

Nursing Times Research

<http://jrn.sagepub.com/>

Research ethics and complex studies

Charles Normand, Julienne Meyer and Jane Bentley

Nursing Times Research 2003 8: 17

DOI: 10.1177/136140960300800104

The online version of this article can be found at:

<http://jrn.sagepub.com/content/8/1/17>

Published by:



<http://www.sagepublications.com>

Additional services and information for *Nursing Times Research* can be found at:

Email Alerts: <http://jrn.sagepub.com/cgi/alerts>

Subscriptions: <http://jrn.sagepub.com/subscriptions>

Reprints: <http://www.sagepub.com/journalsReprints.nav>

Permissions: <http://www.sagepub.com/journalsPermissions.nav>

Citations: <http://jrn.sagepub.com/content/8/1/17.refs.html>

>> [Version of Record](#) - Jan 1, 2003

[What is This?](#)

Research ethics and complex studies

Charles Normand
DPhil, BA
*Professor of Health Economics
London School of Hygiene
and Tropical Medicine*

Julienne Meyer
PhD, MSc, CertEd(FE), RGN, RNT
*Professor of Nursing: Care for
Older People
St Bartholomew School of
Nursing and Midwifery
City University
London*

Jane Bentley
MSc, RGN, RHV
*Research Fellow
St Bartholomew School of
Nursing and Midwifery
City University
London*

The operation of research ethics committees in England now follows standard procedures. However, the new ethical review process favours research where research questions and protocols can be clearly specified in advance of the study. While this may not be problematic for those conducting clinical trials, it can prove more difficult for qualitative researchers seeking to study complex and changing environments, such as the health service. Here, the changing nature of the services being investigated and the emphasis placed on involving users and carers in the research process, makes it hard to predict methods in advance of the study. This paper argues for greater flexibility within the ethical review process better to respond to the needs not only of this type of research, but also to other research and development activities, such as audit and practice development. It highlights the need for trust, ongoing dialogue, approval of frameworks and codes of practice. [*NTR*Research 2003; 8: 1, 17-26]

INTRODUCTION

The tradition of formal ethics approval for medical studies has its origins mainly in the need to protect patients, as laid out in the Declaration of Helsinki (1964). Experimental treatment was provided only if a good purpose could be shown and the patient provided informed consent. This has inevitably widened the scope of ethics scrutiny to include a requirement that the research is well designed, well carried out and likely to provide useful new insights. A further widening of the remit has been for ethics committees to ensure that healthcare professionals and staff are treated appropriately in research and provide consent.

The operation of research ethics committees (RECs) in England now follows standard procedures, and recent changes provide a framework for providing ethics approval for multi-centre studies. However, the model of research envisaged tends to be the clinical trial, where the research questions are concerned with the comparative effectiveness of old and new treatments, and of treatments for different sections of the population. Such studies require that the research questions are clearly specified at the start, the alternative treatment protocols are clearly defined, and the measurement and assessment processes are standardised. Changes to the original protocol may be needed in the event of new knowledge becoming available, or in response to unexpected problems in carrying out the research. However, researchers are encouraged to keep such changes to a minimum. Prior to giving consent, ethics committees like to see full documentation, such as consent forms and questionnaires.

Despite attempts to simplify and streamline the process of gaining ethics approval it can be a heavy burden even in the case of simple biomedical studies, especially when the study is carried out in different centres. However, much more serious problems occur when the study is complex, and when the methods used are such that it is neither possible nor desirable to specify fully the investigation at the start. This is a particular problem with some well-established methods, such as action research, or research using grounded theory. Evaluative research projects often have to change and adapt in response to changes in the innovative services. For simplicity we will refer to research that uses such a range of methods, certain social science methods or methods that evaluate complex interventions as 'complex studies'. The nature of complex studies means that it is not feasible to use the current ethics committee processes and be able to carry out the research efficiently and sensibly.

KEY WORDS

Ethics committees,
Qualitative methods,
Health services research,
Action research

However, it is neither desirable nor feasible to go back to carrying out such research without ethics supervision. This paper discusses the issues in detail and suggests approaches that might ensure that the research can be conducted efficiently within a framework of well-informed ethics supervision.

