Research governance: current knowledge among clinical researchers

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ABSTRACT

Objective: To characterise the understanding of good clinical research practice (GCRP) among clinical researchers.

Design, participants and setting: Survey of all staff within the largest clinical research group (Critical Care and Neurosciences) of a non-government research institute affiliated with a major children's hospital, between 1 April and 31 May 2007.

Main outcome measures: Staff's role and research activity; knowledge of relevant guidelines and translation into practice; GCRP training; and experience of research audits.

Results: 122 of 154 research staff (79%) responded and were divided into three categories: clinicians (45%); research students/junior researchers (32%); and researchers (23%). While 60% of researchers reported they had read (at least in part) the two key Australian documents (the *National statement on ethical conduct in human research* and the *Australian code for the responsible conduct of research*), only 36% of clinicians and 30% of students/junior researchers stated they had done so. GCRP, such as obtaining consent and document storage, was only partially understood. 13% of all respondents had experienced a research project audit and 10% had undertaken formal GCRP training. Reasons given for the lack of GCRP training included insufficient resources, no training provided, and no time. 79% of staff felt that research auditing was important and 74% would like more education in GCRP.

Conclusions: Many clinical researchers are unaware of all the responsibilities involved in GCRP. A formal mandatory training program and GCRP auditing would be likely to improve practice.

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Increasing demand for evidence-based practice and decision making in clinical settings internationally has driven growth in clinically based research activity in recent decades. At the same time, consideration of the wellbeing of the human subject over and above the interests of science and society, as set out in the Declaration of Helsinki,[1] has become the fundamental goal of systems of ethical review, monitoring and governance for research involving humans.

Some countries, such as the United Kingdom,[2] the United States[3] and Canada,[4] have established national regulatory research governance frameworks. The broad objectives outlined in such frameworks are to define the responsibilities of researchers, institutions and research ethics committees. They can include not only policy, but requirements for the implementation of staff education and a system of audit.

In Australia, the *National statement on ethical conduct in human research*[5] and the recently amended *Australian code for the responsible conduct of research*,[6] both from the National Health and Medical Research Council (NHMRC), have aimed to guide institutions and researchers in how to develop and sustain responsible research practices. However, up until the recently revised NHMRC national statement, which includes a specific section on research governance,[5] there was no formalised research governance framework. This left much of the responsibility for following good clinical research practice with individual researchers.

We set out to characterise the understanding of good clinical research practice (GCRP) among clinical researchers at a research institute affiliated with a major children's hospital. Our aim was to provide baseline findings before the implementation of an institution-wide training and audit program, which are likely to be relevant in other clinical research settings.

METHODS

A self-administered anonymous survey was mailed to all researchers, staff and students affiliated with the Critical Care and Neurosciences (CCN) clinical research theme of the Murdoch Childrens Research Institute. This institue is a non-governmental organisation affiliated with the Royal Children's Hospital Melbourne, the largest children's hospital in Australia. The survey was piloted within one of the clinical research groups before being administered to staff affiliated with CCN, which is the largest clinical research theme of Murdoch Childrens Research Institute. Completed forms were returned between 1 April and 31 May 2007.

The survey sought data on staff roles, and the relative proportions of their time that they spent working in various capacities (clinical, research, administration, teaching etc). We categorised respondents into three groups:

- Clinicians included medical specialists, nurse practitioners, clinical nurse specialists or educators, general nurses and allied health clinicians;
- Students/junior researchers were those completing undergraduate (advanced medical science) or postgraduate (PhD or postdoctoral) research study and research assistants; and
- Researchers were research nurses, research fellows and academics.

Staff who held dual roles were placed in the above categories according to what they reported spending most of their time doing.

The survey investigated staff familiarity with the essential national and international documents guiding GCRP, and individual understanding of a selection of the principles outlined within them. The key documents regarded as essential were: (i) the Declaration of Helsinki;[1] (ii) the *National statement on ethical conduct in human research*;[5] and (iii) the *Australian code for the responsible conduct of research*.[6] For each of these documents, staff were asked to respond "yes", "no", or "unsure" as to whether they had read (at least in part) the document. In determining frequencies, the responses "no" and "unsure" were grouped together.

Staff were also questioned as to whether they understood all of the required elements of obtaining informed consent, what consti-

1 Composition of the sample of 122 critical care and neurosciences researchers

Characteristic	No.
Clinician	55 (45%)
Medical specialist	37
Allied health clinician	10
Clinical nurse	2
NP/CNS/educator	2
Other	4
Student/junior researcher	39 (32%)
Trainee doctor	12
PhD/postdoctoral student	8
Medical student	8
Research assistant	11
Researcher	28 (23%)
Research staff	19
Research nurse	4
Research fellow	5

NP = Nurse practitioner.
CNS = Clinical nurse specialist. ◆

tuted serious adverse events (SAE) and their associated reporting requirements, and the requirements for storing confidential data. Responses on SAE were regarded as correct if at least one requirement was correctly listed, and on data storage if at least three requirements were correctly listed.

