OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

Reporting Period: Quarter 1 2022

01/01/2022 - 31/03/2022

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 during the reporting period. The performance of NSW PHOs on health and medical research are reported four times a year, each covering a 3-month period.

Overall Performance Environment

REGIS is the online platform used to manage ethics and governance applications for all NSW Public Health Organisations. OHMR has undertaken data validation activities with LHD Research Office staff to accurately represent research ethics and governance performance on this platform. These rolling validation activities may result in data reported here to differ from previous reports.

Update to Metrics Program

As reported previously, OHMR implemented the following changes to the Research Key Performance Indicators (KPIs) for inclusion in the Chief Executives' Services Agreement:

- Change benchmark to measure Total Time rather than time spent with LHD Research Office alone
- Number of Greater than Low Risk projects (GLR) processed within application total time
 - o 90 days for ethics, 60 days for governance
 - Threshold changes
 - >75% = Performing
 - 55%-75% = Underperforming
 - <55% = Not performing</p>



Ethics Review Timelines of Human Research in NSW PHOs

KPI21-03: Ethics Application Approvals - By the Human Research Ethics Committee (HREC) within 90 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards is for reviewing human research studies by NSW PHO HRECs within 90 calendar days

Definition:

The proportion of Ethics applications (excluding LNR) approved by the HREC within 90 calendar days, approved within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the NHMRC Certification Handbook. Instead, the end-to-end time will be measured. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock is stopped when the HREC formally notifies the applicant of the final decision.

Desired Outcome:

Ensuring timely processing of ethics approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection Criteria Summary:

Scope	Human Research Ethics Applications
Frequency	Quarterly
Inclusions	 Study Type = All Application Type = Greater than low risk Approval Type = Approved/Approved with conditions within the reporting period
Exclusions	 Application Type = Low and negligible risk Approval Type = Not within the reporting period Migrated studies

Total Time:

Total time is defined as the measurement of the total, unadjusted time from the Submission Closing Date of the first meeting the application is assigned to, to when the final decision notification email is sent.

Summary:

Ethics review performance of NSW HRECs according to the <90-day benchmark for studies approved during the reporting period (Quarter 1 2022) are shown in Table 1. During the reporting period, 197 studies (greater than low risk pathway) were approved by an HREC with an average review time (total time) of 63 days. Of these 197 studies, 74 (38%) were classified as clinical trials (Table 2). Further breakdown of clinical trial approvals by sponsor type is provided in Table 3 (by NSW PHOs) and Table 4 (by quarter). Historical performance of NSW PHOs against the old and new benchmarks for the review and approval of human research ethics applications is presented in Table 5.

Table 1. The 90 calendar days benchmark for approval of human research ethics applications (greater than low risk) during the reporting period.

				Approval (Q1 than low risk a			
		9	Total Time 90 Day Benchmarl	K	Total Time (calenda		
NSW PHOs	Total Number of Applications	Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	Count Request for Information
BLLBRRY	27	25	93%	54	27	27	2.1
CINSW	16	8	50%	82	40	42	1.8
HNELHD	22	19	86%	62	20	42	1.7
ISLHD	4	3	75%	80	50	30	1.5
JHFMHN	3	2	67%	134	61	73	1.0
NBMLHD	7	7	100%	70	46	24	1.0
NNSWLHD	2	2	100%	59	38	21	2.5
NSLHD	3	2	67%	80	28	52	2.3
SCHN	9	5	56%	85	45	40	1.8
SESLHD	10	10	100%	54	28	26	2.0
SLHD-CCD	3	3	100%	74	34	40	1.3
SLHD-RPA	34	34	100%	43	20	23	1.2
SVHN	10	8	80%	59	30	29	1.7
SWSLHD	18	15	83%	66	42	24	1.4
WNSWLHD	2	2	100%	43	43	-	0.5
WSLHD	27	19	70%	72	41	31	1.9
TOTAL	197	164	83%	63	32	31	1.7

Table 2. The 90 calendar days benchmark for the approval of clinical trials (greater than low risk) during the reporting period.

				Approval (Q 1 Clinical Trials			
		9	Total Time 90 Day Benchmar	k	Total Time (calend	Breakdown ar days)	
NSW PHOs	Total Number of Applications	Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	Count Request for Information
BLLBRRY	27	25	93%	54	27	27	2.1
CINSW	1	1	100%	53	29	24	1.0
HNELHD	7	7	100%	46	17	29	1.6
ISLHD	2	1	50%	91	53	38	2.0
NSLHD	2	1	50%	97	28	70	3.0
SCHN	3	1	33%	98	52	46	2.3
SESLHD	2	2	100%	73	39	35	2.5
SLHD-CCD	1	1	100%	77	48	29	2.0
SLHD-RPA	10	10	100%	50	24	26	1.0
SVHN	2	2	100%	58	39	19	1.0
SWSLHD	4	2	50%	84	39	46	1.8
WSLHD	13	10	77%	71	40	31	1.9
TOTAL	74	63	85%	62	31	31	1.9

Table 3. Breakdown of NSW PHO performances in clinical trial approvals (greater than low risk) during the reporting period by sponsor type

