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ETHICS REVIEW
IN SOCIAL CARE RESEARCH:
OPTION APPRAISAL AND GUIDELINES

Jan Pahl
University of Kent

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EXECUTIVE SUMMARY

The Research Governance Framework (RGF) stated that the dignity, rights, safety and well-being of participants must be the primary consideration in any research study. The main aim of ethics review is to ensure that this is the case. In response to the RGF the Department of Health undertook extensive consultation about the ethics review of social care research. In general there was support for the principle of review, but considerable concern about the form it might take. This Option Appraisal draws on the consultation and should be read in the context of the Implementation Plan for Social Care: <http://www.dh.gov.uk/assetRoot/04/08/41/83/04084183.pdf>

Four models are proposed for a more comprehensive system of review and questions for consultation are outlined for each one. From most to least costly, the models are:

Model 1: A national system of social care Research Ethics Committees (RECs) similar in operation to NHS RECs, but organisationally distinct;

Model 2: A specialist social care committee system, operating within the existing structures of the Central Office for Research Ethics (COREC);

Model 3: A national system of social care ethics review, operating within a tiered decision-making process and using panel review;

Model 4: A pluralist system of ethics review based on local diversity.

It is proposed that in the first instance the RGF should only apply to work undertaken by researchers employed outside a particular Council with Social Services Responsibilities (CSSR). Guidelines are suggested for the establishment and support of ethics review systems, their membership requirements and working procedures, drawing on the *Governance Arrangements for NHS Research Ethics Committees*. Service users and carers should be involved not only in the process of review of individual projects, but also in more general decisions surrounding the setting up of a process of ethics review. A research proposal should only have to go through one review system, so training, standard setting and accreditation are key issues.

Funding bodies should be responsible for ensuring that all research proposals give details about the ethics review system to which the proposal will be submitted, if funded. The principal investigator or grant holder should be responsible for ensuring that appropriate ethics review has been obtained. Employing organisations and care organisations should be responsible for ensuring that research carried out within that organisation has been through a process of ethics review and approval.

1. INTRODUCTION TO SOCIAL CARE RESEARCH

1.1 This document is produced in response to the publication of the *Research Governance Framework for Health and Social Care* (Department of Health, 2001a). The Research Governance Framework (RGF) stated that the dignity, rights, safety and well-being of participants must be the primary consideration in any research study. The main aim of ethics review is to ensure that this is the case. Obtaining a favourable ethics opinion before research begins is central to good research governance and this applies in social care research no less than in health services research.

1.2 New developments in the international and national legal and regulatory frameworks are changing the context in which research will in future be conducted. In particular, significant changes have been made in order to respond to the standards set by European Directive 2001/20/EC on clinical trials, which came into force on 1 May 2004. Also relevant are the Data Protection Act and Health and Safety legislation. The Government Chief Social Researcher has initiated a debate into the ethical assurance of government social research (Kaduskar and Dawes, 2004). This may be particularly relevant, given the changes in services for children and young people.

1.3 For many years research in the NHS has had the benefit of advice from its Research Ethics Committees (RECs), which were formally established in England under cover of HSG(91)5 for Local Research Ethics Committees (LRECs) and HSG(97)23 for Multi-centre Research Ethics Committees (MRECs). A framework for the review of research in the NHS was set out in *Governance Arrangements for NHS Research Ethics Committees* (GAFREC) (Department of Health, 2001b). However, there is no comparable system for the ethics review for social care research.

1.4 In response to this situation a Working Group at the Department of Health undertook to develop proposals for a system of ethics review for social care research. This was preceded by an extensive period of consultation with relevant stakeholders (Department of Health, 2002). In general there was support for the principle of ethics review, but considerable concern about the form it might take. The results of the consultation were outlined in a Progress Report (Pahl, 2003).

1.5 The process of consultation led to the development of an Implementation Plan, which set out actions and dates for the implementation of the RGF in social care research (Department of Health, 2003b). Actions included: all bodies willing to act as research sponsors to inform DoH of their intention to do so (from May 2004); DoH to work with care organisations and other stakeholders to clarify their roles under the RGF (May to December 2004); national follow up to the Baseline Assessment Survey of CSSRs to review progress with RGF implementation (January 2005); publication of proposals for ethics review in social care and consultation on the proposals (July to December 2004). The last of these refers to this Option Appraisal.

1.6 Many of those who were consulted emphasised the particular characteristics of social care research and its differences from research in the NHS, especially clinical research. Many reported examples of applications by social science researchers to NHS LRECs and MRECs, which had met with misunderstanding and inappropriate responses (Lewis, et al., 2003; Tinker, 2001).

Social care research

1.7 The consultations suggested that there are a number of ways in which a system of ethics review for social care research would have to be different from that for research taking place within the NHS, though the principles underlying ethics review should be the same in both health and social care. One difference is in terms of the **academic disciplines** involved. Typically social care research draws on the social sciences and on disciplines such as social policy, sociology, economics, political science, anthropology, law and social history. In any system of review it will be important that these disciplines are well represented.

1.8 Social care research makes use of a wide range of **research approaches**, mainly drawn from the social sciences. These can run from ethnographic or anthropological approaches, through case studies and surveys, to controlled evaluations and experimental or quasi-experimental approaches. Research techniques in the social sciences are similarly varied, running from participant observation, interviews and self-completion surveys, to the analysis of documents or existing data.

1.9 In terms of **scale**, social care research also varies greatly. At one extreme are the big, national, longitudinal studies, which may collect data every year for 20 or more years, while at the other extreme there are small scale local projects, such as those undertaken by students as part of their training in social work and social care. In between come a variety of projects, such as those carried out by practitioners, in-house researchers or research units, by academics working within universities on externally funded projects, or by professional researchers working free-lance.

1.10 An important aspect of social care research has been the place accorded to **service users/carers and/or research participants**. Compared with research designed to investigate pharmaceutical products or surgical treatments, for example, research on social care is increasingly likely to involve service users, either at the planning stage, as advisers or co-researchers, or at the dissemination stage. This development has been led by researchers who are themselves service users, or by service users who recognise the power of research to influence the future shape of social care provision. In recognition of this, the consultation process involved a series of meetings with service users, facilitated by Involve (formerly Consumers in NHS Research) and by the Learning Disability Research Group.

1.11 The consultations with service users produced some distinctive points. It was argued strongly that service users should be actively involved in decisions about what research is funded, in the process of ethics review and in the debate about what is ethical research (Department of Health, 2003c). Particular concerns included:

ensuring that participants know they have the right to refuse to take part; making the purpose and methods of research clear to participants; recognising that there may be conflicts of interest between service users and those who care for them; paying research participants; providing for a complaints procedure; ensuring that participants were properly thanked for their contribution and giving feedback on research results. It was suggested that avoiding distress might not always be achievable, since some important topics, which should be researched, were by nature distressing: in this case it would be important to aim to minimise distress and to provide appropriate supports.

