An analysis of health and medical research conducted in Queensland public hospitals (January 2011 to December 2016)

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Summary

This report outlines health and medical research activity conducted in Queensland public hospitals for the period January 2011 to 31 December 2016. This report will analyse the impact of new initiatives on research metrics and will allow Hospital and Health Services (HHSs) to compare their performance against median state times. Key findings include:

- nearly 1300 new clinical trials have received ethics approval and about 57% are commercially sponsored clinical trials
- overall time from the submission of an ethics application to research governance authorisation has decreased for clinical trials to 103 median days
- 97 per cent of all Human Research Ethics Committee (HREC) reviews are under the 60 clock day target
- 99 per cent of all Low or Negligible Risk reviews are under the 60 clock day target
- 97 per cent of all research governance reviews are under the 25 clock day target
- Queensland Health and its Hospital and Health Services (HHS) have authorised almost 7500 research projects at their sites and the most frequently researched areas include public health and health services, other medical and health sciences, clinical sciences, oncology, nursing, cardiovascular medicine, paediatrics, psychology, pharmacology and pharmaceutical sciences and nutrition and dietetics.

It is recommended:

- a copy of this report is provided to HHSs and published on the Queensland Health internet website
- the HREC and Research Governance Officers (RGO) compare their local metrics to statewide data
- the Queensland Department of Health provides input into the National Health and Medical Research Council's (NHMRC) proposed accredited training for researchers, RGOs and sponsors in order for Queenslanders to benefit from national standardised research governance processes
- research metrics are monitored to inform future departmental support of HHSs.

1. Introduction

1.1 Purpose

This report outlines health and medical research activity[1] conducted in Queensland public hospitals for the period 1 January 2011 to 31 December 2016. The aim of this report is to provide information to support continued research process improvement in the Queensland public hospital system.

In particular, this report will analyse the impact of significant research approval process reforms implemented in Queensland since 2010[2]. Findings will allow Hospital and Health Services (HHSs) to compare their performance against state averages.

1.2 Background

Since 2010, Queensland Health has implemented streamlined statewide processes and a statewide database to ensure research activity can be monitored for efficiencies and continually improved.

The Research Ethics and Governance Health Service Directive[3] and *Standard Operating Procedures for Queensland Health Research Ethics Committee administrators* provide a framework for researchers to gain permission to conduct their research projects[4]. To conduct research in a public health facility, researchers are required to submit an online application via www.ethicsform.org/au/SignIn.aspx for consideration by an HREC or a LNR Ethics Committee. Following ethics committee approval, an institution's Chief Executive must then authorise the research.

Queensland Health hospitals[5] use the Australian Research Ethics Database (AURED) to maintain research data, as described in the standard operating procedures. Use of the AURED information technology platform enables a system of single ethical review for all multicentre research conducted across Queensland Health facilities.

AURED also enables Queensland to participate in the National Mutual Acceptance Scheme (NMA) for research conducted across Queensland, New South Wales, Victoria, South Australia and Australian Capital Territory. Participation in this scheme saves researchers making multiple applications to ethics committees in multiple states, for the one research project.

1.3 Scope

This report documents research ethics approval timelines and governance authorisation times.

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[1] This analysis does not reflect total ethics committee's activity as only approved research is reported.

[2] http://www.health.qld.gov.au/ohmr/html/regu/multicentre_research.asp

[3] https://www.health.qld.gov.au/__data/assets/pdf_file/0025/494008/qh-hsd-035.pdf

[4] http://www.health.qld.gov.au/ohmr/documents/regu/hrec_sop.pdf

[5] South West, North West and Central West Hospital and Health Services do not use AURED and use manual systems.

1.4 Methods

The information presented in this report is based on data recorded in AURED. AURED is a live database and the report data was extracted on 19 April 2017. The Department of Health examined AURED data and HHSs assisted with data cleansing for any identified errors.

Findings are also based on an analysis of research approvals and activity in Queensland public hospitals from 1 January 2011 to 31 December 2016. This period coincides with the completion of AURED's Queensland implementation in 2010.

2. Statewide research ethics, governance and review times

2.1 Research ethics metrics

The statewide implementation of the Single Ethical Review Process and the NMA Scheme has resulted in a reduction of duplicated ethics reviews. Decreased ethics and governance review timeframes were the primary objectives of the NMA policy reform.

The standard operating procedures specify a maximum ethics review time of 60 clock days. Clock days begin after a valid application is received. The application will then be reviewed at an HREC meeting. The clock stops when the HREC requests further information or clarification from the applicant. The clock recommences when the requested information or clarification has been received. The clock finally stops when the researcher is formally notified of the final decision.