	C	ollaborative group			Commercial entity	1	In	vestigator-initiated	k
NSW PHOs	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
BLLBRRY				25	26	53	2	38	61
CINSW							1	29	53
HNELHD	1	6	29	3	15	42	3	21	55
ISLHD	1	62	104				1	44	77
NSLHD				1	17	69	1	38	125
SCHN				2	69	131	1	19	32
SESLHD				1	38	64	1	39	82
SLHD-CCD							1	48	77
SLHD-RPA				1	21	51	9	25	50
SVHN				1	43	58	1	35	58
SWSLHD				1	29	53	3	42	95
WSLHD				4	36	67	9	42	73
Grand Total	2	34	67	39	29	58	33	34	66

Table 4. Quarterly clinical trial approvals (greater than low risk) between 01/07/2021 and 31/03/2022, by sponsor type

		Q3 2021			Q4 2021		Q1 2022					
Sponsor Type	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)			
Collaborative Group	10	30	87	8	25	41	2	34	67			
Commercial Entity	41	24	57	61	31	60	39	29	58			
Investigator Initiated	40	24	63	31	28	55	33	34	66			
Total	91	25	63	100	29	57	74	31	62			

Table 5. Historical performance of NSW PHOs against **the old and new benchmarks** for the review and approval of human research ethics applications (greater than low risk) between 01/07/2021 and 31/03/2022.

				Q3 2021							Q4 2021							Q1 2022			
		45 Day	Benchmar	k (with		ay Benchr			45 Day	Benchma	rk (with		ay Benchn			45 Day	Benchma	rk (with		ay Benchn	
	of s		clock)		(WI	ithout clo		of S		clock)		(W	ithout cloc		of s		clock)		(W	ithout cloc	-
NSW PHOs	Total Number	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric 3 Time (Days)	Count 90 Day Benchmark	% 90 Day Total Tin Benchmark	Average Total Time (Days)	Total Number of Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric 3 Time (Days)	Count 90 Day Benchmark	% 90 Day Total Tin Benchmark	Average Total Time (Days)	Total Number of Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Metric 3 Time (Days)	Count 90 Day Benchmark	% 90 Day Total Tim Benchmark	Average Total Time (Days)
BLLBRRY	20	19	95%	25	18	90%	55	26	25	96%	26	23	88%	43	27	23	85%	27	25	93%	54
CINSW	21	21	100%	31	17	81%	84	15	13	87%	33	13	87%	108	16	11	69%	40	8	50%	82
HNELHD	35	33	94%	28	29	83%	86	37	37	100%	23	32	86%	63	22	21	95%	20	19	86%	62
ISLHD	6	4	67%	44	5	83%	72	6	4	67%	45	4	67%	92	4	1	25%	50	3	75%	80
JHFMHN	1	1	100%	38	0	0%	602	1	0	0%	76	0	0%	134	3	0	0%	61	2	67%	134
NBMLHD	9	7	78%	38	8	89%	70	8	4	50%	42	6	75%	105	7	1	14%	46	7	100%	70
NNSWLHD	3	1	33%	57	2	67%	232	2	2	100%	36	2	100%	70	2	1	50%	38	2	100%	59
NSLHD	5	5	100%	25	4	80%	56	7	7	100%	15	7	100%	38	3	3	100%	28	2	67%	80
SCHN	14	14	100%	26	13	93%	58	17	10	59%	38	11	65%	74	9	4	44%	45	5	56%	85
SESLHD	13	12	92%	25	13	100%	38	17	15	88%	31	15	88%	69	10	10	100%	28	10	100%	54
SLHD-CCD	17	17	100%	26	8	47%	121	12	12	100%	24	11	92%	56	3	2	67%	34	3	100%	74
SLHD-RPA	57	56	98%	15	47	82%	68	41	41	100%	15	39	95%	42	34	34	100%	20	34	100%	43
SVHN	38	36	95%	26	32	84%	64	33	31	94%	25	33	100%	41	10	10	100%	30	8	80%	59
SWSLHD	22	22	100%	19	20	91%	63	22	19	86%	32	16	73%	82	18	12	67%	42	15	83%	66
WNSWLHD	11	10	91%	32	11	100%	11	4	4	100%	32	4	100%	42	2	1	50%	43	2	100%	43
WSLHD	32	30	94%	32	25	78%	61	21	15	71%	39	18	86%	67	27	18	67%	41	19	70%	72
TOTAL	30 4	288	95%	26	252	83%	72	269	239	89%	28	234	87%	62	197	152	77%	32	164	83%	63



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

KPI21-04: Research Governance Application Authorisations – SSA Authorisations within 60 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards for authorisation of SSA applications is 60 calendar days

Definition:

The proportion of site-specific assessment (SSA) applications (excluding lower to negligible risk) authorised by the Research Governance Office (RGO) within 60 calendar days, authorised within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the National Health and Medical Research Council Certification Handbook. Instead, the end-to-end time will be measured. The SSA application received date is the date the RGO or designee receives an SSA application from a researcher regardless of whether it is complete and/or deemed valid. The clock is stopped when the final SSA decision letter is provided to the site principal investigator.

Desired Outcome:

Ensuring timely processing of site approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection Criteria Summary:

Scope	Site-specific assessment (SSA) applications
Frequency	Quarterly
Inclusions	 Study Type = All Application Type = Greater than low risk Approval Type = "Authorised" or "authorised with conditions" within the reporting period
Exclusions	 Application Type = Low and negligible risk Approval Type = Not within the reporting period Migrated studies

Total Time:

Total time is the measurement of the total, unadjusted time from the Submission Date to when the final decision notification email is sent granting approval.