1.12 Many of the professional bodies of the relevant academic disciplines have already drawn up ethics guidelines for their members. These include the British Sociological Association (2003), the British Psychological Society (2000), the Medical Research Council (2000), the Market Research Society (2003) and the Social Research Association, whose Ethics Guidelines include an extensive review of resources and links on research ethics (Social Research Association 2003).

Coverage of the RGF in social care

1.13 The standards and principles of the RGF currently apply to all research that relates to the responsibilities of the Secretary of State for Health; discussions are in hand about the applications to children's services under the Machinery of Government Changes. This includes any research undertaken by academic or independent bodies or individuals, in or with social care agencies, as well as research undertaken by those agencies themselves.

1.14 A wide range of agencies, both statutory and independent, is involved in the provision of social care services. The focus of the RGF is on all research involving service users/carers, data concerning them, or staff for whom local Councils with Social Services Responsibilities (CSSRs) have a duty of care. This is the case whether the care is provided directly by the local council or contracted to other agencies in the statutory, voluntary or independent sectors. For those social care agencies that are not covered in this way, the RGF is recommended as a model for the governance of research, where poor practice could have a direct impact on the health or well-being of the public.

1.15 Any selected research population will contain individuals who are using services provided by a range of agencies, both within and outside local councils. In identifying whether work will come under the RGF the key issue is the means of *access* to the research population involved. If access is via CSSRs or their contracted agencies, then the research will be covered by the RGF. However, if the service users or staff are accessed via the records of another agency or department within the council (say a local Job Centre), then the research will not be covered by the RGF for Health and Social Care.

1.16 The implication for local councils is that one part of the organisation, the CSSR, will be covered by the RGF, while other areas, such as housing or education, may not be, despite overlapping groups of service users. In some councils the

potential difficulties of this situation have led to the development of the RGF as a fully corporate system. This can produce an ideal situation, but it is recognised that it is for councils themselves to decide what is consistent with their duty of care to their other service users and staff.

1.17 The RGF is likely to cover both adult and child social care, under whatever form of delivery arrangement they are supplied. As new patterns of services for children are shaped, for example via Children's Trusts, it is expected that the requirements of good research governance will apply. Again it will be for local agencies to decide how the safeguards provided by the RGF should be extended outside health and social care.

1.18 The Implementation Plan stated that the RGF will cover:

all forms of disciplined enquiry that set out to address clearly defined questions by the systematic collection of data using explicit research methods and techniques. (Department of Health, 2003b, 4)

This definition is deliberately inclusive and is designed to cover the full range of research-like activity undertaken on or by social care agencies, including non-financial audit. It does not assume that some forms of research activity are, by their nature, more risky than others.

1.19 Two studies were undertaken to provide data about patterns of research and research governance in the field of social care. A series of **Case Studies** undertaken in 2002 revealed a wide range and great diversity in the research activity taking place within local councils. Data were collected about 293 research projects in eight CSSRs. Of these projects, 60 per cent were described as 'internal', 20 per cent consisted of student projects, and 20 per cent were funded from external sources; only 4 per cent had been subjected to ethics review (Boddy and Warman, 2002).

1.20 **The Baseline Assessment Exercise**, which was undertaken in 2002 and which collected data from 101 CSSRs, a response rate of 69 per cent, underlined the great variety of activity currently taking place. All the councils which responded to the questionnaire were carrying out Best Value Reviews, many of which included surveys of the satisfaction of service users. Research by in-house staff was recorded in 89 per cent of councils, research involving external researchers in 83 per cent of councils, and research by social work students in 69 per cent of councils (Pahl, 2002).

1.21 The sheer volume of research-type activity revealed by these studies within social care agencies, particularly that conducted in-house, indicated the need for a staged approach to implementation. It would be impracticable to attempt to encompass all this activity within the RGF, as least in the first instance. As a result it is proposed that *implementation involves two main stages*. *The first* will be concerned with:

all research that involves access to service user or staff by researchers who are not employees of the local council or its contracted agencies.

1.22 This definition will include all research being undertaken by external researchers, including in conjunction with in-house research staff or professionals. The concentration on ‘external’ research in the first instance is for two reasons. First, this type of research is likely to have in place the other key actors, such as a research employer and a sponsor/funder, which are necessary for good governance. The social care agency will not then need to assume the responsibilities of these roles itself. Second, because it will enable social care agencies to develop and test RGF systems on what will be a relatively small and more manageable proportion of their research activity.

1.23 There are particular issues raised for the RGF in respect of research undertaken by students, either as part of social work training, as career development by social care professionals or as part of doctoral research undertaken by students in other social science disciplines. The staged approach to implementation suggested above would differentiate between students who are social care professionals (and thus have a primary duty of care to those they are researching) and those who are not. While research carried out by the former would not be covered by the first stage of RGF implementation, that of the latter would be. However, in all cases it would seem necessary for those involved to question carefully the ethics of allowing those who are effectively ‘researchers-in training’ to learn their skills in real life social care situations (see Doyal, 2004).

1.24 It is expected that CSSRs will implement *the first stage of the RGF* fairly quickly and the Implementation Plan sets out actions and dates for this. In the *second stage of implementation* the RGF will be extended to cover all other forms of research activity within Councils. This stage is likely to occur sooner in some CSSRs than others. The Baseline Assessment Exercise showed that some have already established the capacity for full implementation from the start; others will need some time to develop systems (Pahl, 2002). A particular issue for the implementation of the RGF in social care is the lack of a national system for ethics review, comparable in comprehensiveness with the system in the NHS. This Option Appraisal sets out options for the system.

The volume of research taking place in CSSRs

1.25 Before proposing options it was necessary to have some idea of the volume of research which might have to be reviewed. The Case Studies showed that across eight representative CSSRs in England 20 per cent (n = 58 projects) of the 293 research projects which took place in the prior year received external funding (Boddy and Warman, 2002). Extrapolating to all 178 CSSRs in England and Wales, this would give a total of 6519 projects, of which external bodies funded approximately 1200 projects. The proposals which follow were based on this estimate.

2. CURRENT ARRANGEMENTS FOR ETHICS REVIEW

2.1 The purpose of ethics review is to protect the dignity, rights, safety and well-being of all actual or potential research participants. In the RGF ethics reviewers share this role and responsibility with others, such as the funders and sponsors, researchers and their employers, the care organisations and the professionals who work in them (Department of Health, 2001b). RECs are the committees convened to provide independent advice on the extent to which proposals for research studies comply with recognised ethical standards.

