

# The impact of the Research Methods Support Structure on research capacity in rural New South Wales

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## Abstract

**Objective:** This paper evaluates a Research Methods Support Structure (RMSS) to foster research capacity in the New England region of rural New South Wales.

**Methods:** A quasi-experimental design with a historical control for comparing changes in the number of research submissions and research approval rates since the RMSS inception in July 1998 until December 2004.

**Results:** Comparing the two reporting periods, the total number of research submissions increased from 58 to 197, or 9 per year to 30 per year (odds ratio [OR], 3.33; 95% CI, 1.15–9.90;  $\chi^2=5.06$ ;  $P=0.02$ ); and the total number of ethics approvals increased from 33 to 145, or 5 per year to 22 per year (OR, 2.11; 95% CI, 1.10–4.06;  $\chi^2=5.17$ ;  $P=0.02$ ). Submissions were 2.11 times more likely to receive ethics approval after the inception of the RMSS, with an increase in overall approval rates from 57% to 74%. Locally based rural researchers were 4.89 times more likely to have their submitted research ultimately approved after the inception of the research methods support structure (OR, 4.89; 95% CI, 2.11–11.41;  $\chi^2=16.06$ ;  $P<0.001$ ).

**Discussion:** This evaluation supports an expansion of research methods support structures to increase research capacity in rural Australia.

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HUMAN RESEARCH ETHICS COMMITTEES (HRECs) have a legislated duty to protect the wellbeing of research participants.<sup>1</sup> HRECs must balance this duty against ensuring protection of the rights of society and researchers. Local HREC input is vital to ensure human health research is conducted in compliance with the national statement on the

## What is known about the topic?

There is increasing effort to enhance rural health research capacity to assist evidence-based decision making in Australia.

## What does this paper add?

This paper provides a description and evaluation of a Research Methods Support Structure implemented in rural New South Wales.

## What are the implications for practitioners?

This evaluation suggests there is scope to establish research methods support groups in other rural regions to improve research capacity. ♦

ethical conduct of human research.<sup>1,2</sup> At times, research approved in an urban setting will be validly rejected on ethical grounds by a local rural research ethics committee.<sup>2</sup> Often the proposal will not recognise the logistics of translating the research from an urban setting to a smaller or cross-cultural population.<sup>3,4</sup> A research project may be scientifically and ethically valid but ignore the logistics of implementation within a different

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setting. For example, shortages of personnel or equipment within a rural region may mean the local HREC decides that a project ethically should not proceed.

There is considerable criticism of local HRECs for delaying health care research, adding to the cost, creating barriers to research<sup>5,6</sup> and potentially delaying protection of the public health of the community or treatment of a disease.<sup>7</sup> This criticism fails to recognise that often delays in ethics approval are caused by poorly completed applications with insufficient details to address privacy laws and the national statement on human research.<sup>1</sup>

There is a limited amount of published rural health research,<sup>8,9</sup> and there are increasing efforts to enhance rural health research capacity. Work with researchers to improve research capacity, skills and output is required. Negotiation with HRECs can be a major hurdle for novice researchers developing new research projects. Before 1998, the amount of health research undertaken in the New England region of New South Wales was limited. Most research submitted for ethics approval was clinical (45%) and educational (36%). Population health and public health research comprised only 19% of proposals. This was a significant omission, as the New England region has significant public health needs characterised by excess premature mortality from preventable diseases such as heart disease and suicide.<sup>10</sup>

This paper describes and evaluates the research methods support structure (RMSS) that was established to address the issues limiting rural research. The RMSS became a compulsory stage of the research submission process in the New England region, with peer review of research submissions for ethical and research methodological issues before HREC submission. The RMSS provided expertise and advice for researchers to assist them in their submissions.