THE PURPOSE OF ETHICS

There are four ethical principles relevant to research undertaken on human beings:

1. Non-maleficence (do no harm)
2. Beneficence (do positive good)
3. Autonomy (show respect for rights of self determination)
4. Justice (treat people fairly).

All research carries a risk of doing harm (non-maleficence) to participants either physically or psychologically. Traditionally, the focus has been on physical harm caused by trials using invasive treatments and drugs. However, with the increase in qualitative methods being used in health services research, there is a growing awareness of the psychological impact of exploring sensitive areas (for example, the experience of death and dying), not only on the participant in the research, but also on the researcher(s) (Renzetti and Lee, 1993). This requires researchers not only to be skilled in research, but also to have the necessary interpersonal skills to carry out the research with vulnerable people. There is also a need for funding bodies and academic supervisors to consider the possible impact of doing sensitive research on the researcher and to set up mechanisms (counselling, for example) to support them through the process.

In terms of doing good (beneficence), participants can potentially benefit individually from collaborating in research (they may, for example, benefit from a new treatment or experience relief from sharing a concern), or they can hope that their own involvement in research will lead to others benefiting in the future. This requires research to be well designed and of practical value. Too often research is undertaken without proper attention to its application under normal practice conditions. This is particularly true where research attempts to minimise variation in practice.

The third principle of autonomy requires researchers to allow participants to be self-determining and thus refuse to participate in research. This requires valid consent from participants. Kennedy (1988) suggests that for consent to be valid, it needs to be informed, voluntary and competent. Informed consent requires participants to understand the risks and benefits of being involved with the study. Care needs to be taken to present research in a neutral manner, so that participants are not manipulated into taking part. However, this becomes more complex when the exact process of research cannot be determined in advance of the study. For instance, with action research, the process of research is determined in collaboration with participants and so is not known in advance. Thus consent constantly needs to be renegotiated throughout the study (Meyer, 1993). Informed consent also requires that information given is understood and jargon-free. Sometimes this requires verbal as well as written explanations, and the information may need to be available in different languages.

Voluntary consent is not simple. Without informed consent, you cannot have voluntary consent. Participants must not be coerced to take part, and must understand the consequences in terms of services provided or denied while they are involved in a study and in the event of choosing to withdraw at any stage. However, the pressure to participate does not always come from the researcher.

The process of gaining consent is critical: participants should be required to opt in, and free to opt out, at any stage. Valid consent also requires participants to be physically and mentally competent to decide. Conducting research on non-consenting people, such as those with dementia, needs to be clearly justified, for example, on grounds of utilitarianism (greatest good for the greatest number). Although such consent has no legal standing, it is good practice to gain permission from relatives when a person is not competent to consent and for researchers not to proceed if the non-consenting participants show any signs of distress or of objecting.

The final ethical principle of justice requires participants to be treated fairly and not exploited for research purposes. For instance, this means that care needs to be taken that particular groups are not over-researched. Confidentiality and privacy are also important moral rules in research. It is important that participants in research remain anonymous and feel safe giving information, without their identity being divulged to others. Participants should also feel in control of the information being shared and able not to disclose should they so wish. Again, this places great emphasis on the process of research and the need to renegotiate involvement at all stages. This requires some flexibility, and the need for an ethics framework or code of practice, as opposed to rigid rules and regulations about how research will be conducted in advance of the study. In our view the new governance arrangements for the NHS research ethics committees (DoH, 2001) do not allow for this flexibility.

RIGIDITY OF THE NEW GOVERNANCE ARRANGEMENTS

The document *Governance Arrangements for NHS Research Ethics Committees* (DoH, 2001) recognises that their purpose is to 'protect the dignity, rights, safety and well-being of all actual or potential research participants (para 2.2), to 'take into account the interests, needs and safety of researchers who are trying to undertake research of good quality' (para 2.3), and to take into consideration the principle of justice by ensuring that 'the benefits and burdens of research be distributed fairly among all groups and classes in society, taking into account in particular age, gender, economic status, culture and ethnic considerations' (para 2.4).

It can be argued, however, that the process of governance does not allow this to be done in practice. New guidance is trying to speed up the work of RECs. All such committees must give a decision within 60 days of submission of a research proposal (para 7.11). For multi-centre research ethics committees (MRECs) this includes consideration of locality issues. If responses or amendments are required, review can be made only once. Timing is suspended after request for a response is made and restarted when the answer to the request received. However, regardless of complexity, all RECs must come to a decision within 60 days. Any amendments submitted during the research process should be considered by the original REC and an answer given within 35 days (para 7.12). If amendments are substantial, researchers may need to submit another application for approval. The problem here is that any proposed deviation from an original proposal requires the researcher to notify the REC in advance.

