The Costs of Scrutiny in Applied Health and Social Care Research: A Case Study

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Abstract

Evans et al. (2004) describe the consequences for housing researchers of the introduction of research governance in health and social care. The present paper is informed by the experience of seeking approval to undertake three funded research projects, between them covering 17 locations across England. The time taken to seek approval for one of these projects is described as a case study. Our experience shows that Evans and colleagues' anticipated timetable of three months to gain all the required approvals may be over-ambitious. A number of suggestions for improving the implementation of research governance are offered, including the harmonisation of procedures, greater reciprocity between different organisations, and the registration of researchers.

Keywords: Research governance, ethics, research approval

Introduction

Evans *et al.* (2004) describe the consequences for housing researchers of the introduction of research governance in health and social care. The present paper is informed by our recent experience of seeking approval to undertake three funded research projects, between them covering 17 locations across England. The Department of Health (DH) has recently stated the position it expects to develop in relation to the governance of social care (DH, 2003a), and research governance in health settings has been developing steadily since the guidance was issued in 2001 (DH, 2001; DH 2003b). The present paper takes up some of the themes raised by Evans and colleagues and describes the experience of obtaining ethical and governance approval in a real but anonymously described project which involves three sites. Our experience shows that Evans and colleagues' anticipated timetable of three months to gain all the required approvals may be over-ambitious. Applied research in the social care field is not just faced with social care governance arrangements, but also those of the NHS, because the main groups with whom we are usually concerned are receiving services from both health and social services – in old age and mental health these are increasingly integrated. All three of our current projects involve the NHS and social care agencies.

We should be clear at the outset that we agree with the fundamental need to conduct ethically sound research, and we believe that research should be subject to both academic scrutiny in the form of peer review and ethical scrutiny by an independent body. We recognise that without appropriate checks there is a risk of misconduct, as in the case of well-publicised cases involving the use of bodily organs without the knowledge or consent of family members. The objectives of the research and development reforms in the NHS were to identify and prevent weak and unethical research and also to identify the costs of clinical research to the NHS. We agree with that both of these steps are laudable, but we, and others, find that the mechanisms put into place to secure these ends are not efficient, they could act to reduce the interest and participation in research, and that they are more costly than they need to be (Ward, 2004; Jamrozik, 2004). Part of the reason for this is that rather than develop an appropriate mechanism for the scrutiny of research staff, existing systems devised for one purpose - such as health and safety procedures or occupational health checks for new nursing staff - are used without amendment. So, we are asked whether the researcher has problems in 'lifting and handling' even when the task involves conducting telephone interviews with service managers. In addition, some of the requests to divulge health information could be regarded as both intrusive and unwarranted, especially since these factors will have already been considered by the researcher's employer (and in confidence). Perhaps of greater concern to the research community is the evidence that some of the ethical constraints on approaching and selecting potential respondents can actually compromise the research entirely. Ward *et al.* (2004) report that the requirements demanded of them led to the response rate in their study becoming entirely inadequate (16%). In one of our projects the method of approaching potential participants (by letter with a covering letter from the host agency, with postal reply to the invitation to participate) will almost certainly lead to the same consequence. This method of approach was not in the original design but is included to meet the demands of the ethics committee.

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Some of the difficulties that arise in relation to health governance may well presage some of those in social care governance, because both are essentially dynamic and not static processes. So, for example, when Evans and colleagues describe the honorary contract requirements for researchers as 'not formally implemented' (p.50) they are reporting on a fluid situation - in which guidance has been issued but is not yet universally followed - that honorary contracts obtained in one location should preclude the necessity to apply for another one in a second (or more) location(s). Assuming that the primary purpose of the contract is to provide the researcher and the organisation with indemnity for negligent harm, and given that the wording of such contracts differ from Trust to Trust, it is not surprising to learn that Trusts are reluctant to accept contracts issued by others. Added to this is the fact that an honorary contract is issued only after occupational health clearance and an up to date (which is variably defined) Criminal Record Bureau (CRB) check; some Trusts are also reluctant to accept CRB checks obtained through another organisation. Insofar as the counter-signatory for the host organisation has to verify that the CRB check is being made on the person who is actually doing the work (by checking their driving licence, passport, birth certificate, and references) the researcher will need to present in person when this check takes place. When multiple sites are involved this could be logistically demanding and unreasonably expensive. The resulting burden on the CRB may be increasing their response times.

None of this solves the problem of non-negligent harm which Trust contracts do not cover. So researchers have to have insurance (such as a very substantial no fault compensation clause) from their substantive employer for non-negligent harm. For user-researchers without an affiliation to such an organisation, this might prove to be an insurmountable obstacle.