## **The research methods support structure**

A reference group of regional stakeholders with an interest in rural health research was estab-

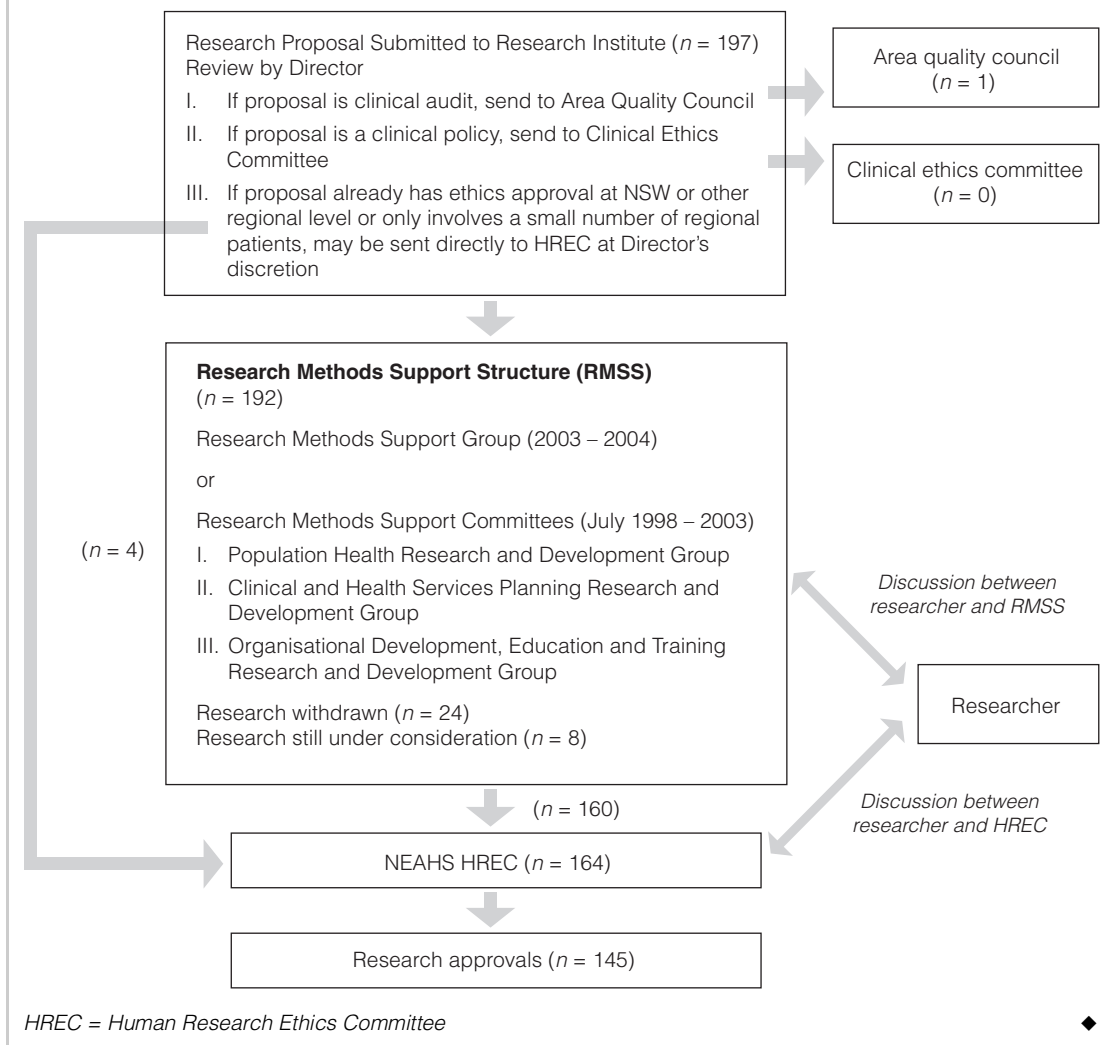
lished. This group reviewed rejected research applications and concluded that many of the proposals required more development of methodological and ethical considerations and that regional research needed to reflect regional health priorities. The reference group also recognised the need to increase research capacity and foster research among novice researchers. To raise the profile of health research in the region, the reference group developed a business case to establish the New England Area Health Service (NEAHS) Research Institute, which was established in July 1998. Flow charting identified that the research support functions of the Institute needed to be separated from the HREC role, and a linked research methods support structure was planned to assist in increasing the quality of research proposals. In particular, the focus was on providing support to researchers in addressing ethical and methodological issues and to develop projects reflecting regional health needs (Box 1).