Summary for Metric 4:

SSA review performance of NSW PHOs according to the <60-day benchmark for studies authorised during the reporting period (Quarter 1 2022) are shown in Table 6. During the reporting period, 418 studies (greater than low risk pathway) were authorised in NSW PHOs with an average review time (total time) of 48 days. Of these 417 studies, 195 (47%) were classified as clinical trials (Table 7). Further breakdown of clinical trial SSA authorisations by sponsor type is provided in Table 8 (by NSW PHOs) and Table 9 (by quarter). Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of governance applications is presented in Table 10.

Table 6: The 60 calendar days benchmark for authorisation of governance applications (greater than low risk) during the reporting period.

				SA Approva iter than lov								
		60 Day Be	enchmark (with	out clock)	Total Time Breakdown (calendar days)							
NSW PHOs	Total Number of Applications	Count of <60 Day Benchmark	% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time				
ASNSW	0	0	-	-	-	-	-	-				
Calvary	13	13	100%	19	11	4	1	3				
CCLHD	16	14	88%	35	8	7	0	21				
HNELHD	40	33	83%	33	8	6	1	19				
ISLHD	10	10	100%	11	7	2	0	1				
JHFMHN	2	2	100%	40	32	9	-	-				
MLHD	3	3	100%	27	12	5	0	10				
MNCLHD	3	3	100%	26	7	3	13	4				
NBMLHD	18	12	67%	56	14	8	8	26				
NNSWLHD	3	3	100%	25	9	5	11	-				
NSLHD	24	16	67%	61	19	8	0	34				
NSWHPTH	5	3	60%	56	7	38	0	10				
SCHN	19	11	58%	66	18	15	1	33				
SESLHD	35	25	71%	42	10	7	-	24				
SLHD-CCD	21	21	100%	25	9	5	-	11				
SLHD-RPA	47	41	87%	32	2	9	5	16				
SNSWLHD	3	1	33%	74	2	-	41	32				
SVHN	29	18	62%	50	13	10	-	27				
SWSLHD	56	32	57%	73	15	11	0	46				
WNSWLHD	8	7	88%	31	2	16	5	8				
WSLHD	63	53	84%	37	12	8	3	15				
TOTAL	418	321	77%	44	11	9	2	23				

Table 7: The 60 calendar days benchmark for the authorisation of clinical trials (greater than low risk) during the reporting period.

			SSA A	Approvals (C Clinical Tria				
		60 Day	Benchmark (without o	clock)	Tota	al Time Breakdo	wn (calendar d	ays)
NSW PHOs	Total Number of Applications	Count of <60 Day Benchmark	% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time
ASNSW	0	0	-	-	-	-	-	-
CALVARY	8	8	100%	12	8	3	1	0
CCLHD	6	5	83%	28	3	8	0	17
FWLHD	0	0	-	-	-	-	-	-
HNELHD	18	14	78%	37	7	5	1	25
ISLHD	4	4	100%	19	13	4	0	3
JHFMHN	0	0	-	-	-	-	-	-
MLHD	1	1	100%	14	8	6	0	0
MNCLHD	1	1	100%	34	7	0	14	13
NBMLHD	8	3	38%	73	23	13	7	30
NNSWLHD	2	2	100%	38	14	7	17	0
NSLHD	12	11	92%	50	24	6	0	20
NSWHPTH	0	0	-	-	-	-	-	-
SCHN	9	5	56%	80	16	16	1	46
SESLHD	11	7	64%	45	11	11	0	23
SLHD-CCD	8	8	100%	30	19	4	0	7
SLHD-RPA	10	7	70%	44	2	9	13	21
SNSWLHD	0	0	-	-	-	-	-	-
SVHN	23	15	65%	43	12	11	0	21
SWSLHD	29	13	45%	95	17	14	0	63
WNSWLHD	2	2	100%	21	2	5	0	14
WSLHD	43	41	95%	27	9	5	3	9
TOTAL	195	147	75%	47	12	8	2	24

Table 8. NSW PHO performances in clinical trial authorisations (greater than low risk) during the reporting period, by sponsor type

	С	ollaborative group			Commercial entity		In	vestigator-initiated	İ
NSW PHOs	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)
CALVARY	1	1	6	4	10	13	3	7	14
CCLHD	3	1	11	1	3	16	2	7	60
HNELHD	1	8	69	8	4	11	9	9	57
ISLHD	2	22	22	2	4	17			
MLHD	1	8	14						
MNCLHD				1	7	34			
NBMLHD	1	61	77	5	14	56	2	26	113
NNSWLHD	1	12	34	1	16	41			
NSLHD	9	25	48	2	23	43	1	15	78
SCHN	1	3	40	4	6	35	4	31	134
SESLHD	4	7	20	5	16	53	2	4	73
SLHD-CCD	1	20	40	5	19	29	2	20	30
SLHD-RPA				6	2	53	4	2	31
SVHN	3	17	53	12	11	44	8	11	39
SWSLHD	5	22	94	15	13	53	9	22	164
WNSWLHD	1	1	35	1	3	6			
WSLHD	1	1	5	27	9	22	15	11	36
Total	35	17	44	99	10	35	61	13	68

Table 9. Quarterly clinical trial authorisations (greater than low risk applications) approved during the reporting period, by sponsor type

		Q3 2021			Q4 2021		Q1 2022					
Sponsor Type	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)			
Collaborative Group	48	9	47	48	9	38	35	17	44			
Commercial Entity	100	10	37	100	10	30	99	10	35			
Investigator Initiated	61	11	84	61	11	82	61	13	68			
Total	209	10	53	209	10	47	195	12	47			

Table 10. Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of SSA applications (greater than low risk) between 06/01/2021 and 31/03/2022.

