



**Community Practitioners' and Health Visitors'
Association,**

The Royal College of Midwives

and

The Royal College of Nursing

A POSITION PAPER

**On the Implementation of Research Governance
Procedures**

This position paper addresses concerns identified by the Research Collaborative of the Community Practitioners' and Health Visitors' Association (CPHVA), The Royal College of Midwives (RCM) and The Royal College of Nursing (RCN) in regard to the implementation of research governance proceduresⁱ across the United Kingdom. It examines the implications of these procedures for research in health visiting, midwifery and nursing and makes recommendations to the government Health Departments of the United Kingdom.

The health and social care research community, and midwives, nurses and health visitors in particular, have long been mindful of the need for ethical, scientific and financial controls in research. For example, the RCN first published its ethical guidance for nurses involved in research 28 years ago. The inappropriate retention of organs wrongly claimed to be kept in the interests of 'research' and other well-publicised examples of unacceptable research practice, make it understandable that a national strategy to prevent poor conduct and future harms was necessary. Indeed, the broad principles of 'research governance' are hardly controversial, amounting to good practice in areas previously less well covered.

Some of these new procedures have been inconsistently and inappropriately applied across the UK to the detriment not only of current research but also with the effect of deterring both experienced and novice researchers from important empirical work. In many cases the measures adopted are completely out of proportion to the possible risksⁱⁱ.

The health services as a whole have a principal duty to reduce harm to service users and staff, or to ensure that any risks are fully understood by research participants and are fully balanced by consequent benefits.

Current procedures

Since research governance procedures are sometimes managed by individuals with little or no research experience, the real aims of the strategy, the reduction or elimination of genuine harms and a desire to improve the quality of research undertaken in the health services, have been lost in a plethora of paperwork, committee meetings and new 'procedures'. Together with the appropriate mechanisms for securing funding and university/local research ethics committee approval, researchers now have to face many more levels of scrutiny, each of which may take several months to complete, such as:

- Approval of appropriate user groups
- NHS local research management committee approval
- Seek NHS Honorary Contract
- Criminal Records Bureau Enquiry
- Data protection approval from NHS Trusts
- The intellectual property rights requirements of different organisations

The Problems for Research

Whilst many of these may become increasingly necessary, the way in which they are locally managed and interpreted can be inconsistent, unhelpful and unnecessarily prohibitive. Research in the health services is done primarily to improve patient services and quality of care. It is done secondarily, but importantly, to train health service staff in the collection and interpretation of evidence so that this evidence can finally be made integral to that care. Research governance arrangements, which are often additional to and different from ethical approval, seem to be having the opposite effect. For example:

- There is evidence that both senior and junior researchers are avoiding research in the NHS.
- Even those with honorary NHS teaching contracts are having to seek new contracts and other research management arrangements to conduct research, and sometimes in several organisations.
- Even where genuine research risks were low in conducting studies (for example a small scale survey of NHS staff on a 'non-sensitive' topic), students have to be given extensions to deal with several levels of external evaluation.
- In order to avoid lengthy scrutiny there is common re-negotiation of projects under new labels such as audit or evaluation of services (even though the actual ethical issues, if any, remain the same).
- Researchers are getting very different decisions from each of the bodies responsible for approval in a given case.
- It is clear that approval often depends on factors other than the design and main ethical issues in a study.
- Some studies are inappropriately rejected by reason of a design with which a panel may be unfamiliar.
- Approval paperwork encourages researchers to undertake 'convenient' research rather than answer important research questions
- The Health Departments and their officials are sometimes inconsistent in the use of research governance procedures.
- Research into a wide range of clinical need is being stifled.
- Instead of reducing the costs of research, it is very likely that these new arrangements greatly inflate the cost of even simple studies to a prohibitive level.