2.2 RECs and others responsible for ethics review are responsible for acting primarily in the interest of potential research participants and concerned communities, but they should also take into account the interests, safety and well-being of researchers

2.3 Ethics reviewers also need to take into consideration the principle of justice. This requires 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. This may mean, for example, using the REC Annual Report to draw the attention of funding bodies and researchers to the relative neglect, or the over-burdening, of particular groups of research participants.

2.4 An ethics review system should provide independent, competent and timely review of the ethics of proposed studies. Although operating within the Governance Framework determined by the Department of Health (DoH), ethics reviewers need to have independence from political, institutional, profession-related or market influences. They need to demonstrate competence and efficiency in their work, and to avoid unnecessary delay. This is particularly so after the implementation on 1 May 2004 of the European Directive 2001/20/EC on clinical trials, which lays down a 60 day limit on making a decision about ethics approval.

2.5 Ethics reviewers should also have regard for the requirements of relevant regulatory agencies, applicable laws and legal indemnity. It is not for the REC to provide specific interpretation of regulations or laws, but it may indicate in its advice to the researcher where it believes further consideration needs to be given to such matters.

2.6 Experienced researchers know that many ethics issues which arise in the course of research could not have been foreseen and would not have been identified by an ethics reviewer. For this reason it would be valuable if it were possible to give continuing advice to researchers when ethics issues arise in the course of the work. This already happens in the case of research which has the benefit of an advisory committee, as is the case research funded by DoH and the Joseph Rowntree Foundation.

The Central Office for Research Ethics Committees

2.7 The Central Office for Research Ethics Committees (COREC):

- co-ordinates the development of operational systems for Local and Multi-Centre Research Ethics Committees (LRECs and MRECs), on behalf of the National Health Service in England;
- establishes and manages regional Offices of Research Ethics Committees (ORECs) to oversee the activity of LRECs;
- maintains an overview of the operation of the research ethics system in England, and alerts the Department of Health and other responsible authorities if the need arises for them to review policy and operational guidance relating to Research Ethics Committees (RECs);
- manages the Multi-centre Research Ethics Committees (MRECs) in England;
- develops and manages a national training programme for Research Ethics Committee members and administrators in England;
- maintains close contact with officials in the Department of Health with policy responsibility for wider issues of research ethics and with colleagues from Scotland, Wales and Northern Ireland;
- with appropriate advice, develops, implements and maintains operating procedures and standards for RECs that will be consistent across the UK.

Central Office for Research Ethics Committees, 2003

2.8 COREC has set high standards for the ethics review of NHS research and has developed a comprehensive system within which RECs can work effectively and efficiently. Clearly one option would be for a system for the ethics review of social care research to be developed within the COREC system. However, the consultation process found that the NHS system of ethics review is currently viewed with suspicion by some research funders, social science researchers and social care professionals (Lewis, *et al.*, 2003; Tinker, 2001).

University-based systems

2.9 Recent research into ethics procedures within universities, funded by the Economic and Social Research Council (ESRC), found that two thirds of the universities contacted were undertaking reviews of their ethics procedures. Ethics review in universities took a variety of different forms, from internal committees, to use of the NHS RECs, to adherence to professional codes of practice. Respondents were concerned about the bureaucratic burden which ethics review could create and argued were that the level of ethics vigilance should be proportionate to the risks borne by research participants (Lewis *et al.*, 2003). This work has now been extended

and the ESRC is funding the development of a framework for the evaluation of social science research ethics (Webster, et al., 2004). The aim is to prepare a Social Sciences Research Ethics Framework which will both meet ESRC requirements and have value to a broader range of stakeholders (Economic and Social Research Council, 2003).

2.10 There have also been debates about research projects carried out by students. Such projects are not necessarily designed to generate new knowledge, but are more educational in focus. Their main aim is to develop students' understanding of research techniques and their skills in applying them. However, student research may raise just as serious ethical issues as other research and the numbers of projects involved are large and growing. This situation led to the setting up of a Working Group on Ethical Review of Student Research in the NHS, and to the development of proposals for Student Project Ethics Committees (Doyal, 2004). These would be similar to RECs in their approach to ethics review, but they would also be responsible for ensuring that the educational goals were achievable.

Ethics review in social care

2.11 The Baseline Assessment Exercise, which set out to document the current situation in research governance in social care, included questions about ethics review in Councils with Social Services Responsibilities (Pahl, 2002). The results showed that in general, ethics review was not well developed. Only 14 per cent of CSSRs could say that all research had had ethics approval, while 27 per cent were planning for a system of ethics review.

2.12 Those CSSRs which had a system in place often made use of university ethics committees, or the local NHS REC. Some had used the more general system for approving research set up by the Association of Directors of Social Services (ADSS). Only two councils said that they currently had their own ethics committees, though several claimed that this was an area which they planned to develop, sometimes adding that they were awaiting guidance from the Department of Health.

2.13 The Case Studies of research activity in eight CSSRs found a very similar picture (Boddy and Warman, 2003). Out of the 293 projects covered in the survey, only 12 (4.3 per cent) were known to have been approved by an independent ethics committee. Just over a fifth of the studies reported some sort of review, by bodies such as the ADSS, research funders or a steering group, while another quarter had only been subject to internal ethics review.

2.14 There are currently a number of different systems for social care ethics review in operation in different parts of the country. There is space here to outline only four, chosen because of their relevance for this option appraisal.

2.15 Essex Learning and Social Care Services established a Research Governance Group (RGG) in 2002, building on an existing committee established in 1998 (Leggett, 2002 and 2003). The definition of research is broad and includes activities

such as audits, reviews and consultation. Applications for ethics review are made by email, with most proposals being sent out to five members of the RGG, which includes both academic and social care professionals. The majority of decisions are made within four weeks and are communicated to researchers by email. The RGG meets on average only 2-4 times per year and the system depends crucially on having a central Research Manager. The estimated cost of ethics review per application has been calculated at £391 (Leggett, personal communication, 2004). As we shall see, this cost is strikingly similar to that calculated for Model 3 in the following chapter.

