RED) on the 26^{th} of April 2018. 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 2018 (6 months)
- Period 4: covers from 1 January 2018 to 31 March 2018 (3 months)*

The performance thresholds and illustrations of measurement calculations were provided in the Metrics manual.

* Period 4 spans across 3 months. The results will be revised at the end of 2017/18 financial year.



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 1st of July 2016 and 31st of March 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, 1550 studies (excluding LNR) were approved by an HREC with a final written notification date (final clock stop date) between 01/07/2016 and 31/03/2018 (Table 1). Of these ethics applications, 400 (26%) 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 (excluding LNRs) between 01/07/2016 and 31/03/2018. The review timelines are calculated using an administrative clock (presented in calendar days). The committees are sorted by descending total application load as well as performance. The overall performance of the NSW HRECs are represented in colour coding: Highly Performing (≥95), Underperforming (95> x ≥75) and Not Performing (<75).

	Research Ethics Approval Activity in 16/17 and 17/18 FY								
	Application Volume				Performance				
		Total # of	applications			% Reviewed under 60 days			
LHD Abbreviation	Period 1	Period 2	Period 3	Period 4*	Period 1 Period 2 Period 3 Period 4				
SLHD-RPAH	108	74	101	35	61%	78%	96%	94%	
HNE	63	52	56	29	100%	100%	96%	93%	
SVH	38	48	37	13	97%	100%	100%	100%	
SESLHD	38	46	35	15	53%	57%	66%	60%	
SWSLHD	43	39	33	14	88%	90%	100%	93%	
NSLHD	45	37	34	10	98%	86%	62%	50%	
WSLHD	35	28	38	15	91%	86%	95%	80%	
SCHN	28	27	36	16	100%	100%	100%	100%	
CINSW	19	24	23	13	68%	79%	83%	54%	
SLHD-Concord	26	30	16	7	65%	87%	75%	71%	
WGONG	10	5	19	7	90%	80%	95%	100%	
WNSWLHD	11	11	13	5	91%	91%	100%	100%	
NEPEAN	8	10	9	5	50%	60%	100%	100%	
JH&FMHN	5	2	1	0	100%	100%	100%	NA	
NNNSWLHD/MNCLHD	1	0	3	0	0%	NA	100%	NA	
RRCS	1	0	0	0	100%	NA	NA	NA	
Total	479	433	454	184	81%	85%	91%	85%	

Table 2: 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 committees are sorted by descending total application load as well as performance. 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 16-18 FY								
		Applicati	on Volume		Performance				
		Total # of	applications			% Reviewed under 60 days			
LHD Abbreviation	Period 1	Period 2	Period 3	Period 4*	Period 1	Period 2	Period 3	Period 4*	
SLHD-RPAH	36	20	35	14	25%	40%	94%	100%	
HNE	15	10	7	6	100%	100%	100%	83%	
SVH	19	23	21	5	100%	100%	100%	100%	
SESLHD	3	4	5	1	67%	75%	20%	100%	
SWSLHD	8	3	5	0	88%	33%	100%	NA	
NSLHD	19	16	17	5	95%	88%	76%	60%	
WSLHD	8	7	12	2	88%	86%	100%	50%	
SCHN	11	9	16	5	100%	100%	100%	100%	
CINSW	0	0	0	0	NA	NA	NA	NA	
SLHD-Concord	8	12	6	2	75%	75%	50%	100%	
WGONG	0	1	0	2	NA	100%	NA	100%	
WNSWLHD	0	0	0	0	NA	NA	NA	NA	
NEPEAN	1		1	0	100%	NA	100%	NA	
JH&FMHN	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	
Total	128	105	125	42	74%	80%	90%	90%	



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 1st of July 2016 and 31st of March 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, 3071 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 31/03/2018 (Table 3). Of these site authorisation applications, 1211 (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 (excluding LNRs) between 01/07/2016 and 31/03/2018. The review timelines are calculated using an administrative clock (presented in calendar days). The public health organisations (sites) are sorted by descending total application load as well as performance. The overall performance of the NSW sites are represented in colour coding: Highly Performing (\geq 95), Underperforming (\leq 55), underperforming (\leq 55).

	Research Authorisation Activity in 16/17 and 17/18 FY									
	Application Volume				Performance					
		Total # of	applications		% authorised under 30 days					
LHD Abbreviation	Period 1	Period 2	Period 3	Period 4*	Period 1	Period 2	Period 3	Period 4*		
WSLHD	114	91	149	61	96%	76%	70%	80%		
SWSLHD	106	102	104	41	16%	36%	76%	90%		
SLHD-RPAH	119	101	91	39	96%	98%	98%	100%		
HNE	106	93	108	41	94%	87%	96%	90%		
SESLHD	96	99	89	31	97%	93%	99%	97%		
NSLHD	72	51	67	22	83%	88%	70%	32%		
SVH	52	69	80	7	96%	86%	99%	100%		
SCHN	61	55	68	22	97%	100%	100%	91%		
SLHD-Concord	57	52	45	20	56%	62%	71%	80%		
NEPEAN	39	34	34	19	90%	88%	97%	100%		
NNSWLHD/MNCLHD	29	20	46	17	66%	70%	85%	71%		
WGONG	22	18	24	17	100%	94%	100%	100%		
WNSWLHD	17	14	29	10	100%	100%	100%	100%		
CCLHD	12	16	16	6	100%	100%	94%	100%		
MLHD	5	10	8	6	100%	80%	88%	100%		
SNSWLHD	3	3	1	1	100%	100%	100%	100%		
HCARE	1	1	5	0	100%	100%	100%	NA		
JH&FMHN	1	3	1	0	0%	67%	100%	NA		
ASNSW	1	0	0	0	100%	NA	NA	NA		
RRCS	0	1	0	0	NA	0%	NA	NA		
TOTAL	913	833	965	360	82%	81%	87%	87%		