Health visitors, nurses and midwives have coped with these new arrangements with a good deal of patience. These professions are often among the most compliant when new procedures are developed whose aim is the enhancement of quality of care or the protection of the public from harms. However, concerns extend beyond the ambitions of researchers where these arrangements may frustrate the completion of a funded study or the achievement of a thesis or dissertationⁱⁱⁱ. Those very service users who will benefit from high quality research (such as older people and minority

populations) may be excluded from a study because researchers feel forced into the study of non-patient groups, and perhaps to entirely literature-based work. In order to develop research-based professions and practice, the best research can only be learned in the real world of health care. Service users, in whose benefit research governance procedures are said to exist, would often be the last to object to much of the research which is stifled by the current arrangements.

Summary

The concerns of the Research Collaborative of the CPHVA, the RCM and the RCN in regard to the detrimental effects of the implementation of research governance can be summarised as follows –

1. The inhibiting effects upon capacity building in potential and novice researchers
2. The cost burden that governance processes represent to the NHS
3. The inhibition of all forms of empirical research by research governance processes
4. The effects upon research education

Recommendations

In view of the above issues the Research Collaborative of the CPHVA, the RCM and the RCN recommends that the Health Departments of the United Kingdom consider seriously the following:

1. An urgent, rigorous review of the implementation of research governance across the UK to include a cost-benefit analysis
2. A clear interpretation of which types of activity (audit, evaluation, practice development, should be considered under research governance arrangements and why.
3. Further clarification and assistance for managers in the sensible interpretation of research governance arrangements.
4. The Health Departments should commission a systematic inquiry into the current genuine risks (and likely benefits) posed by contemporary research methods in the main health service disciplines so that research governance policy can be developed accordingly in a risk management context.
5. Work should be done to assist research governance managers in the assessment and grading of risks.
6. A consideration of alternative ways of regulating research focussing upon strategies such as the creation of registered researchers or collaborative supervisory processes

CPHVA, RCM and RCM Research Collaborative Group

Cheryll Adams, Professor Sarah Cowley, Dr Lois Goding; Community Practitioners' & Health Visitors' Association
Professor Kate Gerrish, Professor Martin Johnson, Ann McMahon; Royal College of Nursing
Sue Macdonald, Ann Matthew; Royal College of Midwives

Appendix 1 - Examples

Example 1.1 One health visitor researcher sought MREC approval for a national telephone survey. She subsequently had to seek NHS Trust research governance approval from many Trusts which was extremely arduous and bureaucratic. Most required copies of all the paperwork sent to the LREC/MREC and asked researchers to complete their own local forms, some of which are very long – up to 19 pages is not unusual. Many Trusts required honorary contracts to be in place which seems excessive for this type of study.

Example 1.2 A midwife sought ethical and governance approval for a study of postnatal care across two NHS Trusts. Ethical approval was granted for both Trusts but research governance procedures varied greatly in these neighbouring Trusts. In one the researcher was required to obtain criminal record bureau clearance and to secure honorary contracts, in the other she was not.

Example 1.3 A nurse undertaking an equity audit (which required analysis of anonymous patient data) on behalf of two PCTs was required to submit for MREC approval, meet NHS research governance requirements and in particular was required by at least one NHS Trust to secure an honorary contract.

Example 1.4 A national postal survey of nurses in Trusts/PCTs was commissioned by the Department of Health for England. This involved negotiating research governance approval in over 100 organisations. The time taken to obtain governance approval ranged from 4 weeks to 8 months. In many organisations approval has been dependant upon the research team undergoing health checks, CRB checks, be issued with honorary contracts and negotiate widely divergent interpretations of data protection and intellectual property requirements

ⁱ Department of Health (2001) Research governance framework for health and social care. <http://www.dh.gov.uk/assetRoot/04/01/47/57/04014757.pdf> (accessed 10/02/05)

ⁱⁱ Warlow, C (2004) Clinical Research under the cosh again *British Medical Journal* 31st July 241

ⁱⁱⁱ Jones, A Bamford, B (2004) The other face of research governance *British Medical Journal* 31st July 280-281