The new governance guidelines suggest that researchers can deviate from the protocol agreed by the REC only if it is necessary to 'eliminate immediate hazards to research participants or when the change involves only logistical or administrative aspects of the research (para 7.24). Under these circumstances changes can be made immediately, researchers must inform the REC within seven days and the REC may reconsider its opinion as a result. These new

arrangements might work well for some forms of research — biomedical models, for example — but they are potentially constraining for other more qualitative methods.

THE NEED FOR MORE FLEXIBILITY

The need for flexibility when using more qualitative methods has been identified, as have the difficulties in applying rigid biomedical model codes to qualitative research (Murphy et al., 1998). In particular, flexibility is seen as important to cope with the 'emergent' nature of some research. Researchers need to be able to respond to a rapidly changing health service, the blurring of boundaries between research and development, the impact of user and carer involvement, and the needs of research participants, who are getting older and are potentially more vulnerable.

Changing health services

The National Health Service is in a state of constant change. As a result, the thing we set out to research is not always the thing we end up studying. Researchers need to be able to respond to these changes as they naturally occur, but this does not always neatly fit into the time frames of the REC governance arrangements. For instance, City University was recently given funding to evaluate the patient advocacy and liaison services (PALS) in London. The PALS is a new service to be introduced in all NHS trusts (acute, primary care and mental health) in England. An action research approach was planned, and communication with the PALS providers was to be through meetings co-ordinated by the London NHSE Regional Public Involvement Office. Within six months the service had changed to patient advice and liaison services, and the literature review needed to change substantially. The London NHSE was then disbanded and the responsibility for co-ordinating the PALS meetings was left open. Partners in the research project (London NHSE Quality Taskforce) were not sure of their future existence and the funding body (London NHSE Organisation and Management Research and Development Committee) ceased to exist.

Originally, the research team planned to study the first cohort of London PALS providers in order that they could develop patient-centred criteria to evaluate the service and to share the lessons learned with other PALS providers who were setting up a similar service. However, the second cohort received much less funding for PALS development, and the remaining trusts were given no funding. As a result of these changes, it became apparent that the ideas for the study needed to change. It was lucky that, technically, the study had not started, so it was possible to incorporate the changes into the MREC application.

This example highlights the effect of changes in the planned service development and wider changes in the NHS environment on the focus of research and plans for its execution. It also demonstrates that REC processes were not established to cope with such changes. They do not provide for on-going dialogue in response to evolving research plans. An alternative approach is needed that relies more on frameworks and codes of practice in place of prescriptive rules and regulations.

Blurring the boundaries between R&D

A range of methods is being actively encouraged in health services research, including action research (Meyer, 2001). Action research blurs the boundaries between research and development. It focuses on working with and for people, rather than doing research on them (Meyer, 2000). Increasingly, practi-

tioners are being encouraged to research their everyday practice and to share their learning with others. This leads to the same work being done (that is, research), under different labels (for example, audit, practice development).

The need for ethics supervision does not depend on arbitrary distinctions or names for activity. If ethics supervision is needed for action research (and we argue that it is), then it is also appropriate for innovative and experimental practice development. Action research (and some service developments) can place participants in vulnerable positions, therefore, mutually acceptable codes of practice should be negotiated with participants as part of the initial informed consent process (Meyer, 1993).

The guiding impulse of action research is the 'improvement of situations involving a practical responsibility for others' well-being' (Winter and Munn-Giddings, 2001). They highlight a number of ethical issues and principles of procedure (*ibid.* pp220-224). RECs should be ensuring that research is carried out within the framework of an agreed code of practice. This can accommodate the need for flexibility, but guide how this is applied. Conventional information sheets (with signed consent forms) may be no longer relevant by the time the research is under way, and are unlikely to provide for the inevitable changes.