Human health research was considered by the NEAHS Research Institute if the research was to be undertaken by employees of the area health service or by outside individuals or organisations. Approval by an HREC was necessary for researchers to access area health service staff, patients or data. The Research Institute objectives were to:

- identify research and development needs;
- set research priorities;
- oversee design of relevant research approaches;
- identify, negotiate with and support suitable agencies to undertake research and development projects;
- identify funding for research;
- refer research proposals to a relevant ethics (clinical or research) or quality committee; and
- monitor and report progress in regional research.

The chair of the RMSS reported to the Director of the Research Institute on the progress of these objectives. Furthermore, the RMSS's brief was to make recommendations to improve development of research methodology, ethical considerations, research documentation and consent processes of submitted proposals. The RMSS could advise on the logistics of implementing the proposed

# I New England Area Health Service (NEAHS) Research Institute, number of submissions July 1998–2004



research in the local rural area in terms of resources availability and suitability of the research to meet proposed objectives.

Research proposals were sent to the NEAHS Research Institute and assessed by the Director (Box 1). Research proposals broadly included proposals which explored new ideas and collected new information outside the scope of routine care and practices of the area health service. Research proposals also included evalua-

tions of routine functions of the area health service where researchers planned to publish their findings. Projects constituting clinical audit (internal evaluation of health service functions undertaken as part of quality assurance, and not intended to be published) were referred to the Area Quality Council of the New England Area Health Service. Projects which related to the implementation and development of clinical policy and practices, for example recommendations

of a policy on palliative care, were referred to the Area Clinical Ethics Committee. State-based multi-centre clinical trials that were approved by the Shared Scientific Assessment Scheme of the NSW Health Department were sent directly to the HREC.

Initially, the research methods support structure comprised three research and development committees focusing on submissions received in the areas of population health, clinical and health service planning, and organisational development, education and training research. In 2003, this structure was condensed into one research methods support group (RMSG) to streamline the research process. The RMSG comprised medical, nursing and allied health professionals, and staff with expertise in clinical review and health service planning. Representatives were also recruited from external organisations/affiliates, such as the University of Sydney, University of New England, and the University Department of Rural Health at the University of Newcastle, and included an Aboriginal representative. This structure offered a skills mix in quantitative and qualitative methods across clinical, population health and education research.

The RMSG was a compulsory entry point for most proposals to be considered by the HREC. The proposals were peer-reviewed based on methodological and ethical considerations in accordance with the *National statement on ethical conduct in research involving humans*,<sup>1</sup> similarly to scientific sub-committees of other HRECs. In addition, the resource and policy implications of the proposed research were considered based on knowledge of the region's human and financial resources. Specific methodological issues more common in a rural area, such as small-population research where low numbers in demographic groups would make maintaining subject confidentiality more difficult or where the researcher might be involved in dual clinical or research roles in the same community, were raised with researchers. The RMSG made recommendations to improve the research methodology, ethical considerations, documentation and consent process of submitted proposals. Often, the research

team was directly approached by the nominated contact officer to check that the research proposal could be re-drafted in an appropriate way before the deadline for submissions to the HREC.

These strategies were also used to expedite the research project approval process. Researchers were invited to discuss their projects directly with the committee. Researchers who rejected the RMSG views on their proposal could complain directly to the Director of the New England Research Institute or write to the Chair of the RMSG refuting the views of the committee. Where consensus was not reached or valid arguments for a different view were presented by the researcher, the proposal was forwarded to the HREC with the RMSG concerns noted to the Chair.