2.16 West Sussex Social and Caring Services (WSSCC) also defines research very broadly, including surveys, focus groups, evaluations, best value reviews and student projects, but not the routine collection of management information (West Sussex Social and Caring Services, 2003). The ethics review system is run by the Research Unit, and the process of approval involves a tiered system of decision making with five levels, depending on the sensitivity of the research and the number of agencies involved. Proposals involving secondary data or research within WSSCC are placed at levels one or two and are assessed by expert reviewers within the Research Unit. Proposals involving other departments within West Sussex are reviewed at levels three and four by the Research Unit and professionals in the field who have had research training. Proposals which are judged to be level five go to the South East Authorities Research and Information Group. A similar system is being developed by Kent Social Services (Kent Social Services, 2004)

2.17 This tiered approach is similar to the Research Governance Risk Framework which is being developed by an external Working Group advising the DH (Working Group on the Implementation of the RGF in Social Care, 2004). This aims to ensure that the level of scrutiny given to a research proposal in social care is proportional to the likely degree of risk to the participants. Vulnerability is assessed in terms of the characteristics of participants, the nature of the information being sought, the methods of data collection, the competence of the researcher and other considerations. It is suggested that the Framework could be used by CSSRs to assist those responsible for ethics review and to guide researchers.

2.18 Another model is provided by the Office for Research Ethics Committees in Northern Ireland (ORECNI). This has recently developed a system of ethics review, in collaboration with COREC, in which proposals from both health and social care research are considered. The system uses COREC standard operating procedures, application forms, and data base and is compliant with GAFREC. Three committees have been established, each with a range of expertise, including social care professionals and academic social scientists with expertise in quantitative and qualitative research. Each committee meets monthly, thus creating a system in which a committee meets somewhere on most weeks of the year, so that proposals can be reviewed without undue delay. Members were recruited to the committees by a public appointment process and joint training has ensured mutual understanding of different approaches to research and to ethics review (Office for Research Ethics Committees in Northern Ireland, 2004)

3 FOUR OPTIONS FOR THE ETHICS REVIEW OF SOCIAL CARE RESEARCH

3.1 This chapter sets out four models, representing different options for the ethics review of social care research, together with questions for the consultation. These options are not mutually exclusive and it may be that the final result will involve some local diversity, as Model 4 suggests. However, we are presenting Models 1, 2 and 3 as distinctively as possible, in order to clarify the key characteristics of each one. In delineating options there are at least three different variables to be considered and it is the combination of these variables which produces the models.

3.2 First, there is the question of **the method of review** used to assess research proposals. In the current NHS system proposals are reviewed in committees, with the members meeting face to face and discussing each proposal in turn. However, re-submissions or re-applications, are dealt with by sub-committee action by chairs of committees. Standard operating procedures are defined for NHS RECs by COREC. Models 1 and 2 below are based on a similar committee system, with decisions about proposals made at meetings.

3.3 Alternatively research can be reviewed by a panel of expert reviewers, which does not necessarily meet face to face, with most proposals being circulated electronically or by post. There would still be a need for a central point, at which decisions are made about the level of review for each proposal and the most appropriate reviewers, and after the review process, about the recommendations of the reviewers. This system is already used in some universities, reflecting the fact that academics are familiar with the peer review system and are at home with electronic communication. Model 3 below is based on a tiered system, which involves some committee work, but draws heavily on panels of expert reviewers communicating electronically.

3.4 Second, there is **the organisational context** within which the system of ethics review is located. At present these contexts are many and various. Ethics review can take place in LRECs and MRECs within health authorities and trusts, in different locations within CSSRs, in universities and research institutes, via the peer review systems of research funders, within social care organisations run by the voluntary and private sectors, or in consortia bringing together two or more of these. Model 2 below assumes an organisational base within the Central Office for Research Ethics Committees (COREC) system, whereas Models 1 and 3 below assume an independent base, perhaps within the regional Government Offices. Model 4 allows for regional diversity in organisational context.

3.5 COREC has established eleven OREC regions, based on the nine regional Government Offices, with two of the Government regions being divided into two in order to produce more manageable units for the purposes of ethics review. We have suggested that these might provide a suitable geographical basis for the system of social care ethics review, whether or not the system operates within the COREC structure or independently of it. Models 1 and 2 are based on the eleven geographical

areas currently used by COREC, while it is proposed that Model 3 could be based on the nine regional Government Offices.

3.6 Third, there are **the resources** required for ethics review. Clearly the method of review is relevant and a system which involves face-to-face meetings will be more expensive than one based on review by panel members who do not necessarily meet. The costs will be much greater for a new, free-standing system than for one which can make use of expertise and facilities within an existing organisation. Over the years the LREC and MREC system has been subsidised by the NHS organisations within which the committees are located. RECs are now explicitly funded via COREC by the Department of Health. Given the much more fragile funding base for research within CSSRs, and the lack of any spare capacity in most social care organisations, funding may prove to be a key issue.

3.7 As well as the costs of running the system, there would be initial set-up costs, which could be considerable, especially in terms of recruitment and training, advice/support posts, accreditation and annual audit costs, and so on. Other costs will reflect the fact that those involved in the work of ethics review will need initial and continuing training regarding research ethics, methods and governance. There is also a need for administrative support and overall management of the system. Administrators and managers should have a sound knowledge of the Research Governance Framework, be trained in the work of ethics review, and be of sufficient seniority to provide detailed operational advice to the officers, reviewers and researchers. The cost implications are likely to be different for the different models.

Four models for a national system of ethics review

3.8 It is in this context that we outline options for four models of ethics review, and raise questions for consultation. From most to least costly, the models are

Model 1: A national system of social care RECs, similar in operation to the NHS RECs, but organisationally distinct;

Model 2: A specialist social care committee system, operating within the COREC structure;

Model 3: A national system of social care ethics review, operating within a tiered decision-making process and using electronic communication;

Model 4: A pluralist system of ethics review based on local diversity.

3.9 All models should have the potential to expand to cater for a wider definition of research in future years. They will also need to comply with the EU directive on clinical trials, which became law on 1 May 2004.

Model 1: A national system of social care RECs, similar in operation to NHS RECs, but organisationally distinct

3.10 A national system of social care RECs, similar in operation to the NHS RECs but organisationally distinct, would be likely to incur costs similar to those of the NHS committees but with additional costs because of being organisationally distinct. This makes it the most expensive of the four models.

3.11 It is proposed that such a system might be located in the regional Government Offices. The aim of these offices is to work with local authorities and regional agencies to achieve government aims in a coordinated way: as such they might be an appropriate base for the work of research ethics review. COREC already bases its own organisational structure on these regions, with two being divided in half to make 11 regions in total.

3.12 Model 1 assumes a committee in each regional office, which would handle research proposals from that region. Each committee would need a full time administrator, a part time chair, and around 15 members. We have assumed that in the first instance the number of research proposals would be around 1200 per annum (see page 8 above). On the basis of 11 committees and monthly meetings, this would mean that each committee would deal with nine applications per meeting, comparable to the amount handled by MRECs (an average of 10 new applications per meeting).