Table 1 shows the number of approved research applications and ethics review times have decreased each year since 2011, and now 97 per cent of all HREC reviews, are under the 60 clock day target.

Table 1 Queensland Human Research Ethics Committee approved research applications

Year	Number of Queensland Full HREC approvals	Median clock days	> 60 clock days	% of HREC review < 60 clock days
2011	649	29	90	86%
2012	542	27	47	91%
2013	506	27	34	93%
2014	480	24	30	94%
2015	517	23	23	96%
2016	588	21	18	97%

Table 2 **Queensland Low or Negligible Risk (LNR) Ethics Committee approved research applications**

Year	Number of Queensland LNR ethics approvals	Median clock days	> 60 clock days	% of HREC review < 60 clock days
2011	472	18	50	89%
2012	524	14	41	92%
2013	500	15	25	95%
2014	424	14	9	98%
2015	526	14	7	99%
2016	520	11	2	99%

Table 2 shows the number of approved research applications and ethics review times have decreased each year since 2011, and now 99 per cent of all Low or Negligible Risk (LNR) ethics reviews, are under the 60 clock day target.

The reduction in review times is likely due to researchers becoming better at preparing applications, increased HREC review efficiencies and monitoring and support from the Health Innovation, Investment and Research Office (HIIRO).

2.2 Research governance metrics

The standard operating procedures allow a maximum research governance review turnaround time of 25 clock days. Table 3 shows all governance review times in calendar days. In 2016, 99 per cent of all research governance reviews were under the 25 clock day target. The improved timeframes are likely to be a consequence of improved governance applications by researchers, increased governance review efficiencies and monitoring and support from the Health Innovation, Investment and Research Office (HIIRO).

Table 3 **Research governance authorised research applications**

Year	Number of research governance authorisations	Median Calendar days	% of governance authorisations < 25 calendar days
2011	1193	8	85%
2012	1123	7	92%
2013	1279	5	90%
2014	1218	4	96%
2015	1384	3	95%
2016	1393	3	97%

2.3 Overall clinical trial research approval times

The streamlined ethics and governance processes have also had a positive impact on clinical trial approval time frames for trials reviewed by Queensland Health HRECs and conducted at Queensland sites. Table 4 shows there has been a reduction in overall approval times since 2011. Times are impacted by delays of site specific assessment submissions to research governance officers (RGOs) caused by prolonged budget negotiations or other regulatory requirements such as *Public Health Act 2005* or Queensland Civil and Administrative Tribunal approvals, where required.

Sustained focus on encouraging parallel submission of SSAs with HREC applications will result in continued reduction in the delays between HREC approval and SSA submission.

Only clinical trials that were reviewed by Queensland Health HRECs and conducted at Queensland public hospitals are included in this analysis.

Table 4 Overall clinical trial research approval times in calendar days

Year	Number of clinical trial governance authorisations	Median Calendar Days from HREC Approval to SSA Submission	Median Calendar Days from HREC Validation to SSA Authorisation
2011	269	60	133
2012	290	78	149
2013	327	70	137
2014	273	94	188
2015	371	49	106
2016	286	39	103

Queensland Health has led national policy change to encourage parallel review of ethics and governance applications. All jurisdictions are working with the National Health and Medical Research Council (NHMRC) and the research community to develop policy drivers to facilitate a parallel review.