Members of the RMSGs and ethics committees who submitted research declared a conflict of interest and excluded themselves from the peer review process of their project until asked for comment from the remainder of the committee.

An administrative officer (0.2 full-time equivalent) provided support to the RMSS. The RMSG met for about 2 hours per month, and reading time outside of meetings ranged between 2 and 4 hours per month. The group members who volunteered to work with researchers could spend varying time with novice researchers, depending on shared interests and motivation to promote new research in the region. The Chair of the RMSG estimated 8 hours a month in additional meetings and correspondence. In later years, a member of the RMSG was also appointed to the HREC to improve continuity and communication within the Research Institute. This person worked as a 0.2 full-time equivalent project officer in these roles.

Research priorities developed by the RMSS incorporated area priorities identified in the former New England Area Health Service strategic plan, chronic and complex care of conditions identified in the National Health Priorities, aged care, information management and implementation of the NSW State Quality Framework as well as local issues identified by service providers in the course of their work.

## 2 Research submissions and ethics approvals before and after introducing the Research Methods Support Structure (RMSS)

	Jul 1992–Jun 1998 (before RMSS)	Jul 1998–Dec 2004 (after RMSS)	Change between two periods
No. of submissions	58	197	OR, 3.40; 95% CI, 2.28–5.07; $\chi^2 = 39.69$ ; $P < 0.01$
Average annual rate of submissions	9	30	OR, 3.33; 95% CI, 1.15–9.90; $\chi^2 = 5.06$ ; $P = 0.02$
Total number of ethics approvals	33	145*	OR, 2.11; 95% CI, 1.10–4.06; $\chi^2 = 5.93$ ; $P = 0.02$
Average annual rate of ethics approvals	5	22	OR, 4.4; 95% CI, 1.14–18.73;† $\chi^2 = 4.71$ ; $P = 0.03$

\* Includes four approvals by director with direct submission to the ethics committee. † Exact confidence limit (EpiInfo version 6, Atlanta, Ga: Centers for Disease Control and Prevention, 1993). ◆

## Methods

We hypothesised that the RMSS could increase the number of research submissions in the New England region and increase the proportion of research submissions which achieved ethics approval. Published reports and the databases of the New England Research Institute were reviewed.

A quasi-experimental design was used to compare the number of research submissions and research approvals during the two reporting periods. The  $\chi^2$  test for association was used to test for significant differences. A Yates correction was used for small fields (less than 5). Further analysis of data focused on the type of research and location of the researchers. Research submissions were coded as being clinical, population health or education and training, and as local or originating outside the region. A local research project had at least one researcher resident in the New England region. The number of research proposals, origin

of researchers and approvals by the HREC are reported from July 1992 to June 1998 and July 1998 to December 2004.

## Outcomes of the Research Methods Support Structure

Box 2 demonstrates that the total number of submissions and ethics approvals of submissions increased significantly following the inception of the RMSS. Comparing the two reporting periods, the total number of research submissions increased from 58 to 197, or 9 per year to 30 per year (odds ratio [OR], 3.33; 95% CI 1.15–9.90;  $\chi^2 = 5.06$ ;  $P = 0.02$ ); and the total number of ethics approvals increased from 33 to 145, or 5 per year to 22 per year (OR, 2.11; 95% CI, 1.10–4.06;  $\chi^2 = 5.17$ ;  $P = 0.02$ ). Submissions were 2.11 times more likely to receive ethics approval after the inception of the RMSS, with an increase in overall approval rates from 57% to 74%.