3.13 There would also have to be a central development and support function which would play a role similar to that which COREC plays in the NHS. This would be responsible, in discussion with regional committee members as appropriate, for:

- policy formulation and development;
- setting up the system and devising working procedures;
- financial management of the system;
- support of administrators of regional committees;
- recruitment of committee members;
- administration of a central allocation system, like that used for NHS RECs, to ensure that there is minimum delay by allocating applications to the next available slot;
- reviewing/approving multi-site applications;
- dealing with complaints;
- organising training in ethics review.

3.14 The way in which specialist social care committees would operate would differ in various ways from the operation of the RECs in the NHS. One important difference would be in terms of the greater involvement of service users. This might mean that the process of implementation would be slower, especially early on, when all committee members were learning the ropes.

Model 1: questions for consultation

3.15 There are a number of questions which will require further discussion in respect of Model 1. First, where should the central policy development, support and allocation functions be located? This would be essential in any system, but is already in existence in any system which builds on the work done by COREC. In Model 1 it might be located in one of the regional Government Offices, or provided by an expanded version of the existing ADSS multi-site approval process, located within a local CSSR.

3.16 The second question concerns setting up the system. How would this be managed and resourced? In the early stages there would be the need to develop the social care research ethics application forms, the database and systems for tracking proposals. Clearly the scale of the task would be much less than for the ethics review of medical and health service research, within the existing NHS REC system. However we would need to consider how these functions would be provided if the Social Care REC system were to be freestanding. We also need to consider if the benefits of a freestanding system would outweigh the efficiency gains delivered by integration with the NHS system.

3.17 Thirdly, there is a question about the accreditation of systems for the ethical review of social care research. This will be necessary in order to ensure that all ethical review systems maintain the same high standards, so that each research proposal does not have to go through more than one review process. How will standards be maintained and assured?

Model 2: A specialist social care committee system, operating within the COREC structure

3.18 The consultation process made it very clear that the present NHS REC system has not proved satisfactory for the review of social care and social science research. So though this model would come within the COREC framework, the committees would have to have different membership from the current NHS RECs and there would have to be some central social care expertise. In particular the membership, both nationally and regionally, should represent the academic disciplines and the professional expertise of those working in this field, as well as incorporating service users or their representatives.

3.19 Model 2 assumes a specialist social care committee system, operating within the COREC structure. It would be covered by the Governance Arrangements for Research Ethics Committees (GAFREC) and would be largely committee-based. The number of meetings would be dictated by the flow of applications. The costs for Model 1 assumed 1200 new applications per year, and monthly meetings of eleven committees at a rate of around nine applications per meeting. For Model 2 an equivalent number of applications, committees meetings and support functions would be required, so the ongoing costs would be very similar to those for Model 1.

3.20 However, the costs for central administration and setting up could be very different. We have discussed above the ways in which COREC already provides standards, offers accreditation, and performs guidance and policy functions, as well as maintaining the central database and working to ensure the most efficient allocation of research proposals. These could constitute substantial costs for the organisationally independent Model 1, but may not apply to such an extent if social care ethics review operated within the NHS system, though it would be important to have social care experts within COREC to ensure that the necessary expertise were available.

3.21 The set up costs of the two models could also be very different. The COREC system and database is already in existence for allocating and monitoring applications. As a result of restructuring, the NHS ethics review system may have excess capacity in some areas. Historically ethics committees were set up on a geographical basis rather than being demand led, so in various parts of the country committees are being combined in order to ensure that they meet often enough to comply with EU requirements that the decision should be made within 60 days.

3.22 The setting up of a system for social care ethics review could be integrated into this process of restructuring rather than having to set up new committees from scratch in a stand alone system. The Office for Research Ethics in Northern Ireland has developed, in collaboration with COREC, a variant of this system, in which health and social care research are subject to a joint process of ethics review. Overall it is likely that the costs for Model 2 would be lower than the costs of Model 1.

Model 2: questions for consultation

3.23 Model 2 raises a number of issues for discussion. First, would a system located within the existing COREC structure be able to maintain its distinctiveness, and would it gain the trust of the social care research and practice communities?

3.24 Secondly, would the working procedures and governance systems of COREC be sensitive to the constitution and operation of social care research ethics committees? What developments would be needed in order to ensure that this was so? Conversely, would COREC welcome a substantial expansion of its current responsibilities, especially when these could involve new working procedures and a new body of stakeholders?

3.25 Thirdly, would it be more logical for these committees to undertake, in addition to social care research, the review of health services and public health research? This would bring together all research based on social science disciplines, so that LRECs and MRECs could focus on clinical and medically based research.

Model 3: A national system of social care ethics review, operating within a tiered decision-making process and using electronic communication

3.26 Model 3 would replace many of the committee meetings of Models 1 and 2 with ethics review carried out by expert panel members working independently and not necessarily meeting face to face. Much of the work would be done by means of electronic communication.

3.27 The system could be based in the regional Government Offices, in a regional consortium of local authorities, or in a partnership between local universities and social care organisations. The proposed system has many of the features of the systems currently operating in Essex and West Sussex (Leggett, 2002 and 2003; West Sussex Social and Caring Services, (2003).

3.28 Model 3 assumes that most of the work will be done at regional level, where a research administrator, working to the chair of the ethics committee, would review incoming proposals and decide on the most appropriate form of ethics review. Most proposals would then be sent out electronically or by post to three members of the ethics review panel. One member of this panel would be responsible for summarising the decisions made. This summary would be returned to the research administrator, who would have the authority to agree ethics approval for non-contentious research proposals, after discussion with the chair if necessary.

3.29 There would also have to be a central office, playing the same sort of role as the central office in the other systems, which could be based in one of the regional offices.

3.30 Model 3 assumes that more ethically contentious proposals, or those where there was disagreement between panel members, or some other reason for concern, would go to a regional committee meeting. It is proposed that there should be nine regional committees, each meeting twice a year. In order to ensure that research was not unnecessarily delayed, there should be a central allocation system by which proposals could go to the next committee meeting, even if that was not in the region from which the research had come. This would involve the national office, which would maintain a record of when committee meetings were due to take place, and allocate proposals to the next available meeting.

3.31 The model proposed here assumes nine regional committees, based, for example, in the nine regional Government Offices. The location of the Regional Offices would have to be negotiated with the relevant bodies. It is assumed that around 80 per cent of proposals could be dealt with by expert review and would not need to go to a committee; 10 per cent of the proposals would be so non-contentious that they could be dealt with by the administrator in consultation with the chair, and 10 per cent would go to a full committee meeting.