There are other examples of the dynamism of the situation, which have produced delay or dismay depending on the beholder. The health and the social care governance regulations both define the role of the sponsor of research, but this definition was delayed for several months. Its purpose is clear, which is to make the responsibility for the scientific validity of the research lie with the sponsor of the research and not the ethics committee (where it was located previously). Before 'sponsor' was clarified however, there was a period of some confusion and delay (and more cost).

Research governance requires the organisation to satisfy itself that the research being proposed has had a peer review. In one case, the authority implementing social care governance, of an externally funded, ethically and research governance approved project, insisted on sending the proposal out for further peer review. Presumably the person responsible did not appreciate that any changes required by this fourth review, would mean that if amendments were required and made, the proposal would have to go back through the health ethics and R&D procedures again, resulting in further delay and expense (eg Jones and Bamford, 2004).

While peer review applies to most funded research, there are also unfunded projects and student projects which also need this scrutiny. The quality of review in some higher educational establishments is questionable (and in others exemplary) but the costs of this peer review process fall either to the HEI through its own ethics procedures or to the Trust or social care organisation through its R&D procedures. Smaller Trusts or social care organisations with a limited track record in research may find this difficult (and also costly) to arrange because they do not have a ready source of expertise upon which to draw. One way to improve the system would be to use central or regional resources, such as the NHS R&D development groups, to administer this function and use wider local research networks to conduct the reviews. This would help to address a problem experienced by some social science researchers that their methods are not always understood by clinically orientated committees (eg we were once asked why our study involving multiple regression modelling of national data did not have a control group).

Another change, of which the logic is apparent, is that investigators with multiple site studies should seek ethical approval from an MREC (multi-site research ethics committee) rather than several LRECS (local research ethics committees).

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However, before MRECs and COREC were established investigators had to seek approval from many sites independently with the result that conflicting decisions were made (and thence re-applications, and more cost). Even with MREC approval, there may be reasons why the project has to have a site-specific assessment (SSA) by any or all of the LRECS.

Currently, there are few examples of health and social care organisations coming together to harmonise their research governance application procedures, and there is no national standard format for these. Local or regional research (and R&D) networks can help by introducing such harmonisation among members, but this does not help if one site is Wigan and one is Woking (and another is in Wales). One of the ways in which the system could be made to work better would be remove this variability in the content, length and format of the R&D application forms.

A Case Study

The following example (edited and anonymised) is offered here to illustrate that although the spirit is willing (and appropriate) the flesh so to speak is anything but. One cause of difficulty in the example is that within the same organisation, there are several component parts involved and some or all, can apply rigid and often inappropriate rules to the procedures. So for instance, the CRB checks and honorary contracts involve R&D and sometimes clinical governance departments as well as human resources and occupational health. So it is not only the quality of the relations between the organisation and the external researchers that is important for the approval process to proceed smoothly, but also the quality of the internal communication and working relationships between these component parts of the organisation.

The information in Box 1 portrays the length of time rather than the actual costs involved. Ward *et al.* (2004) estimated that the cost of completing the COREC form, about 44 hours work was £850. Box 1 begins with the submission of the proposal, but of course this leaves out the time taken to construct the initial bid (between four and eight weeks). We have added a time line dated from the first submission in the governance process to show how long governance arrangements have contributed after the submission of the application and being awarded the research grant. At the time of writing we are 34 weeks from the submission date and 22 weeks from the first research governance application.

As the reader can see from the third column in Box 1, a lot of the delays arise simply because of the time the NHS organisations take to reply. CRB checks came back within the specified time period in operation at that time, four weeks. The MREC which heard our application informed us that the meeting would be in ten weeks time. We were able to respond to the points they raised within one week, but it was about another 10 weeks before the approval finally came through. (In one of the sites, the eventual research governance approval was granted after almost a year, without any further information having to be supplied).

Discussion

Evans and colleagues are right to worry that this kind of experience may be off-putting to those who are beginning researchers, or small organisations, as well as to the more experienced of us (from large organisations with several studies going on at once in 17 sites located between Berwick and Barnstaple) who find that we cannot match their exhortation to keep our 'sense of humour' about all this. Two of the authors of the present paper are user-researchers who work on a freelance basis. They find the lengthy procedures demoralising and a disincentive to becoming involved in research, and while they recognise and applaud government initiatives to service users involved they consider that the present circumstances as reported here, do not provide an encouraging or welcoming arena for new user researchers.

There may be a growing temptation in some services to bypass the complexities of research governance by following the audit rather than the research route, when the work is in-house, and the purpose is service improvement rather than the generation of new knowledge. To the extent that this becomes popular, our ability to generalise from the same research in many contexts will be diminished.