3. Statewide research activity

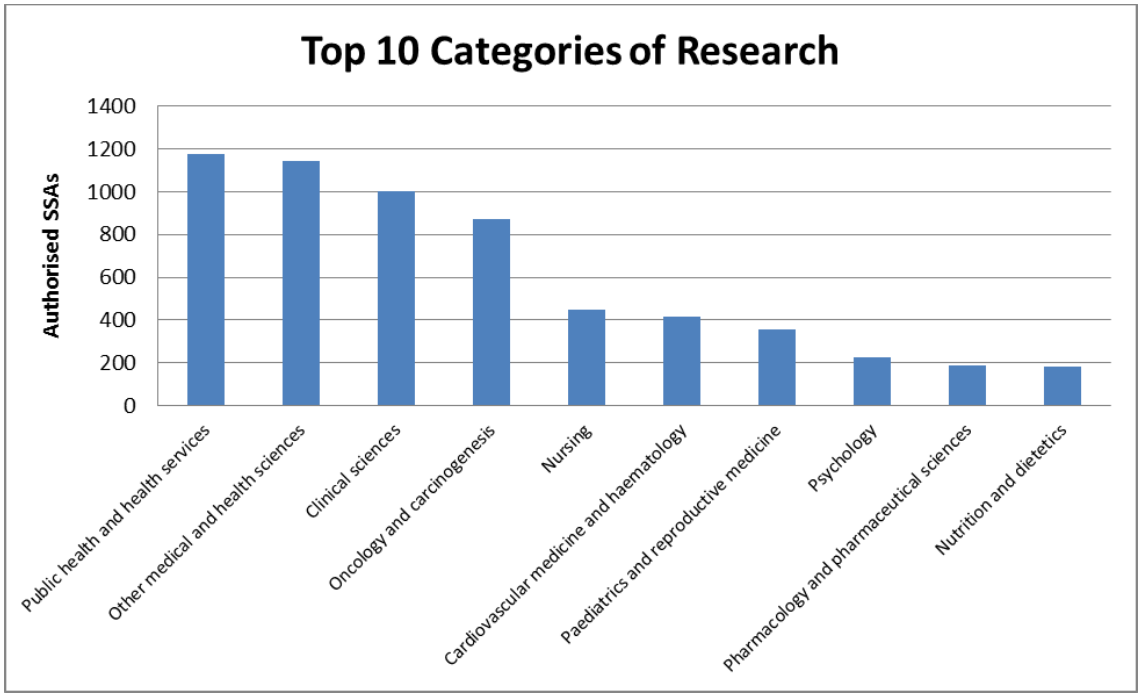
Table 5 **Authorised research projects categorised by the National Health and Medical Research Council fields of research, by calendar year**

NHMRC group	2011	2012	2013	2014	2015	2016	Total
Applied economics	0	1	3	2	3	1	10
Applied ethics	0	0	0	1	1	7	9
Biochemistry and cell biology	1	1	4	3	2	4	15
Biomedical engineering	7	10	16	5	16	12	66
Cardiovascular medicine and haematology	45	50	88	71	84	76	414
Clinical sciences	112	118	188	180	182	223	1003
Cognitive science	2	0	2	0	1	4	9
Complementary/alternative medicine	2	0	2	1	2	3	10
Dentistry	2	0	4	3	5	1	15
Econometrics	0	0	0	0	1	2	3
Genetics	6	5	10	7	4	4	36
Human movement and sports science	4	3	8	8	3	9	35
Immunology	8	7	11	10	8	3	47
Medical biochemistry and metabolomics	2	3	2	1	2	3	13
Medical biotechnology	3	1	7	1	1	1	14
Medical microbiology	14	26	25	12	23	25	125
Medical physiology	3	4	4	2	2	5	20
Medicinal and biomolecular chemistry	0	0	0	2	1	2	5
Nanotechnology	0	1	0	0	0	0	1
Neurosciences	18	23	25	24	43	32	165
Nursing	54	57	72	72	105	87	447
Nutrition and dietetics	9	27	52	37	29	30	184
Oncology and carcinogenesis	140	116	120	148	184	164	872
Optometry	0	1	1	2	0	1	5
Other medical and health sciences	118	145	195	210	258	218	1144
Other physical sciences	1	0	0	5	0	3	9
Other psychology and cognitive sciences	10	5	6	0	12	8	41
Paediatrics and reproductive medicine	18	41	55	69	80	92	355
Pharmacology and pharmaceutical sciences	25	25	44	24	31	38	187
Psychology	28	36	48	35	41	38	226
Public health and health services	137	186	216	205	201	229	1174
Statistics	1	1	9	4	3	4	22
Not populated	423	230	62	74	56	64	909
Total	1193	1123	1279	1218	1384	1393	7590

The decrease in the "Not populated" category in Table 5 is evidence of improved data entry by researchers and HHS administrators. This demonstrates the benefit of a centralised information technology platform which allows for data cleansing and continued guidance on data quality. Future examination of the research outputs and potential translation of evidence would assist in demonstrating benefits from research investment.

Figure 1 shows the most researched areas are public health and health services, other medical and health sciences, clinical sciences, oncology, nursing, cardiovascular medicine, paediatrics, psychology, pharmacology and pharmaceutical sciences and nutrition and dietetics. Public health and health services research are almost exclusively non-commercially sponsored research. Further analysis of research collaborations, both nationally and internationally, is planned for future reporting.