				Q3 20	21						Q4 202	1						Q1 202	2		
	Applications		ay Benchi with clock			Day Benchn vithout cloc		Applications	15	Day Bench (with cloc			Day Benchi without clo		ations		Day Bench with clock)	mark		Day Bench without clo	
LHD	Number of Applic	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Applic	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Applications	Count of 15 Day Benchmark	% 15 Day Benchmark	Average Metric Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)
ASNSW	0	0	-	-	0	-	-	0	0	-	-	0	-	-	0	0	-	-	0	-	-
CALVARY	10	7	70%	11	9	90%	20	13	12	92%	8	13	100%	13	13	9	69%	11	13	100%	19
CCLHD	7	2	29%	25	4	57%	130	20	14	70%	19	15	75%	63	16	15	94%	8	14	88%	35
FWLHD	0	0	-	-	0	-	-	0	0	-	-	0	-	-	0	0	-	-	0	-	-
HNELHD	33	33	100%	5	28	85%	42	57	46	81%	10	43	75%	54	40	35	88%	8	33	83%	33
ISLHD	18	16	89%	5	16	89%	34	17	17	100%	2	17	100%	11	10	9	90%	7	10	100%	11
JHFMHN	0	0	-	-	0	-	-	0	0	-	-	0	-	-	2	0	0%	32	2	100%	40
MLHD	4	4	100%	6	4	100%	19	4	3	75%	12	4	100%	21	3	3	100%	12	3	100%	27
MNCLHD	6	4	67%	13	1	17%	177	8	6	75%	16	6	75%	56	3	3	100%	7	3	100%	26
NBMLHD	19	9	47%	21	10	53%	102	23	12	52%	16	16	70%	71	18	11	61%	14	12	67%	56
NNSWLHD	4	2	50%	24	4	100%	27	6	4	67%	12	6	100%	25	3	2	67%	9	3	100%	25
NSLHD	26	26	100%	6	18	69%	64	38	37	97%	6	24	63%	59	24	10	42%	19	16	67%	61
NSWHPTH	11	7	64%	13	6	55%	80	5	5	100%	6	2	40%	122	5	5	100%	7	3	60%	56
SCHN	35	27	77%	10	19	54%	68	36	21	58%	18	14	39%	85	19	11	58%	18	11	58%	66
SESLHD	44	37	84%	7	30	68%	57	35	27	77%	10	26	74%	81	35	27	77%	10	25	71%	42
SLHD-CCD	20	18	90%	9	13	65%	61	29	27	93%	7	23	79%	59	21	15	71%	9	21	100%	25
SLHD-RPA	45	37	82%	7	33	73%	49	60	56	93%	4	49	82%	38	47	47	100%	2	41	87%	32
SNSWLHD	7	3	43%	37	5	71%	50	0	0	-	-	0	-	-	3	3	100%	2	1	33%	74
SVHN	33	25	76%	10	23	70%	61	46	36	78%	13	31	67%	79	29	22	76%	13	18	62%	50
SWSLHD	64	63	98%	5	40	63%	103	60	46	77%	11	40	67%	58	56	35	63%	15	32	57%	73
WNSWLHD	14	14	100%	1	14	100%	10	15	15	100%	3	14	93%	23	8	8	100%	2	7	88%	31
WSLHD	71	66	93%	9	59	83%	62	75	69	92%	8	61	81%	43	63	49	78%	12	53	84%	37
TOTAL	471	400	85%	9	336	71%	65	547	453	83%	10	404	74%	56	418	319	76%	11	321	77%	44

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

Human Research Ethics Committee/ Research Governance Office Name	Abbreviation used in the tables	Ethics	Site
Ambulance Service of NSW	ASNSW		Yes
Bellberry	BLLBRRY	Yes	
Calvary Mater Hospital Newcastle	CALVARY		Yes
Central Coast LHD	CCLHD		Yes
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 – CCD	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



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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OHMR Research Ethics and Governance Metrics Program



Metrics Activity Report for NSW PHOs

Reporting Period: Quarter 2 2022 01/04/2022 - 30/06/2022

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 during the reporting period. The performance of NSW PHOs on health and medical research are reported four times a year, each covering a 3-month period.

Overall Performance Environment

REGIS is the online platform used to manage ethics and governance applications for all NSW Public Health Organisations. OHMR has undertaken data validation activities with LHD Research Office staff to accurately represent research ethics and governance performance on this platform. These rolling validation activities may result in data reported here to differ from previous reports.