3.32 Each committee would meet twice a year, and have nine members, working with a panel of around 40 reviewers. Committee meetings would be used to:

- consider more ethically contentious proposals;
- bring together the comments made by reviewers in cases where there was disagreement and make final decisions on proposals;
- oversee and record decisions made by panel members;
- provide support and advice to researchers, research employers and sponsors;
- consider broader issues related to standards, training, guidance and policy.

3.33 Model 3 has the advantage that it is efficient and delays are kept to a minimum, as the review process is set in motion immediately on receipt of an application, and reviewers are given two weeks to agree a response. If they cannot meet this deadline other panel members are selected. The process of identifying panel members and ensuring that they can respond takes the bulk of administrative time and cost, and can operate entirely electronically. However, it could operate by a mix of electronic and postal communication if this were more appropriate. Consultations with service users revealed that many would welcome a system which made use of their expertise without demanding their attendance at formal meetings.

3.34 It is likely that the costs for Model 3 would be approximately half those for Model 1.

Model 3: questions for consultation

3.35 Model 3 raises a number of issues for discussion. First, there are all the problems involved in managing a system without many committee meetings. Would it be possible to reach agreement in the absence of face-to-face meetings? Would there be time delays without the deadlines created by regular meetings? How would transparency and accountability be maintained? Would the pressure on the central administrative function be too great?

3.36 Secondly there could be problems arising from extensive reliance on the use of electronic communication. Some service users expressed their preference for a system which did not demand attendance at meetings, but other reviewers could require support in setting up and using the system. How would this be developed and delivered?

3.37 Thirdly, would such a system be recognised by the NHS RECs? Without such mutual recognition, research which involved both health and social care might have to go to several RECs, with damaging delays to the work. Would the system be trusted by the funding bodies, the research employers and sponsors and by all those involved in social care research?

Model 4: A pluralist system of ethics review based on local diversity

3.38 All three models which we have presented assume a regional basis for ethics review, whether the regions involved are the Government Offices, the NHS REC structure, regional consortia of local authorities, or partnerships between a university and local social care organisations. Model 4 acknowledges that the current situation is one of considerable diversity and proposes a pluralist system that enables a degree of local diversity to continue, within a national ‘accreditation’ system.

3.39 Model 4 is based on the idea that it would be possible for some localities to adopt a committee-based system, either inside or outside of the NHS REC structure, while others might adopt a system which made use of a panel of ethics reviewers to a greater or lesser extent. The national Baseline Assessment Exercise made it clear that Councils with Social Services Responsibilities (CSSRs) differ enormously in the extent to which they already have a system of research governance in place or plans to implement the RGF (Pahl, 2002).

3.40 Model 4 would acknowledge this and would allow some parts of the social care field to move forward, while also providing examples of good practice for CSSRs which were still developing their systems.

3.41 Appropriate funding would be necessary for Model 4. This funding would have to cover such items as the setting up of standards and procedures, the development of application forms and data bases, policy development, training and accreditation. There would also be the day-to-day running costs of the system, such as administration, processing of applications, meeting expenses, payments to members of committees and communications with researchers and other relevant individuals and organisations.

Model 4: questions for consultation

3.42 Model 4 raises a number of questions. First, there is the issue of how standards would be maintained and consistency assured in a situation in which very different working procedures, methods of review and organisational contexts applied in different parts of the country. A national accreditation system is assumed in the model, but how and by whom could this be provided?

3.43 Secondly, there is a question about how the system would be funded and how financial and other resources would be delivered and managed. Would funds be made available by the Department of Health and if so, would CSSRs and other bodies bid for resources to set up their own ethical review systems? Would CSSRs be able to offer any support from within their own resources and what forms might this take?

3.44 Thirdly, there is an issue about the fact that the majority of social care is provided, not directly by CSSRs, but through contracting out to the private and voluntary sectors. How would research in these areas be brought into any system for ethical review?

Overview of options

3.45 The four options are presented as distinctively as possible in order to support an informed discussion, though it is acknowledged that there are areas of overlap between them.

3.46 Model 1, a national system of social care RECs, similar in operation to the NHS RECs, but organisationally distinct, would be the most costly. However, it would provide a comprehensive system, which could be tailored to the particular requirements of social care research. There remain decisions to be made about the location of the central support function, and about the costs of setting up the system and providing for accreditation.

3.47 Model 2, a specialist social care committee system, operating within the NHS REC structure, would take advantage of the expertise and structures developed by the NHS, so costs would probably be less than for Model 1. However, it would be important to maintain a separation from the NHS in terms of members of committees and chairs, and in terms of policy and practice at central levels, if this system is to gain the trust of the social care community. The Office for Research Ethics in Northern Ireland has shown a variant of this system in which health and social care research are subject to a joint process of ethics review, working to standards and conditions as set out in the Governance Arrangements for Research Ethics Committees (GAFREC). There remain questions about whether social care research would be able to maintain its ways of working within the NHS system, about the demands which might be made on COREC, and about the place of social science research in a system focused on clinical trials.

3.48 Model 3, a national system of social care ethics review, operating within a tiered decision-making process and using panel review by electronic communication, would incur costs of about half of those for Model 1. However, it would require the development of both central and regional organisational systems and the creation of panels of expert reviewers. It might also be harder to ensure consistency between panels and regions and there could be difficulties in establishing its credibility with the NHS REC system. Questions remain about the problems which might be involved in running the system, and in relying on electronic communication; there may also a question about recognition by the NHS REC system.

3.49 Model 4, a pluralist system of ethics review based on local diversity, corresponds most closely to what is currently occurring in the social care field. Its strength would be to recognise and support developments suited to local contexts. However, diversity could also be a weakness, if consistent national standards of practice are to be ensured. New funding would certainly be necessary for an activity which is not currently undertaken by most CSSRs. The questions for consultation are concerned with maintaining standards, with the funding of the system and with the broader context within which the system would be located.

4 THE ESTABLISHMENT AND SUPPORT OF A SYSTEM OF ETHICS REVIEW

4.1 Whichever system is chosen, it is important that the dignity, rights, well-being and safety of research participants are protected, that good projects are not unnecessarily delayed, and that social care research can continue to contribute to the development of high quality social care services.

4.2 Any system of ethics review with the authority to offer an opinion on social care research will require a structure within which to operate. In making proposals in this and the following chapters we have drawn on the *Governance Arrangements for NHS Ethics Committees* (Department of Health, 2001b).

4.3 Whatever system is chosen it will be necessary to have a central point in a responsible organisation or appointing Authority. Clearly there will be some differences between, on the one hand, a system based on committee meetings and, on the other hand, one based mainly on a panel of reviewers, with less frequent meetings. However, it will be important that the same principles apply whatever system is chosen. Since a committee system is likely to be more costly and complex, the chapters which follow tend to focus on RECs, making reference to the tiered system and panel review only when these are substantially different.