Figure 1 **Most frequent categories of authorised research by National Health and Medical Research Council fields of research from 2011–2016**



3.2 Statewide clinical trial activity

Table 6 shows details of all Queensland Health sites authorised to conduct a clinical trial by calendar year and Table 7 breaks this down to commercially sponsored clinical trial sites. Table 8 shows the number of HREC approved clinical trials (clinical trials may have multiple sites, and this is reflected in Tables 6 and 7) and Table 9 breaks this down to commercially sponsored trials. It is important to note that trials can run over many years and that future analysis is planned to assess the clinical trial capacity of the entire health ecosystem in Queensland.

Table 6 **Authorised Queensland Health clinical trial sites categorised by product type, by calendar year**

Study Type (all authorised SSAs)	2011	2012	2013	2014	2015	2016	Total
Clinical trial - other	43	66	102	75	82	43	411
Clinical trial of a device	2	13	26	22	29	25	117
Clinical trial of a drug	223	200	193	202	253	211	528
Clinical trial of a drug and device	1	9	4	0	2	3	19
FTIH/FTIP clinical trial – device	0	1	0	0	1	0	2
FTIH/FTIP clinical trial – drug	0	1	2	4	4	4	21
Total	269	290	327	303	371	286	1846

Table 7 **Authorised Queensland Health commercially sponsored clinical trial sites categorised by product type, by calendar year**

Study Type (all commercially sponsored all SSAs)	2011	2012	2013	2014	2015	2016	Total
Clinical trial - other	2	6	4	3	7	2	24
Clinical trial of a device	0	8	15	10	8	5	46
Clinical trial of a drug	156	143	136	136	166	116	883
Clinical trial of a drug and device	0	6	4	0	2	1	13
FTIH/FTIP clinical trial – device	0	0	0	0	1	0	1
FTIH/FTIP clinical trial – drug	0	1	1	2	3	4	11
Total	158	164	160	151	187	128	948

Table 8 **Number of approved clinical trials conducted in Queensland Health categorised by product type, by calendar year**

Approved Clinical Trials	2011	2012	2013	2014	2015	2016	Total
Clinical trial - other	28	42	61	31	39	33	234
Clinical trial of a device	2	12	24	20	21	18	97
Clinical trial of a drug	174	136	154	134	177	148	923
Clinical trial of a drug and device	1	6	2	0	2	2	13
FTIH/FTIP clinical trial – device	0	1	0	0	1	0	2
FTIH/FTIP clinical trial – drug	0	1	2	3	4	4	14
Total	205	198	243	188	244	205	1283

[6]First Time In Human (FTIH) and First Time in Patient (FTIP)

Table 9 **Number of approved commercial clinical trials conducted in Queensland Health categorised by product type, by calendar year**

Commercially Approved Clinical Trials	2011	2012	2013	2014	2015	2016	Total
Clinical trial - other	2	5	3	1	5	2	18
Clinical trial of a device	0	8	14	9	5	5	41
Clinical trial of a drug	118	103	111	100	123	90	645
Clinical trial of a drug and device	0	6	2	0	2	1	11
FTIH/FTIP clinical trial – device	0	0	0	0	1	0	1
FTIH/FTIP clinical trial – drug	0	1	1	2	3	4	11
% Commercially Funded	59	62	54	60	57	50	57
Total	120	123	131	112	139	102	727

4. Hospital and Health Service research activity

Table 10 provides details on ethics committee activity at each HHS. Queensland Health introduced mutual acceptance of ethics reviews between Queensland Health ethics committees in July 2010. In November 2011, interstate HREC approvals for clinical trials were accepted under the NMA Scheme. This has resulted in a decrease of required ethics reviews which is a contributing factor to the reduction of average ethics review timeframes.

Ethics committees with limited activity have been encouraged to reallocate resources and disband. The Queensland Health Central Office committee stopped accepting new projects in 2015 and was formally closed in November of 2015.

Table 10 Ethics research applications approved by Human Research Ethics Committee

Queensland Health HREC	2011	2012	2013	2014	2015	2016
Metro South	285	248	248	201	242	251
Royal Brisbane and Women's Hospital	229	184	168	191	222	188
Children's Health Queensland	121	143	102	136	135	253
The Prince Charles Hospital	140	150	186	109	129	128
Townsville HHS	86	99	105	69	86	77
Gold Coast HHS	82	83	69	85	120	115
Redcliffe*	29	21	0	0	0	0
Cairns HHS (Far North Queensland)	48	51	47	46	38	25
Darling Downs	35	17	35	35	34	24
Queensland Health Central Office*	38	32	13	3	0	0
West Moreton	7	7	13	2	15	10
Central Queensland	10	13	5	5	9	10
Forensic and Scientific Services	9	11	2	1	1	2
Bayside*	0	1	1	0	0	0
Mackay*	0	1	0	0	0	0
Total	1119	1061	994	883	1031	1083

***Active studies from closed HRECs were reallocated to other Queensland Health HRECs**

Table 11 details research activity in each HHS and reports research governance authorised research projects. Future analysis is planned to determine HHS therapeutic area strengths. The Queensland Database of Research Activity (DoRA) is the public database of authorised research in Queensland and is populated by AURED. DoRA is available at http://access.health.qld.gov.au/DORA/view/search.aspx.