Update to Metrics Program

As reported previously, OHMR implemented the following changes to the Research Key Performance Indicators (KPIs) for inclusion in the Chief Executives' Services Agreement:

- Change benchmark to/measure/Total Time/rather than time spent with LHD Research Office alone
- Number of Greater than Low Risk projects (GLR) processed within application total time
 - o 90 days for ethics, 60 days for governance
 - Threshold changes
 - >75% = Performing
 - 55%-75% = Underperforming



Ethics Review Timelines of Human Research in NSW PHOs

KPI21-03: Ethics Application Approvals - By the Human Research Ethics Committee (HREC) within 90 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards is for reviewing human research studies by NSW PHO HRECs within 90 calendar days

Definition:

The proportion of Ethics applications (excluding LNR) approved by the HREC within 90 calendar days, approved within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the NHMRC Certification Handbook. Instead, the end-to-end time will be measured. Where a valid application is received, the clock starts on the submission closing date for the HREC meeting at which an application will be reviewed. The clock is stopped when the HREC formally notifies the applicant of the final decision.

Desired Outcome:

Ensuring timely processing of ethics approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection	Criteria	Summary	/:

Scope	Human Research Ethics Applications
Frequency	Quarterly
Inclusions	 Study Type = All Application Type = Greater than low risk Approval Type = Approved/Approved with conditions within the reporting period
Exclusions	 Application Type = Low and negligible risk Approval Type = Not within the reporting period Migrated studies

Total

Total time is defined as the measurement of the total, unadjusted time from the Submission Closing Date of the first meeting the application is assigned to, to when the final decision notification email is sent.

Summary for Metric 3

Ethics review performance of NSW HRECs according to the <90-day benchmark for studies approved during the reporting period (Quarter 2 2022) are shown in Table 1.

During the reporting period, 226 studies (greater than low risk pathway) were approved by a NSW Health HREC with an average review time (total time) of 60 days. Of these 226 studies, 90 (40%) were classified as clinical trials (**Table 2**).

Further breakdown of clinical trial approvals by sponsor type is provided in **Table 3** (by NSW PHOs) and **Table 4** (by quarter). Historical performance of NSW PHOs against the old and new benchmarks for the review and approval of human research ethics applications is presented in **Table 5**.

Table 1. The 90 calendar days benchmark for approval of human research ethics applications (greater than low risk) during the reporting period.

				Approval (Q2 than low risk a			
			Total Time 90 Day Benchmark	,	Total Time		
NSW PHOs	Total Number of Applications	Count <90 Day Benchmark	% <90 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Researcher Time	Count Request for Information
BLLBRRY	16	14	88%	55	27	28	2
CINSW	13	12	92%	61	36	24	2
HNELHD	15	15	100%	49	21	28	2
ISLHD	6	2	33%	89	58	31	2
JHFMHN	0	0	-	-	-	-	-
NBMLHD	2	2	100%	57	37	20	2
NNSWLHD	0	0	-	-	-	-	-
NSLHD	14	10	71%	77	37	41	2
SCHN	19	17	89%	60	29	30	1
SESLHD	11	9	82%	56	32	24	2
SLHD-CCD	11	11	100%	41	22	18	2
SLHD-RPA	43	43	100%	36	15	21	1
SVHN	27	24	89%	58	30	29	2
SWSLHD	25	19	76%	99	38	61	3
WNSWLHD	1	1	100%	4	4	0	0
WSLHD	20	17	85%	69	45	23	1
TOTAL	226	196	87%	60	30	30	2

Table 2. The 90 calendar days benchmark for the approval of clinical trials (greater than low risk) during the reporting period.

	,	по по пре	Ethics	Approval (Q2	2022)	,	
				Clinical Trials			
			Total Time 90 Day Benchmark	ζ.		Breakdown ar days)	
	Total Number of	Count	% <90 Day	Average	Average Research	Average	Count
NSW PHOs	Applications	<90 Day Benchmark	Total Time Benchmark	Total Time (Days)	Office Time	Researcher Time	Request for Information
BLLBRRY	16	14	88%	55	27	28	2
CINSW	2	2	100%	53	25	28	3
HNELHD	5	5	100%	54	22	31	2
ISLHD	2	0	0%	113	86	28	3
NSLHD	4	0	0%	98	35	63	3
SCHN	11	10	91%	64	31	33	1
SESLHD	2	2	100%	44	30	14	1
SLHD-CCD	4	4	100%	58	30	28	2
SLHD-RPA	16	16	100%	33	12	21	1
SVHN	8	8	100%	42	27	15	2
SWSLHD	9	5	56%	155	42	113	3
WSLHD	10	9	90%	65	40	25	1
TOTAL	90	76	84%	65	30	36	2

Table 3. Breakdown of NSW PHO performances in clinical trial approvals (greater than low risk) during the reporting period by sponsor type

	Co	llaborative grou	ıp	C	ommercial entit	y.	Investigator-initiated			
NSW PHOs	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	
BLLBRRY	0	-	-	14	27	55	2	29	54	
CINSW	0	1	-	0	1	-	2	25	53	
HNELHD	1	19	46	3	26	60	1	14	43	
ISLHD	0	-	-	0	-	-	2	86	113	
NSLHD	0	-	-	3	34	98	1	38	97	
SCHN	0	-	-	7	33	67	4	28	59	
SESLHD	1	22	34	1	38	53	0	-	-	
SLHD-CCD	1	35	53	0	-	-	3	28	60	
SLHD-RPA	3	9	28	1	14	42	11	12	33	
SVHN	1	42	51	3	28	48	4	24	36	
SWSLHD	0	-	-	4	50	153	5	37	157	
WSLHD	1	56	85	5	40	65	4	35	59	
Grand Total	8	25	44	41	32	70	40	28	65	