## 3 Research proposals before establishment of the Research Methods Support Structure by origin of researcher and type, July 1992–June 1998

	Type of research			Research approved	Report received
	Clinical	Population health	Education and training		
Total ( $n = 58$ )	26 (45%)	11 (19%)	21 (36%)	33 (57%)	22 (38%)
Outside origin ( $n = 20$ )	13 (65%)	5 (25%)	2 (10%)	17 (85%)	8 (40%)
Local origin ( $n = 38$ )	13 (34%)	6 (16%)	19 (50%)	16 (42%)	14 (37%)

#### 4 Research proposals after establishment of the Research Methods Support Structure by origin of researcher and type, July 1998–December 2004

	Type of research			Research approved	Report received
	Clinical	Population health	Education and training		
Total ( <i>n</i> = 197)	104 (53%)	52 (26%)	41 (21%)	145 (74%)	43 (22%)
Outside origin ( <i>n</i> = 74)	48 (65%)	11 (15%)	15 (20%)	49 (66%)	18 (34%)
Local origin ( <i>n</i> = 123)	56 (46%)	41 (33%)	26 (21%)	96 (78%)	25 (23%)

Box 3 shows the number of proposals from July 1992 to June 1998 before the establishment of the research methods group, classified by origin and type of research. During this period, 58 proposals were considered by the HREC, averaging 9 per year. Researchers from outside the area health service were 7.79 times more likely to have research approved than local researchers (OR, 7.79; 95% CI, 1.75–46.78). This difference was statistically significant ( $\chi^2 = 9.83$ ;  $P = 0.004$ ).

Box 4 shows the number of proposals from July 1998 to December 2004, classified by origin and type. During this period, 197 proposals were considered by the RMSS before recommending submission to the HREC, averaging 30 proposals per year. Locally based rural researchers were 4.89 times more likely to have their submitted research ultimately approved after the inception of the RMSS (OR, 4.89; 95% CI, 2.11–11.41;  $\chi^2 = 16.06$ ;  $P < 0.001$ ). Outside researchers had an approval rate of 85% before the RMSS. This decreased to 66% after the establishment of the RMSS. While concerning, this trend did not reach statistical significance (OR, 0.35; 95% CI, 0.07–1.43;  $\chi^2 = 1.83$ ;  $P = 0.18$ ). Box 1 shows the flow of the 197 proposals received after the inception of the RMSS. Of 197 reviewed by the Director, four were referred directly to the HREC, one to the Area Quality Council and 192 to the RMSS. Of the 192 received by RMSS, 24 proposals were withdrawn and eight were still under consideration in December 2004.

Before the RMSS, 45% of research was clinical, 36% related to education and training and 19% related to population health. After the RMSS, clinical research increased to 53% and population health research to 26%. Population health

research among local researchers increased from 16% to 33%. Completion reports have been received for 23% of local-researcher approved projects and 34% of outside-researcher approved projects since the RMSS was established. There was no statistically significant difference between these reporting rates. (OR, 1.65; 95% CI, 0.74–3.68;  $\chi^2 = 2.03$ ;  $P = 0.15$ ). Some approved research projects are still in progress.

## Discussion

Our data show a significant increase in the number of research submissions and research approval rates coinciding with the development of an RMSS in a rural area health service. However, a number of initiatives to improve research capacity have coincided with the reporting period compared with the historical control, including those of the NSW Department of Health Research and Development Policy Branch and the NSW Primary Health Care Research Capacity Building Program. Additional staff with a research objective to their job description were recruited to work in the New England area at the local University Department of Rural Health or employed as academic general practitioner registrars. These employees have worked collaboratively with the RMSS structure as part of their job descriptions. Additionally, a number of scholarship programs to increase clinicians' research capacity have been conducted in the region.