Staff were questioned as to whether or not they had experienced a research project audit and, further, whether they considered this an important component of the research process. Additionally, the survey investigated staff numbers with specific training in GCRP and research design, their interest in pursuing this, and reasons why they may not have previously undertaken such training.

Data were entered into an EpiData database, version 3.02 (EpiData Association, Odense, Denmark) and exported for descriptive analysis into Stata, version 10.0 (Stata Corporation, College Station, Tex, USA).

This project was approved as a clinical audit by the Human Research Ethics Committee (HREC) at the Royal Children's Hospital, Melbourne, Australia.

RESULTS

Completed surveys were returned by 122 of 154 CCN clinical research theme staff (79%). The composition of the sample is shown in Box 1. The largest group were clinicians, 75% of whom considered themselves to be "Clinicians who participate in research". These clinicians reported an average of 69% of their work time to be spent as a clinician, with their remaining work time divided between research and administration. Thirty-two per cent of respondents indicated they were primarily students or junior researchers, reporting an average of 60% of their time dedicated to research, with the remainder of their time divided between studies and unrelated part-time work. A further 23% of respondents indicated they were primarily researchers, with an average of 80% of their time dedicated to research. Responses to subsequent questions in the survey were then considered on the basis of whether participants were clinicians, students/junior researchers or researchers.

Research project experience and participants' involvement in authorship are shown in Box 2. Publication numbers for clinicians were of similar proportions to those of the researchers, while students had been involved in fewer projects and had published less.

Thirteen respondents (11%) had previously been or were currently members of an HREC and 34 (28%) had been reviewers for an HREC.

Box 3 shows the numbers of staff who stated that they had read (at least in part) the Declaration of Helsinki;[1] the *National statement on ethical conduct in human research;*[5] and the *Australian code for the responsible conduct of research*.[6] While 60% of researchers had read (at least in part) the two Australian documents,[5,6] only 36% of clinicians and 30% of students/junior researchers stated they had done so.

Overall, 73% of staff stated that they understood all the required elements when obtaining informed consent from a patient for medical research, 62% that they understood the requirements concerning the storage of confidential data and 39% reported that they understood what constitutes an SAE. When asked to list requirements for confidential data storage and SAE and associated reporting requirements only 16% (for each) answered the questions correctly.

Ten per cent of all staff involved in research projects had undergone formal training in GCRP (7% of clinicians, 5% of students/junior researchers, 21% of researchers). When asked why respondents had not completed such training, 50% stated they were unaware it was necessary, 30% that no training was available, 29% that they had no time, 16% that they had insufficient resources and 3% that they were not interested. Seventy-four per cent of staff stated they would like more education in GCRP.

Thirteen per cent of all staff stated they had ever experienced a research project audit on any project in which they had participated. When questioned whether or not staff felt that auditing was an important

2 Involvement in research and authorship for the 122 critical care and neurosciences researchers

Involvement in research projects		Authorship on publications*	
Clinician		Clinician	
< 5 projects	15 (27%)	< 5 articles	28 (51%)
5–10 projects	15 (27%)	5–10 articles	6 (11%)
11–50 projects	20 (36%)	11–50 articles	16 (29%)
> 50 projects	5 (9%)	> 50 articles	5 (9%)
Student/junior researcher		Student/junior researcher	
< 5 projects	23 (59%)	< 5 articles	36 (93%)
5–10 projects	12 (31%)	5–10 articles	2 (5%)
11–50 projects	4 (10%)	11–50 articles	1 (3%)
> 50 projects	0	> 50 articles	0
Researcher		Researcher	
< 5 projects	7 (25%)	< 5 articles	17 (61%)
5–10 projects	7 (25%)	5–10 articles	1 (4%)
11–50 projects	13 (46%)	11–50 articles	8 (29%)
> 50 projects	1 (4%)	> 50 articles	2 (7%)

* In a peer-reviewed journal. ◆

3 Knowledge and practice of good clinical research practice among 122 critical care and neurosciences researchers comprising 55 clinicians, 39 students/junior researchers and 28 researchers

Response to question	Clinician	Student/junior researcher	Researcher	Total
Have read Declaration of Helsinki[1]*	28 (51%)	16 (41%)	13 (46%)	57 (47%)
Have read *National statement on ethical conduct in human research*[5]*	37 (67%)	22 (56%)	21 (75%)	80 (66%)
Have read *Australian code for the responsible conduct of research*[6]*	20 (36%)	13 (33%)	19 (68%)	52 (43%)
Claim to understand good clinical research practice principles†	34 (62%)	21 (54%)	21 (75%)	76 (62%)
Claim to understand informed consent	39 (71%)	27 (69%)	23 (82%)	89 (73%)
Claim to understand confidential data storage	36 (65%)	20 (51%)	20 (71%)	76 (62%)
Claim to understand serious adverse events and their reporting requirements	26 (47%)	8 (21%)	13 (46%)	47 (39%)

* At least in part. † Responded "yes" to the question: "Do you know what is meant by good clinical research practice?" ◆

part of the research process, 79% responded that it was important.