Table 4. Quarterly clinical trial approvals (greater than low risk) between 01/10/2021 and 30/06/2022, by sponsor type

		Q4 2021			Q1 2022		Q2 2022			
Sponsor Type	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	
Collaborative Group	8	25	41	2	34	67	8	25	44	
Commercial Entity	61	31	60	39	29	58	41	32	70	
Investigator Initiated	31	28	55	33	34	66	40	28	65	
Total	100	29	57	74	31	62	89	30	65	

Table 5. Historical performance of NSW PHOs against **the old and new benchmarks** for the review and approval of human research ethics applications (greater than low risk) between 01/10/2021 and 30/06/2022.

	Q4 2021									Q1 2022							Q2 2022				
			ay Bench with cloc			ay Bench ithout clo				ay Bench with cloc			ay Bench ithout clo				ay Bench with cloc			ay Bench ithout clo	
NSW PHOs	Total Number of Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Research Office Time (Days)	Count 90 Day Benchmark	% 90 Day Total Time Benchmark	Average Total Time (Days)	Total Number of Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Research Office Time (Days)	Count 90 Day Benchmark	% 90 Day Total Time Benchmark	Average Total Time (Days)	Total Number of Applications	Count 45 Day Benchmark	% 45 Day Benchmark	Average Research Office Time (Days)	Count 90 Day Benchmark	% 90 Day Total Time Benchmark	Average Total Time (Days)
BLLBRRY	26	25	96%	26	23	88%	43	27	23	85%	27	25	93%	54	16	16	100%	27	14	88%	55
CINSW	15	13	87%	33	13	87%	108	16	11	69%	40	8	50%	82	13	10	77%	36	12	92%	61
HNELHD	37	37	100%	23	32	86%	63	22	21	95%	20	19	86%	62	15	15	100%	21	15	100%	49
ISLHD	6	4	67%	45	4	67%	92	4	1	25%	50	3	75%	80	6	2	33%	58	2	33%	89
JHFMHN	1	0	0%	76	0	0%	134	3	0	0%	61	2	67%	134	0	0	-	-	0	-	-
NBMLHD	8	4	50%	42	6	75%	105	7	1	14%	46	7	100%	70	2	1	50%	37	2	100%	57
NNSWLHD	2	2	100%	36	2	100%	70	2	1	50%	38	2	100%	59	0	0	-	-	0	-	-
NSLHD	7	7	100%	15	7	100%	38	3	3	100%	28	2	67%	80	14	12	86%	37	10	71%	77
SCHN	17	10	59%	38	11	65%	74	9	4	44%	45	5	56%	85	19	16	84%	29	17	89%	60
SESLHD	17	15	88%	31	15	88%	69	10	10	100%	28	10	100%	54	11	8	73%	32	9	82%	56
SLHD-CCD	12	12	100%	24	11	92%	56	3	2	67%	34	3	100%	74	11	11	100%	22	11	100%	41
SLHD-RPA	41	41	100%	15	39	95%	42	34	34	100%	20	34	100%	43	43	43	100%	15	43	100%	36
SVHN	33	31	94%	25	33	100%	41	10	10	100%	30	8	80%	59	27	25	93%	30	24	89%	58
SWSLHD	22	19	86%	32	16	73%	82	18	12	67%	42	15	83%	66	25	20	80%	38	19	76%	99
WNSWLHD	4	4	100%	32	4	100%	42	2	1	50%	43	2	100%	43	1	1	100%	4	1	100%	4
WSLHD	21	15	71%	39	18	86%	67	27	18	67%	41	19	70%	72	20	11	55%	45	17	85%	69
TOTAL	269	239	89%	28	234	87%	62	197	152	77%	32	164	83%	63	226	191	85%	30	196	87%	60



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

KPI21-04: Research Governance Application Authorisations – SSA Authorisations within 60 calendar days

NSW State Benchmark: The benchmark for the 2021/22 financial year onwards for authorisation of SSA applications is 60 calendar days

Definition:

The proportion of site-specific assessment (SSA) applications (excluding lower to negligible risk) authorised by the Research Governance Office (RGO) within 60 calendar days, authorised within the reporting period.

Context:

The measure will no longer account for clock stops in accordance with the National Health and Medical Research Council Certification.

Handbook. Instead, the end-to-end time will be measured. The SSA application received date is the date the RGO or designee receives an SSA application from a researcher regardless of whether it is complete and/or deemed valid. The clock is stopped when the final SSA decision letter is provided to the site principal investigator.

Desired Outcome:

Ensuring timely processing of site approvals for research and clinical trials supports better health outcomes for the people of NSW and maintaining competitiveness through access to the latest treatments from clinical trials.

Selection (Criteria Summary:
Scope	Site-specific assessment (SSA) applications
Frequency	Quarterly
	Study Type = All
	• Application Type = Greater than low risk
Inclusions	 Approval Type = "Authorised" or "authorised with conditions" within the reporting period
	 Application Type = Low and negligible risk
Exclusions	Migrated studies

Total Time:

Total time is the measurement of the total, unadjusted time from the Submission Date to when the final decision notification email is sent granting approval.