4.4 The Baseline Assessment Exercise showed that some CSSRs already have such a central point. In their replies to the questionnaire a third of CSSRs said that in 2002 they had a system in place to ensure that all research is notified to an appropriate person, approved and monitored. Another third of CSSRs had plans to establish a system for the notification and approval of research (Pahl, 2002).

4.5 However, Chapter 3 set out other options for the location of a responsible organisation or appointing Authority for the ethics review of social care research. These included the nine regional Government Offices and the 11 ORECs currently managed by COREC. Alternatively the system could be based in consortia of CSSRs or in partnerships between a university and a number of CSSRs. A small number of such consortia already work satisfactorily in various parts of the country.

4.6 Each appointing Authority should identify a named officer who will have lead responsibility for the establishment, support and running of the system. The appointing Authority should also set an annual budget for the adequate support of the system of ethics review for which it is accountable, irrespective of any income received from charges made for review, in cases where this is appropriate.

4.7 Each appointing Authority should establish sufficient capacity within its boundary to cope with the workload, and must provide adequate administrative support for their business. In some cases the system may involve an initial sift, at which stage approval can be given for some projects, while others go on to a more rigorous scrutiny, as in the West Sussex system. For example, it may not be necessary for all student projects to go through the full process involved for externally

funded research; a less formal process may be established by which the supervisor or two peer reviewers may be able to approve straightforward projects, with proposals which may involve ethical dilemmas being forwarded to a more formal committee.

4.8 The RECs within a particular geographical area should work collaboratively, so that proposals can be directed to the most appropriate committee. It is important that good research should not be impeded by inappropriate bureaucratic procedures. Each proposal should only have to go through one review system.

4.9 As far as possible RECs, and ethics review more generally, should be independent of the organisation within which the research is to be carried out. The difficulty of maintaining this principle is shown in the case of NHS RECs, where often members are also employees of the Health Authority. In this case independence is partly protected by the provision that at least one third of the membership will be lay members who are independent of the NHS, and whose primary personal or professional interest is not in research. The principle of having at least one third lay membership, and members representing service users and carers, should be followed in any REC or ethics review system dealing with social care research.

Legal liability

4.10 The appointing Authority is responsible for providing suitable facilities in which the work of ethics review can be undertaken in a confidential manner. These facilities should include adequate provision for handling and storing confidential documents.

4.11 The appointing Authority should also take full responsibility for all the actions of a member in the course of the performance of his or her duties as a member of the REC or ethics review panel, other than those involving bad faith, wilful default or gross negligence.

5 MEMBERSHIP REQUIREMENTS AND PROCESSES

5.1 Members of social care RECs and expert ethics review panels should:

- be independent and unbiased in their working
- be selected following a transparent process
- include service users and their representatives
- be offered appropriate training and education
- maintain confidentiality about their deliberations
- have a rotation system for membership.
- have an identified Chair and an Administrator

5.2 Any social care ethics review system would be expected to follow the broad principles of ethics review set out in Chapter 8. More specifically, it should be constituted to ensure the competent review of all ethics aspects of the research, to include expertise from a wide range of relevant disciplines, and to ensure that the review can be executed free from bias and from any influence that could affect independence in reaching a decision.

5.3 Appointment of the Chair and members should be by an open and transparent process. Vacancies should be filled following public advertisement in the press, and/or by advertisement via local professional, service user and other networks, as appropriate to the vacancy to be filled. Potential candidates should be required to complete an application form. The process for the selection of members shall be laid down in standard operating procedures.

5.4 An appointed member of a social care REC or ethics review panel must be prepared to have published his/her full name, profession and affiliation. When making appointments, conflicts of interest should be avoided if at all possible. There should be transparency with regard to such interests, and they should be recorded and published with the above personal details.

5.5 Normally an appointed member of a REC would be required to attend in full at least two thirds of all scheduled meetings in each year, barring exceptional circumstances. A member of an ethics review panel would be expected to review between 10 and 15 proposals per year, in the system costed in Chapter 3.

5.6 As a condition of appointment, a member must agree to take part in initial and continuing education appropriate to his or her role as an REC or panel member. Members would be expected to maintain confidentiality regarding meeting deliberations, applications, information on research participants, and related matters.

5.7 An appointed member should be informed in writing of the terms of the appointment, including its duration, the policy for renewal, the disqualification procedure and the resignation procedure, the policy concerning declaration of interests, and details of allowable expenses. The appointing Authority should provide

each appointed member with a personal statement regarding the indemnity provided, and its conditions.

5.8 Members should be appointed for fixed terms, normally five years. Terms of appointment may be renewed, but not normally more than two consecutive terms should be served on the same REC or ethics review panel. However, a member may subsequently serve in another research ethics review system. The appointing Authority should ensure that a rotation system for membership is in place that allows for continuity, the development and maintenance of expertise within the review system, and the regular input of fresh ideas.

5.9 Each REC or tiered system should have a Chair or Research Governance Manager who would be responsible for ensuring that the system worked efficiently. Some CSSRs already have a member of the Senior Management Team who takes responsibility for research, or a Research Officer who could undertake this role. A Chair drawn from outside the organisation might expect to be paid, or at least given an honorarium, while someone from inside the organisation would expect research governance to be recognised as part of his or her work load.

5.10 Having an administrator is essential if the work of ethics review is to be conducted efficiently and without undue delays. The administrator of a REC should not be a member of the committee, but should be responsible for keeping track of proposals as they go through the system, arranging meetings, ensuring that papers are circulated in advance, taking notes of the discussion and communicating approvals to researchers. Where the REC has reservations about the proposed research, these should be communicated to the researchers by the Chair of the committee.

5.11 The administrator of a system in which proposals are reviewed by a panel of ethics reviewers will be responsible for keeping track of proposals as they go through the system, arranging meetings, ensuring that papers are sent to appropriate reviewers, re-allocating proposals if reviewers are not able to respond within the time limits, and, when reviewers disagree, coordinating responses for committee meetings. Where the ethics reviewers, and/or the Chair, have reservations about the proposed research, these should be communicated to the researchers by the Chair of the committee.

6 THE COMPOSITION OF A SYSTEM OF ETHICS REVIEW

6.1 Social Care RECs or ethics review panels should be set up in such a way that the membership:

- contains expertise in the relevant academic disciplines and research techniques
- includes members who are service users and their relatives
- has a spread in terms of age and gender, and if possible ethnicity and disability
- has at least one third of the membership being independent of the organisation where the research is to take place
- is large enough to guarantee the presence of a quorum at each meeting.