As a result, it is impossible to determine whether the changes in research submissions and approvals are directly associated with the establishment of the RMSS. Nevertheless, this trend is encouraging and suggests that the aims of the

NEAHS Research Institute were being met by increasing research capacity in a rural community. Furthermore, more population health research was conducted since the inception of the RMSS. This may relate to prospective researchers having better access to a group of experienced researchers in this type of research methodology. This type of research is useful to rural health, as the collection of strategic data can be used to address the high levels of mortality and morbidity in rural areas of Australia.<sup>10</sup>

## Limitations

This evaluation has a number of limitations. We are unable to determine whether the HREC and the RMSS developed increased expertise in critiquing research studies and skills in assessing the logistics of translating research to a rural setting during the reporting period. This study noted a decrease in external researcher approval rates from 85% to 66%. This change was not statistically significant but is of interest and concern. It is possible that local researchers were better able to gain support and research expertise from the RMSS than researchers from urban settings. The RMSS was not exclusive and offered assistance to all researchers who submitted research proposals. Researchers from larger urban institutions should have had better access to their own institutional research expertise than isolated rural researchers. There is a need to monitor this trend to ensure research is encouraged in rural settings regardless of the origin of the researcher.

There may be differences in how ethics committees conduct their work in rural areas when compared with their urban counterparts.<sup>2,11</sup> This is an area requiring more research. Rural HRECs may consider fewer proposals, resulting in less experience among their members. Furthermore, rural HREC members draw their members from smaller populations with fewer available experienced researchers and ethicists. The converse of this argument is that a local research ethics community will be more familiar with issues affecting rural health research, such as small populations, issues related to concurrent clinical

roles and where informed consent and autonomy of a community is difficult to achieve.<sup>2-4</sup>

Another limitation of this evaluation is that the database from July 1992 to June 1998 was not complete for all projects. Some research proposals were directly approved by the Chief Executive Officer in the period 1992–1998. These are not recorded on the Research Institute database, and we were unable to include these projects in this analysis.

There is a lack of published approval rates of ethics committees in the literature. A British study of the Royal College of General Practitioners' ethics committee found an approval rate of 82% for major clinical trials submitted by pharmaceutical companies.<sup>12</sup> The submitted approval rate of the local research ethics committee would appear comparable with this rate, considering it includes both novice and experienced researchers' proposals.

Research ethics committees have been criticised for delays in research approval.<sup>5-7</sup> Appointing the RMSS as a mandatory stage of HREC structure has added an additional stage to the research approval process. We lack the data to quantify the average length of time from submission to approval. Several methods to streamline processes were developed to reduce delays in research. This included timing RMSS meetings for before local HREC meetings, developing small working groups to fast-track projects, and appointing a project officer to improve communication between the RMSS and the HREC. We believe that the resulting benefits of increased research capacity in the New England Region and the likelihood that ensuring research is likely to be of higher quality outweighs any delays to individual projects.

The reported completion rate of research approved by the HREC is low, at 23% for local researchers and 34% for outside researchers. A bias is present in these data, as researchers were required to send their report to the Research Institute. There may be completed projects where reports were not received. In addition, many of the approved research projects are still in progress. There is a lack of published completion rates of projects after approval by an ethics

committee. A British study<sup>13</sup> found nine (11%) out of 39 studies failed to commence after ethics approval. At 1 year, 20 projects (51%) were intended for completion and publication of their findings. However, only 11(28%) were able to produce progress reports.

Some ethics committees are extending their role to monitoring the conduct of research,<sup>13</sup> and Australian HRECs are encouraged to increase their monitoring role of Australian research.<sup>14</sup> This evaluation found a gap between the approval and implementation of research. Pearn<sup>15</sup> considers there is an ethical imperative for all approved HREC research to be submitted for publication. There is an opportunity cost for resources to be diverted to a research project which is not implemented. Additionally, publication can be an indirect monitor of HREC quality assurance processes.<sup>15</sup> There is scope to extend the role of the RMSS to provide advice during the implementation phase of research.

## Conclusion

This evaluation demonstrates increased research submissions and approvals coinciding with the establishment of a Research Methods Support Structure. There is scope to establish research methods support groups in other rural regions to improve research capacity.

## Competing interests

The authors declare that they have no competing interests.

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