Summary:

SSA review performance of NSW PHOs according to the <60-day benchmark for studies authorised during the reporting period (Quarter 2 2022) are shown in Table 6. During the reporting period,

studies (greater than low risk pathway) were authorised in NSW PHOs with an average review time (total time) of **37** days.

Of these 442 studies, 210 were classified as clinical trials (Table 7).

Further breakdown of clinical trial SSA authorisations by sponsor type is provided in **Table 8** (by NSW PHOs) and **Table 9** (by quarter). Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of governance applications is presented in **Table 10**.

Table 6: The 60 calendar days benchmark for authorisation of governance applications (greater than low risk) during the reporting period.

	oo caremaar aay	SSA Approvals (Q2 2022) All greater than low risk applications												
		60 Day B	All gre		Total Time Breakdown (calendar days)									
NSW PHOs	Total Number of Applications		% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time						
ASNSW	1	1	100%	56	0	56	0	0						
Calvary	9	9	100%	7	5	0	2	0						
CCLHD	7	6	86%	26	2	8	0	15						
FWLHD	1	1	100%	16	3	10	0	3						
HNELHD	33	32	97%	18	6	6	1	5						
ISLHD	22	20	91%	20	4	5	0	11						
JHFMHN	4	3	75%	59	20	4	0	34						
MLHD	3	3	100%	20	11	3	1	4						
MNCLHD	8	7	88%	50	13	2	10	26						
NBMLHD	14	10	71%	57	8	32	4	13						
NNSWLHD	5	5	100%	31	26	0	3	2						
NSLHD	25	14	56%	57	34	9	0	14						
NSWHPTH	6	3	50%	95	6	77	2	10						
SCHN	27	18	67%	52	10	17	1	25						
SESLHD	39	32	82%	39	12	13	0	14						
SLHD-CCD	22	22	100%	30	12	5	6	7						
SLHD-RPA	47	41	87%	24	2	10	7	5						
SNSWLHD	3	3	100%	10	1	3	6	0						
SVHN	23	16	70%	53	7	10	0	36						
SWSLHD	62	47	76%	42	7	9	0	27						
WNSWLHD	8	7	88%	23	6	13	0	5						
WSLHD	73	64	88%	36	7	9	3	17						
TOTAL	442	364	82%	37	9	11	2	15						

Table 7: The 60 calendar days benchmark for the authorisation of clinical trials (greater than low risk) during the reporting period.

	SSA Approvals (Q2 2022) Clinical Trials												
	Total Number	60 Day Ber	nchmark (without	· · · · · · · · · · · · · · · · · · ·	Total Time Breakdown (calendar days)								
NSW PHOs	of Applications	Count of <60 Day Benchmark	% <60 Day Total Time Benchmark	Average Total Time (Days)	Average Research Office Time	Average Head of Dept Time	Average Chief Exec Time	Average Researcher Time					
ASNSW	0	0	-	-	-	-	ı	-					
CALVARY	7	7	100%	7	5	0	2	0					
CCLHD	4	4	100%	11	3	4	0	4					
FWLHD	1	1	100%	16	3	10	0	3					
HNELHD	10	10	100%	18	4	5	1	7					
ISLHD	13	13	100%	10	1	6	0	3					
JHFMHN	0	0	-	-	-	-	-	-					
MLHD	1	1	100%	15	6	8	1	0					
MNCLHD	6	6	100%	42	9	3	9	21					
NBMLHD	8	6	75%	52	9	28	5	10					
NNSWLHD	1	1	100%	37	36	1	0	0					
NSLHD	15	8	53%	60	35	12	0	14					
NSWHPTH	0	0	-	-	-	-	-	-					
SCHN	10	8	80%	41	8	15	1	17					
SESLHD	17	14	82%	45	11	19	0	15					
SLHD-CCD	13	13	100%	37	15	4	9	9					
SLHD-RPA	21	18	86%	31	2	12	12	5					
SNSWLHD	0	0	-	-	-	-	-	-					
SVHN	11	9	82%	46	6	8	0	31					
SWSLHD	31	22	71%	48	7	11	0	30					
WNSWLHD	3	3	100%	14	9	5	0	0					
WSLHD	38	37	97%	33	7	10	4	13					
TOTAL	210	181	86%	36	9	10	3	14					

Table 8. NSW PHO performances in clinical trial authorisations (greater than low risk) during the reporting period, by sponsor type.

	Со	llaborative gro	up		Commercial enti	ty	Investigator-initiated			
NSW PHOs	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	
CALVARY	1	1	1	6	5	8	0	-	-	
CCLHD	2	4	15	2	3	6	0	-	-	
FWLHD	-	-	-	-	-	-	-	-	-	
HNELHD	1	5	13	4	5	22	5	4	15	
ISLHD	7	1	8	5	1	12	1	0	12	
JHFMHN	-	-	-	-	-	-	-	-	-	
MLHD	1	6	15	0	-	-	0	-	-	
MNCLHD	3	3	47	2	11	31	1	22	48	
NBMLHD	0	-	-	7	10	53	1	3	50	
NNSWLHD	1	36	37	0	-	-	0	-	-	
NSLHD	5	40	72	8	32	49	2	29	79	
NSWHPTH	-	-	-	-	-	-	-	-	-	
SCHN	3	9	17	4	5	46	3	11	58	
SESLHD	8	10	41	8	13	51	1	5	33	
SLHD-CCD	2	5	50	6	12	29	5	22	41	
SLHD-RPA	2	4	39	11	1	25	8	3	39	
SNSWLHD	-	-	-	-	-	-	-	-	-	
SVHN	2	9	25	8	6	48	1	6	69	
SWSLHD	6	6	36	13	5	51	12	10	52	
WNSWLHD	1	6	14	0	-	-	2	10	14	
WSLHD	2	6	22	26	7	29	10	6	45	
Total	47	10	33	110	8	35	53	9	43	