DISCUSSION

In surveying clinical researchers at a research institute affiliated with a public hospital, we found that two-thirds of clinicians and students/junior researchers and over a third of researchers admitted to not having read key Australian documents related to GCRP.[5,6] Further, although most respondents claimed to understand what is meant by "good clinical research practice", this was not demonstrated in a practical understanding of the key principles in these documents. While it might be expected that students and junior researchers would be less experienced in research practice than those we have classified as researchers, it may be these junior researchers who undertake most recruitment of participants and data management. Critically, these junior staff would be supervised by senior staff, who, according to our survey, are not universally more aware of GCRP requirements.

The *Australian code for the responsible conduct of research*[6] clearly describes institutional responsibility for providing adequate training for those conducting research. Few survey respondents had undertaken formal GCRP training; among those who had not, many were unaware it was necessary or that there was no provision for training at their workplace. Errors and omissions associated with GCRP potentially expose researchers and affiliated institutions to charges of ethical misconduct or legal risks. Although there are a number of quality assurance processes available, such as reporting and complaints systems, systemic or root cause analysis and the research equivalent of clinical morbidity and mortality meetings, some of the overseas research governance frameworks[2-4] have also included education and audit to improve GCRP. At our institution, efforts to improve GCRP include a review of current practice and to propose and implement an improvement model, including education, accreditation, monitoring and auditing. Performance management systems can be used to implement mandatory GCRP education; however, implementing change may be more difficult when clinical researchers are employed by a public hospital and affiliated with and only under the indirect control of a research institute or university, as will be the case at many major public hospitals in Australia.

In Australia, the regulatory model for overseeing research in health care has been heavily reliant on the HREC system. The increasing load on this system is straining its skill and resources.[7,8] The HREC system has been criticised as lacking in transparency and accountability,[8] and for its focus on research permission[9] rather than ethical problems during the execution of projects.[10] The *National statement on ethical conduct in human research*[5] and the *Australian code for the responsible conduct of research*[6] ascribe essential governance responsibility to the institution, distinct from the ethical review and HREC reporting requirements for projects. Calls for the development of an institutional model of responsibility for research governance,[7] and new recognition of institutional responsibility for monitoring are likely to increase project auditing — experienced by few researchers in our study, but seemingly welcome by most.

Our study has a number of limitations. The categorisation of staff into three separate groups was somewhat arbitrary as there was some overlap in position descriptions. Participants responding that they had read a document does not equate to them actually having done so, and having read a document does not equate to ethical practice. While this study was performed at a private research institute affiliated with a public hospital, unless GCRP systems are in place, the findings would likely be similar at a public research institute or university.

Many clinical researchers, particularly students and junior researchers, are unaware of the key responsibilities involved in GCRP. Establishing a research governance system that provides mandatory staff education and project monitoring throughout the course of research projects will require additional resources, but is likely to improve clinical research practice and be welcomed by clinical researchers.

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COMPETING INTERESTS

None identified.

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REFERENCES

1 World Medical Association. World Medical Association declaration of Helsinki. Ethical principles for medical research involving human subjects. http://www.wma.net/e/policy/b3.htm (accessed May 2008).

2 United Kingdom Department of Health. Research governance framework for health and social care. 2nd ed. London: Department of Health, 2005.

3 United States Department of Health and Human Services. Code of federal regulations. Part 46: protection of human subjects. 2005; Jun. http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm (accessed May 2008).

4 Medical Research Council of Canada; Natural Sciences and Engineering Research Council of Canada; and Social Sciences and Humanities Research Council of Canada. Tri-council policy statement: ethical conduct for research involving humans. 1998 (with 2000, 2002 and 2005 amendments). http://pre.ethics.gc.ca/english/pdf/TCPS%20October%202005_E.pdf (accessed May 2008).

5 National Health and Medical Research Council; Australian Research Council; and Australian Vice-Chancellors' Committee. National statement on ethical conduct in human research. 2007. http://www.nhmrc.gov.au/publications/synopses/e72syn.htm (accessed May 2008).

6 National Health and Medical Research Council; Australian Research Council; and Universities Australia. Australian code for the responsible conduct of research. 2007. http://www.nhmrc.gov.au/publications/synopses/_files/r39.pdf (accessed May 2008).

7 Walsh MK, McNeil JJ, Breen KJ. Improving the governance of health research. *Med J Aust* 2005; 182: 468-471.

8 Australian Law Reform Commission and Australian Health Ethics Committee. Essentially yours: the protection of human genetic information in Australia. 2003. ALRC report 96. http://www.austlii.edu.au/au/other/alrc/publications/reports/96 (accessed May 2008).

9 Watson R. Research governance: for whose benefit? *J Adv Nurs* 2002; 39: 515-516.

10 Lewis J. Research and development in social care: governance and good practice. *Res Policy Planning* 2002; 17: 3-11. http://www.ssrg.org.uk/publications/rpp/2002/issue1/article1.pdf (accessed May 2008).

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