User and carer involvement

The involvement of users and carers in health research is now policy within the UK (DoH, 2001; DoH, 2000). Wherever possible it is recommended that participants or their representatives be involved in the design, conduct, and analysis and reporting of research. Such involvement has the potential to ensure that, in future, a greater proportion of health research targets those areas of service delivery that are, from the perspective of service-users, in need of further development. However, these policy recommendations mean that RECs will have to adapt quickly to a range of new challenges. For example, a greater emphasis on user-led research will increase the number of submissions for studies using a range of qualitative methods.

At present, although RECs are required to ensure their membership includes 'a sufficiently broad range of experience and expertise' to be able to assess the science, ethics and potential practical issues relating to such methods (Central Office for Research Ethics Committees, 2001: 13), in practice, committees remain heavily dominated by biological scientist and medical personnel, who are less familiar with this type of research. Some investigators have reported that they have found RECs too inflexible or too pedantic in their demands for safeguards in relation to qualitative studies, and this can greatly hinder the research process (Ferguson, 2001). To facilitate the expansion of user-focused health service research, REC chairs should be encouraged to recruit more members with experience of qualitative methodologies (Moore and Savage, 2001; Stevenson and Beech, 1998).

Another related issue for RECs is that user participation in research requires more flexibility and latitude within research proposals than more traditional clinical studies. This will allow researchers to adapt to changing circumstances and promote reciprocal relationships with participants. REC members need to be aware that stipulating overly formal procedures, such as when obtaining informed consent, may serve to inhibit the formation of a good working relationship with those taking part. For example, in Moore and Savage's (2002) study incorporating participant observation in a ward, the researchers had agreed with their LREC that staff consent to be observed be gained on a day-to-day basis during data collection. In practice, they found that constantly seeking permission to attend regular meetings undermined the rapport that had

developed between the researcher and practice staff and seemed to question the judgement of staff who had already agreed to be observed.

Such issues are especially relevant in studies involving more vulnerable or 'hard to reach' groups. Orb et al. (2001) emphasise that with these groups in particular, researchers must negotiate access to participants in the field, therefore it is the quality of the relationship between researcher and participants that facilitates or inhibits access to data.

It may be possible in an ethics application to describe the broad approach to numbers sought and methods to be used for recruiting participants. However, in the case, for example, of recruiting drug addicts it may be necessary in practice to negotiate access to recruits via such methods as 'snowballing', whereby researchers seek recommendations for further potential individuals to recruit from those in similar circumstances (Robson, 1997). This type of study would benefit from RECs providing approval on the basis of on-going dialogue between researchers and the committee to review emerging ethical issues in such cases, rather than requiring researchers to specify the approach in detail at the start. Similarly, in these areas greater flexibility may be needed in the processes for obtaining informed consent for participation. Several researchers (Murphy and Savage, 2002; Ferguson, 2002; Murphy and Dingwall, 2001) suggest that more vulnerable people (such as frail older people or people with mental health problems) may find that too much information about their rights in relation to research, and the process of being asked to sign formal consent forms in itself promotes anxiety, and may make such people reluctant to take part in research.

While it is the role of RECs to protect the dignity, rights and safety of research participants (Central Office for Research Ethics, 2001), if these committees hold rigidly to particular procedures such as getting written informed consent it may be that such studies will become unfeasible and prevent study of certain settings and groups of people.

CONCLUSION

Appendix 1 suggests a practical approach to ethics supervision of complex studies. It is based on building trust between researchers and committees, a continuing dialogue, the approval of frameworks for carrying out research in the case of complex studies, and the development of codes of practice that can be adopted. The first need is to recognise that if proper ethics supervision is to be developed for complex studies it cannot be done solely on the basis of approaches developed for simple (in the sense that it can be easily specified) biomedical research. Second, ethics committees must be constituted so as to include skills in a wider range of research methods. Third, the process of ethics supervision must be seen not simply as gaining permission at the start of the study, but with the expectation that the issues be dealt with over the course of the study, that the approval is for an approach to the research and codes of practice, that change in the research will be reported to and discussed with RECs, but that so long as they are within the agreed framework, they will not delay or disrupt the work. Such an approach requires a relationship of trust, and recognition that the benefits of good ethics supervision (and the adherence to the principles of ethical research) will be realised only if research can proceed without undue delay.

In the past it was not common for many aspects of research on service delivery and organisation to be supervised by ethics committees. Sometimes this was because the work was classified as service development or audit. The early attempts to provide ethics supervision have shown the need for different skills, different approaches and different procedures.