Table 11 **Research governance applications authorised by Hospital and Health Service and Australian Research Ethics Database**

RGO	2011	2012	2013	2014	2015	2016
Metro South HHS	361	294	335	299	359	302
Royal Brisbane and Women's Hospital	213	175	206	205	255	253
Royal Children's Hospital/Lady Cilento	69	103	108	138	111	144
The Prince Charles Hospital	85	89	142	85	99	112
Townsville HHS	85	93	115	82	87	108
Gold Coast HHS	77	89	79	95	153	136
Redcliffe	43	36	43	42	45	53
Cairns HHS	72	63	69	64	62	60
Nambour	60	66	65	55	62	74
Darling Downs	36	17	36	29	34	33
Queensland Health Central Office	13	23	4	7	4	1
West Moreton	34	31	28	18	25	26
Central Queensland	24	25	21	3	32	19
Cape and Torres Strait	0	0	7	51	12	17
Mackay	21	19	21	23	19	20
Wide Bay	0	0	0	22	25	35
Total	1193	1123	1279	1218	1384	1393

5. Acknowledgements

The human research ethics chairpersons, committee members, administrators and RGOs who maintain research approval data within AURED are thanked for their assistance with the data collection which made this report possible.

Vanessa Druett, HREC Coordinator, Gold Coast Hospital and Health Service, is also acknowledged for providing essential data cleansing and metrics data for this report.

Abbreviations

AURED	Australian Research Ethics Database
DoRA	Database of Research Activity
HHS	Hospital and Health Service
HREC	The Human Research Ethics Committee is an institutional body established in accordance with Chapter 5.1 of the National Health and Medical Research Council/Australian Research Council/Australian Vice Chancellors' Committee National Statement on Ethical Conduct in Human Research and conducts the ethical review of research. Under the national approach, a single Human Research Ethics Committee conducts an ethical review that is accepted by multiple institutions.
NHMRC	National Health and Medical Research Council
NMA	National Mutual Acceptance is the inter-jurisdictional operationalisation of the national approach for clinical trials. It is limited to state public health organisations and is governed by a Memorandum of Understanding.

Glossary

Clinical trial	Research involving an unapproved or approved therapeutic good, intervention or treatment.
Clock day	The standard operating procedures specify a maximum ethics review time of 60 clock days. Clock days begin after a valid application is received. The application will then be reviewed at a Human Research Ethics Committee (HREC) meeting. The clock stops when HREC requests further information or clarification from the applicant. The clock recommences when the requested information or clarification has been received. The clock is finally stops when the researcher is formally notified of the final decision.
Ethics review	An ethical review of a research project conducted either by a National Health and Medical Research Council (NHMRC) registered Human Research Ethics Committee or another ethics committee who only reviews low or negligible risk research in accordance with the NHMRC's National Statement on Ethical Conduct in Human Research.
National Statement on Ethical Conduct in Human Research (the National Statement)	The National Statement on Ethical Conduct in Human Research (2007), developed jointly by the National Health and Medical Research Council, the Australian Research Council and the Australian Vice-Chancellor Committee, sets outs standards for the ethical design, review and conduct of research involving humans. It describes the roles and responsibilities of institutions, researchers, sponsors and HRECs in conducting ethical research and applies whether the research is single centre or multi-centre.
Research	Original investigation undertaken to gain knowledge, understanding and insight (see the National Statement and the Code for a more detailed discussion on the definition of research)
Research governance	An institutional framework to effectively oversee and administer research so that its conduct complies with relevant legislation and meets appropriate standards of quality, safety, privacy, risk and financial management. The Site Specific Assessment form is a component of research governance assessment.
Single ethical review process	Single Ethical Review Process is the ethical review in Queensland undertaken by a single Human Research Ethics Committee where the outcome of the review will enable multiple institutions to decide whether or not to participate in a given study. The single ethical review includes the scientific review of a research proposal.