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Box 1: Time line for research governance approvals		
Action	Weeks from submitted proposal [weeks from first R&D submission]	Delay
Proposal submitted	Week 1	
Approval and meeting with funders	Week 4	
Meetings between the three co-applicant organisations to finalise design issues and prepare ethics and R&D applications. Submitted the following: 1 Invitation letter for staff 9 the questionnaire for patients 2 invitation letter for patients 10 the questionnaire for workers 3 consent form for staff 11 the questionnaire for other staff 4 consent form for patients 12 Job content questionnaire 5 information sheet for staff 13 Job satisfaction scales 6 information sheet for patients 14 Moos Work Environment Scale 7 consultant's letter 15 the QoL scale (MANSA) 8 the original protocol/application 16 the principal investigator's CV	Weeks 5 to 12	3 months to meet and finalise applications
Submission for R&D approval to site A (site A requires R&D approval before ethical approval)	Week 13 [1]	
Submission for ethical approval via COREC*	Week 14 [2]	
Request R&D procedures from sites B and C	Week 16 [4]	2 weeks after COREC application
Site B sends R&D application	Week 20 [8]	4 weeks after request
Honorary contract information requested by Site A	Week 20 [8]	7 weeks after application
Submit CRB applications	Week 20 [8]	
MREC inform us meeting will be week 24	Week 21 [9]	MREC meeting is 10 weeks after application
Honorary contract details sent to Site A	Week 22 [10]	2 weeks after request
CRB approval for research worker granted	Week 24 [12]	4 weeks after request
20 points to answer from MREC	Week 26 [14]	
Replied to MREC	Week 27 [15]	Points answered in one week
Re-request re honorary contract situation (all sites)	Week 30 [18]	
Meeting in site A to finalise honorary contracts	Week 33 [21]	
Still no R&D approval yet in sites B and C	Week 34 [22]	18 weeks since first application
Still no CRB approval yet for senior researcher	Week 34 [22]	
Awaiting final ethical approval by Chair's action (within 8 weeks of week 27)	Week 34 [22]	

How can the system be improved? As indicated above, the harmonisation of some processes would help, and measures to remove the requirement to have honorary contracts and CRB checks in more than one place, if for no other reason than to reduce the unnecessary bombardment of duplicate requests to the CRB.

There are a number of suggestions by Evans et al. with which we concur and which can help facilitate the process: do not apply to several committees for approvals at once, they may come back with conflicting advice; where possible and appropriate apply for staged approval so that the work can begin promptly; be clear which type of ethical committee is the most appropriate to apply to.

The large, unposed and unanswered question is who is paying for all this? For one of our projects the funders insightfully agreed that the project should not begin until all the approvals were in place. This ensures that no project time is wasted, but shifts the funding burden to the investigator because in this case there was no funding provision to cover the period spent gaining approval. In two other projects however, the approval process has taken even longer than the case study example we present here, so that we have spent nine months of the funding in gaining the necessary approvals. Hopefully social care research governance can be streamlined to avoid this. We plan to include the costs of approvals in our funding proposals in future so that the HEI is not bearing all the costs.

Our preferred solution would be for the registration of research professionals in the same way that GSCC and other regulatory bodies scrutinise the professions. All registered researchers should, as in the case of market researchers, be licensed to practice, and should arrange to carry their own portfolio of references, occupational health clearance, CRB checks and indemnity arrangements (including a copy of their substantive employer's insurance cover), to avoid the bureaucratic duplication that currently bedevils the research community. Jamrozik (2000) also suggests that investigators should be trained and licensed, and registered researchers should be monitored to detect infringement of governance regulations. The ultimate sanction would be to be 'struck off' the register. Since most researchers in our field come from the HE sector this would shift some of the costs back to that sector but retain some of the responsibility (and cost) where it properly lies, with the *central* administration that introduced the requirements in the first place. There has not been, so far as we are aware, any increase in research funding anywhere in the system to reflect these additional responsibilities. We hoped that Lord Warner's review of ethical procedures can be extended to cover research governance issues, and that those considering the social care governance issues in conjunction with officials in the Department of Health can be assisted to avoid some of the pitfalls identified in this article and related research.

Our experience in this encounter with research governance reminds us that as well as safeguarding research participants, we all have an obligation to protect the rights of people to participate in research, and not deny them this through unnecessarily protective or paternalistic behaviours. The benefit that arises from the participation in an individual study may be limited, but, the purpose of most research in our field is the generation of findings that have wider applicability and that are of potential benefit to individuals, groups or the wider society. On balance we believe this should be encouraged. To paraphrase Burke 'research itself is only beneficence acting by rules'.

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