KEY POINTS

- Research ethics committee procedures favour research where the methods can be specified in advance
- Qualitative researchers seeking to study complex and changing environments find it hard to predict methods precisely
- More flexibility, trust, ongoing dialogue, approval of frameworks and codes of practice are needed in the ethical review process

REFERENCES

- Central Office for Research Ethics Committees (COREC) (2001) *Governance Arrangements for NHS Research Ethics Committees*. COREC: London.
- Declaration of Helsinki (1964) In: *The British Medical Journal* 2: 177.
- Department of Health (2000) *Research and Development for a First Class Service*. London: Department of Health Publications.
- Department of Health (2001) *Governance Arrangements for NHS Research Ethics Committees*. London: DoH. (<http://www.doh.gov.uk/research/documents/gafrec.doc>)
- Department of Health (2001) *Research Governance Framework for Health and Social Care*. London: Department of Health Publications.
- Ferguson, P. (2001) Do researchers feel an LREC hinders research? *Bulletin of Medical Ethics* 165: February, 17-19.
- Kennedy, I. (1988) The law and ethics of informed consent and randomised controlled trials. In: *Treat me Right: Essays in medical law and ethics*. Oxford: Clarendon Press, ch10, 213-224.
- Meyer, J. (1993) New paradigm research in practice: The trials and tribulations of action research. *Journal of Advanced Nursing* 18: 1066-1072.
- Meyer, J. (2000) Qualitative research in health care: Using qualitative methods in health-related action research. *British Medical Journal* 320: 178-181.
- Meyer, J. (2001) Service delivery and organisation: The case for action research. In: Fulop, N., Allen, P., Black, N. et al. *Methods for Studying the Organisation of Health Services*. London: Routledge.
- Moore, L., Savage, J. (2002) Participant observation, informed consent and ethical approval. *Nurse Researcher* 9: 4, 58-69.
- Murphy, E., Dingwall, R. (2001) The ethics of ethnography. In: Atkinson, P. Coffey, A., Delamont, S. et al. (eds). *Handbook of Ethnography*. Sage: London.
- Murphy, E., Dingwall, R., Greatbatch, D., et al. (1998) Qualitative research methods in health technology assessment: A review of the literature. *Health Technology Assessment Programme* 2: No. 16. www.nchta.org (select 'Publications and Projects'; Select 'Select Publications'; Search on 'qualitative'.
- Orb, A., Eisenhauer, L., Wynaden, D. (2001) Ethics in qualitative research. *Journal of Nursing Scholarship* 33: 1, 93-96.
- Renzetti, C. M., Lee, R. M. (1993) *Researching Sensitive Topics*. London: Sage Publications.
- Robson, C. (1997) *Real World Research*. Oxford: Blackwell.
- Stevenson, C., Beech, I. (1998) Playing the power game for qualitative researchers: The possibility of a post-modern approach. *Journal of Advanced Nursing* 27: 4, 790-797.
- Winter, R., Munn-Giddings, A. (2001) *A Handbook for Action Research in Health and Social Care*. London: Routledge.

Appendix 1

ETHICS SUPERVISION AND COMPLEX RESEARCH STUDIES

The aims of ethics supervision in complex studies are the same as for any other research involving humans: participants should be protected while ensuring that the research is as likely as possible to generate worthwhile new knowledge.

Complex studies tend to focus more on providers of care than on patients, but this difference is of degree and not kind. The research process tends often to be interactive, with the early parts influencing how the later parts are carried out. There is, therefore, a much greater risk that approval in the conventional way for each small change in the research plans would be highly disruptive. The relationship between researchers and researched is more of a partnership than in most conventional biomedical research, and this leads to a need for a more specifically interactive relationship between the researchers and the ethics approval bodies.

Membership of research ethics committees has tended to be a combination of experienced researchers, clinical staff and lay people. As befitted the task, the research skills represented tended to be in the conduct of clinical trials and studies. This has meant that there has been only limited representation of researchers who undertake complex studies.

A framework of ethics supervision of complex studies requires some innovation in the way in which ethics committees assess proposals, the types of response given to researchers and the continuing relationship between ethics committees and researchers. It is suggested below that this should take the form of a two-stage process — first to establish an agreed framework for development of the study, and second, to set up a process of informing the committee of developments in the work.