Table 4: The performance of NSW PHOs in authorising clinical trial applications (excluding LNRs) between 01/07/2016 and 31/03/2018. The review timelines are calculated using an administrative clock (presented in calendar days). The public health organisations (sites) are sorted by descending total application load as well as performance. The overall performance of the NSW sites are represented in colour coding: Highly Performing (\geq 95), Underperforming (\leq 55), underperforming (\leq 55), Underperforming (\leq 55).

	Clinical Trial Authorisation Activity in 2016-18 FY								
		Applicati	on Volume		Performance				
	Total # of applications				% authorised under 30 days				
LHD Abbreviation	Period 1	Period 2	Period 3	Period 4*	Period 1	Period 2	Period 3	Period 4*	
WSLHD	45	43	66	30	96%	72%	76%	83%	
SWSLHD	39	32	37	14	21%	69%	89%	93%	
SLHD-RPAH	42	30	36	11	90%	97%	94%	100%	
HNE	39	34	41	12	92%	79%	95%	83%	
SESLHD	40	29	36	10	100%	90%	100%	90%	
NSLHD	35	25	33	14	83%	88%	67%	43%	
SVH	23	35	52	3	96%	86%	98%	100%	
SCHN	21	16	34	12	100%	100%	100%	92%	
SLHD-Concord	18	23	24	14	39%	35%	50%	79%	
NEPEAN	15	9	10	4	100%	67%	100%	100%	
NNSWLHD/MNCLHD	17	12	23	4	65%	75%	83%	75%	
WGONG	6	5	7	4	100%	100%	100%	100%	
WNSWLHD	4	2	4	2	100%	100%	100%	100%	
CCLHD	6	12	7	4	100%	100%	86%	100%	
MLHD	1	1			100%	0%	NA	NA	
SNSWLHD					NA	NA	NA	NA	
HCARE		1	2		NA	100%	100%	NA	
JH&FMHN		1			NA	100%	NA	NA	
ASNSW					NA	NA	NA	NA	
RRCS					NA	NA	NA	NA	
TOTAL	351	310	412	138	82%	80%	87%	84%	



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 (≥95), Underperforming (95> x ≥75) and Not Performing (<75).

		Research Et	Ethics Approval Activity in 2017/18 FY						
	Applicati	ion Volume	Performance						
	Total # of	applications	% Reviewed	under 60 days		% Reviewed under 45 days New Benchmark Simulation)			
LHD Abbreviation	Period 3	Period 4*	Period 3	Period 4*	Period 3	Period 4*			
SLHD-RPAH	101	35	96%	94%	82%	83%			
HNE	56	29	96%	93%	93%	90%			
SVH	37	13	100%	100%	86%	85%			
SESLHD	35	15	66%	60%	31%	33%			
SWSLHD	33	14	100%	93%	94%	86%			
NSLHD	34	10	62%	50%	21%	10%			
WSLHD	38	15	95%	80%	53%	27%			
SCHN	36	16	100%	100%	92%	100%			
CINSW	23	13	83%	54%	57%	46%			
SLHD-Concord	16	7	75%	71%	56%	43%			
WGONG	19	7	95%	100%	84%	100%			
WNSWLHD	13	5	100%	100%	46%	80%			
NEPEAN	9	5	100%	100%	44%	40%			
JH&FMHN	1	0	100%	NA	100%	NA			
NNSWLHD/MNCLHD	3	0	100%	NA	67%	NA			
RRCS	0	0	NA	NA	NA	NA			
Total	454	184	91%	85%	70%	68%			



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								
	Applicat	ion Volume		Perfo	rmance				
	Total # of	applications	% authorised	d under 30 days	% authoris	sed under 15 days			
LHD Abbreviation	Period 3	Period 4*	Period 3	Period 4*	Period 3	Period 4*			
WSLHD	149	61	70%	80%	44%	66%			
SWSLHD	104	41	76%	90%	28%	39%			
SLHD-RPAH	91	39	98%	100%	81%	92%			
HNE	108	41	96%	90%	66%	66%			
SESLHD	89	31	99%	97%	78%	52%			
NSLHD	67	22	70%	32%	39%	18%			
SVH	80	7	99%	100%	86%	100%			
SCHN	68	22	100%	91%	93%	64%			
SLHD-Concord	45	20	71%	80%	31%	35%			
NEPEAN	34	19	97%	100%	65%	89%			
NNSWLHD/MNCLHD	46	17	85%	71%	61%	53%			
WGONG	24	17	100%	100%	75%	76%			
WNSWLHD	29	10	100%	100%	90%	100%			
CCLHD	16	6	94%	100%	75%	100%			
MLHD	8	6	88%	100%	62%	67%			
SNSWLHD	1	1	100%	100%	100%	100%			
HCARE	5	0	100%	NA	100%	NA			
JH&FMHN	1	0	100%	NA	100%	NA			
ASNSW	0	0	NA	NA	NA	NA			
RRCS	0	0	NA	NA	NA	NA			
TOTAL	965	360	87%	87%	62%	63%			

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	GWAHS
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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