Table 9. Quarterly clinical trial authorisations (greater than low risk applications) approved during the last 3 reporting period, by sponsor type

		Q4 2021			Q1 2022		Q2 2022				
Sponsor Type	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)	Total # of Applications	Average Research Office Time (days)	Average Total Time (days)		
Collaborative Group	48	9	38	35	17	44	47	10	33		
Commercial Entity	100	10	30	99	10	35	110	8	35		
Investigator Initiated	61	11	82	61	13	68	53	9	43		
Total	209	10	47	195	12	47	210	9	36		

Table 10. Historical performance of NSW PHOs against the old and new benchmarks for the review and authorisation of SSA applications (greater than low risk) between 01/10/2021 and 30/06/2022.

	Q4 2021						Q1 2022						Q2 2022								
	15 Day Benchmark (with clock)			60 Day Benchmark (without clock)		cations	15 Day Benchmark (without clock)		60 Day Benchmark (without clock)		Applications	15 Day Benchmark (with clock)			60 Day Benchmark (without clock)						
LHD	Number of Applications	Count of 15 Day Benchmark	% 15 Day Benchmark	Average RO Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Applications	Count of 15 Day Benchmark	% 15 Day Benchmark	Average RO Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)	Number of Appli	Count of 15 Day Benchmark	% 15 Day Benchmark	Average RO Time (Days)	Count of 60 Day Benchmark	% 60 Day Total Time Benchmark	Average Total Time (Days)
ASNSW	0	0	-	-	0	-	-	0	0	-	-	0	-	-	1	1	1	0	1	100%	56
CALVARY	13	12	92%	8	13	100%	13	13	9	69%	11	13	100%	19	9	8	89%	5	9	100%	7
CCLHD	20	14	70%	19	15	75%	63	16	15	94%	8	14	88%	35	7	7	100%	2	6	86%	26
FWLHD	-	-	-	-	-	-	-	-	-	-	-	-	-	-	1	1	100%	3	1	100%	16
HNELHD	57	46	81%	10	43	75%	54	40	35	88%	8	33	83%	33	33	30	91%	6	32	97%	18
ISLHD	17	17	100%	2	17	100%	11	10	9	90%	7	10	100%	11	22	21	95%	4	20	91%	20
JHFMHN	0	0	-	-	0	-	-	2	0	0%	32	2	100%	40	4	1	0.25	20	3	75%	59
MLHD	4	3	75%	12	4	100%	21	3	3	100%	12	3	100%	27	3	2	67%	11	3	100%	20
MNCLHD	8	6	75%	16	6	75%	56	3	3	100%	7	3	100%	26	8	6	75%	13	7	88%	50
NBMLHD	23	12	52%	16	16	70%	71	18	11	61%	14	12	67%	56	14	13	93%	8	10	71%	57
NNSWLHD	6	4	67%	12	6	100%	25	3	2	67%	9	3	100%	25	5	1	20%	26	5	100%	31
NSLHD	38	37	97%	6	24	63%	59	24	10	42%	19	16	67%	61	25	4	16%	34	14	56%	57
NSWHPTH	5	5	100%	6	2	40%	122	5	5	100%	7	3	60%	56	6	5	83%	6	3	50%	95
SCHN	36	21	58%	18	14	39%	85	19	11	58%	18	11	58%	66	27	25	93%	10	18	67%	52
SESLHD	35	27	77%	10	26	74%	81	35	27	77%	10	25	71%	42	39	32	82%	12	32	82%	39
SLHD-CCD	29	27	93%	7	23	79%	59	21	15	71%	9	21	100%	25	22	14	64%	12	22	100%	30
SLHD-RPA	60	56	93%	4	49	82%	38	47	47	100%	2	41	87%	32	47	47	100%	2	41	87%	24
SNSWLHD	0	0	-	-	0	-	-	3	3	100%	2	1	33%	74	3	3	100%	1	3	100%	10
SVHN	46	36	78%	13	31	67%	79	29	22	76%	13	18	62%	50	23	21	91%	7	16	70%	53
SWSLHD	60	46	77%	11	40	67%	58	56	35	63%	15	32	57%	73	62	60	97%	7	47	76%	42
WNSWLHD	15	15	100%	3	14	93%	23	8	8	100%	2	7	88%	31	8	7	88%	6	7	88%	23
WSLHD	75	69	92%	8	61	81%	43	63	49	78%	12	53	84%	37	73	68	93%	7	64	88%	36
Total	547	453	83%	10	404	74%	56	418	319	76%	11	321	77%	44	442	377	85%	9	364	82%	37

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	
Calvary Mater Hospital Newcastle	CALVARY		Yes
Central Coast LHD	CCLHD		Yes
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 – CCD	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



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

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