Stage 1

The first stage involves putting in place the clear statements about the purpose of the work, the agreed research strategy, the main approaches and techniques to be used, the range of potential participants in the work and the framework for ensuring full and informed consent. Ethics approval would mean approval to proceed with the work within this framework. This may include some specified codes of practice for dealing with changes in processes and unexpected events. In addition, approval might also require adherence to more generic codes of practice. (For instance, Appendix 2 outlines a code for ethical practice for action research suggested by Winter and Munn-Giddings, 2001.)

Ethics approval would also set out the agreed provision of information and consultation to be carried out over the course of the study. If questionnaires or other data collection instruments are to be used in the early stages of the study, copies of these are likely to be included, but what would be approved is an approach or framework, not detailed plans.

Stage 2

In Stage 1 the kinds of research approaches would be agreed, but only limited details would be given. While the research is being undertaken, more detail would be provided to the ethics committee, including detailed changes in who would be asked to participate, more detail of methods to be developed or adopted, data collection and analysis plans, developments in consent instru-

ments to reflect the changing plans for the work and more detailed plans for providing feedback and dissemination of the work.

The approach would have to be light touch and quick enough not to disrupt the progress of the study, but this should be easier in the context of an agreed framework and approach.

The ethics committee would be expected to nominate one or more members to receive the Stage 2 papers and to report on any issues to the full committee. There would need to be a mechanism that allowed the nominated person(s) to stop a part of the research pending discussion in the full committee, were the suggested changes or developments to fall outside the agreed framework. However, the approach would be to establish a greater degree of trust and involvement that would make such occurrences the exception.

This is the first attempt to outline a process of ethics supervision that would take account of the different approaches typical in complex studies. A number of questions remain; for example, would this process operate from the MREC without LREC participation, or could the approach accommodate a continuing dialogue with LRECs but with the power to stop studies vested in the MREC? To what extent would the membership of ethics committees have to change to allow this procedure to work? However, if it is accepted that a framework of ethics supervision is essential for all health research, but the current biomedical model delays and increases costs of research, is not well suited to complex studies and therefore fails to provide the full require protection for participants, it is essential that a new approach be developed.

Appendix 2

ENSURING ETHICAL PRACTICE IN ACTION RESEARCH

Winter and Munn-Giddings (2001) highlight a number of ethical issues and principles of procedure. These are divided into three areas:

1. A 'professional' relationship between the researcher and participants that operates under such principles as:
 - Duty of care
 - Respect for the individual irrespective of race, gender, age, disability etc.
 - Respect for cultural diversity
 - Respect for individual dignity
 - Protection from harm
2. Principles common to all social research:
 - Informed consent
 - Protection from harm
 - Honesty
3. Processes to be followed:
 - Make sure discussions are fully documented, so that the process can be made available to those who are not present. (This needs to be agreed and procedures negotiated for recording or taking notes.)
 - Procedures for taking joint decisions need to be negotiated, ensuring that the voices of all participants are taken fully into account
 - Ensure that the work of the project is distributed as widely as possible among all participants. In other words, circulate regular progress reports,

- so that the work remains fully 'visible' to all participants
- Get agreement from participants that their contributions have been accurately described and in a form that can be shared with others by general consent. Thus all 'interpretations' need to be 'checked back' and 'authorised' before being circulated.
 - Enable participants to amend their contribution before it is circulated to others
 - Ensure that progress reports clearly invite participants to make suggestions concerning future developments
 - Differentiate clearly between documents that are confidential to project participants and reports that are intended for wider publication
 - Negotiate rules of confidentiality that are acceptable to all participants, for which all agree to accept responsibility, and which are appropriate for the different uses to be made of the various project documents
 - Make clear that reports intended for an audience beyond the group of participants will be circulated in advance, and that individual participants will have the right to withdraw any material containing a reference that may identify them
 - Negotiate in advance how possible disagreements concerning publication will be resolved in a way that preserves a balance between individual, minority and majority rights
 - Make it clear that participants need to negotiate with the group in advance if they wish to write up their work as part of an assignment for an academic qualification
 - Ensure various principles of procedure are drawn up early in the work, so that they are available in the form of a clear statement which can guide potential participants when making their decision on their involvement or otherwise.