6.2 For a REC the maximum number of members in any one committee might be 12-15, meeting monthly. The numbers in a tiered system will be greater, but their tasks will be rather different. The costed option in Chapter 3 assumes that each region might have a panel of 40 reviewers, but around nine committee members, meeting formally twice a year.

6.3 Overall the REC and the review panel should have a balanced age and gender distribution. Members should be drawn from both sexes and from a wide range of age groups. Every effort should also be made to recruit members from black and ethnic minority backgrounds, as well as people with disabilities. At least a third of the members must be independent of any organisation where research under ethics review is likely to take place.

Expertise among the members

6.4 The members of an REC or an expert review panel should be chosen to ensure that the following are available:

- academic expertise in the social sciences, including, for example, specialists in social policy, sociology, economics, political science, anthropology and the law
- research expertise in a range of qualitative and quantitative research methods
- professional practice in one of the relevant professions, such as social work, occupational therapy, probation, counselling and so on
- expertise acquired from recent experience as a service user or as the relative of a service user.

6.5 Questions have been raised about the potential conflicts of interest involved in university RECs reviewing proposals from academics, and students, working within the same institution. This point also applies in NHS RECs, which often review research proposals coming from clinicians employed by the same health authority or trust. Any system of research governance will need effective checks and balances, so that the sectional interests of one agent, such as the researcher or research employer, are balanced by the different interests of other agents, such as the funder or care

organisation. It is particularly important that the operation of ethics review is independent from that of any other sectional interest.

Non-representative roles

6.6 Despite being drawn from groups identified with particular interests or responsibilities in connection with health and social care issues, REC and panel members are not in any way the representatives of those groups. They are appointed in their own right, to participate in the work of the REC as equal individuals of sound judgement, relevant experience and adequate training in ethics review.

Employed members

6.7 Organisations should provide encouragement to their staff who wish to serve as members of RECs. The time required for undertaking such service and the necessary training should be protected, and form a recognised part of the individual's job plan.

Quorum requirements

6.8 For REC meetings at which research ethics review is undertaken, there should be guidance as to what constitutes a quorum. This should include the Chair and/or Vice-Chair, at least one member with the relevant academic and/or methodological expertise, one 'professional' member, one service user member as defined above, and at least one member who is independent of the institution or specific location where the research is to take place.

7 WORKING PROCEDURES

7.1 A system of ethics review should have standard governance arrangements and operating procedures that state:

- the Authority under which the REC or panel is established
- the functions and duties of the REC or panel
- membership requirements
- the terms and conditions of appointment of members
- procedures for handling proposals
- quorum requirements for committees

7.2 The appointing Authority is responsible for the governance of the REC or of the panel in this respect, and should ensure that account is taken of all guidance issued by the Department of Health.

7.3 All reimbursement for work or expenses, if any, within or related to a REC should be recorded and made available, by the Authority, to the public on request.

7.4 A register should be kept of all the projects which come for ethics approval. This register will be available for public consultation. The register should form the basis of the Annual Report to the appointing Authority.

7.5 An ethics review system should retain all relevant records for a period of at least three years after completion of a research project, and should make them available upon request to any regulatory authorities.

7.6 It should always be possible to demonstrate that the REC or panel has acted reasonably in reaching a particular decision. When research proposals are rejected, the reasons for that decision should be made available to the applicant.

7.7 Ethics review systems should be able to consider valid applications in a timely manner. A decision should be reached and communicated to the applicant within 60 calendar days of the submission of a valid application, following the deadline set by the European Directive 2001/20/EC.

7.8 It follows that there should be a sufficient frequency of REC meetings, or a large enough panel of reviewers, to complete the business in a timely manner. The systems should not be expected to accept a workload that compromises the quality of ethics review. When this is likely, the Authority should establish additional RECs, or make formal arrangements for other methods of reviewing proposals.

Confidentiality of proceedings

7.9 Ethics reviewers need to be able to discuss freely the proposals that come before them. For these reasons REC meetings will normally be held in private and any

system of expert review should maintain confidential records. However the reviewers' final decision should be made publicly available, together with a summary of the research proposal prepared by the researchers. Publicly available information should include:

- the names of the researcher and sponsor, and of the research site
- a simple summary of the research proposal comprehensible to a lay person
- the committee's conclusions and overall opinion.

Producing an Annual Report

7.10 Within six months of the end of each financial year, an Annual Report should be prepared for the appointing Authority. The report, which should be available for public inspection, should include:

- the names, affiliations and occupations of committee/panel members
- number and dates of meetings held
- attendance of members
- a list of proposals considered, and the decisions reached on each
- time taken from acceptance of application to final decision on each proposal
- the training undertaken by the committee and by its members

8 THE PROCESS OF ETHICS REVIEW

8.1 The following principles are important in the process of ethics review:

- there should be an established procedure for the ethics review of research proposals, which is well publicised within the appointing authority
- time standards should be set up and adhered to
- the welfare of research participants should be the prime consideration
- the issues considered should include informed consent by research participants and their relatives, respect for privacy and confidentiality, data protection and storage, and any risks to participants or to research staff

8.2 Procedures for the review of social care research should be established by the appointing Authority and set out in a publicly available document. These should be well publicised, and researchers should be encouraged to submit a proposal as soon as approval for the research has been granted by the funding body or by the organisation where the work is to take place.

8.3 In applying for ethics approval researchers should complete an application form and attach copies of the research proposal and any other relevant documents. The application form should not be unduly complicated. In most cases it is not reasonable to ask researchers to submit copies of research instruments. In much social care research developing the instruments is done in collaboration with service users and may well be part of the research process.

8.4 In general RECs should meet regularly on scheduled dates that are announced in advance. Meetings should be planned in accordance with the needs of the workload, but RECs must meet the time standards for review. REC members should be given enough time in advance of the meeting to review the relevant documents.

8.5 The timescale should be such that research is not unduly delayed. Much social care research takes place over relatively short time spans so it is important that the dates of meetings and the time standards for the approval of proposals are well publicised.

8.6 The applicant (and if appropriate, the sponsor and/or other investigators) shall be invited to be available to elaborate on or clarify specific issues as required by the REC at its meeting. Any process of ethics review should not cause unnecessary delay by deferring consideration of an application when the necessary further information it requires could have been obtained from the applicant before the meeting.

Research methods and legal requirements

8.7 The Research Governance Framework makes it clear that the sponsor is responsible for ensuring the quality of the science. Thus proposals submitted for ethics review should already have had prior critique by experts in the relevant

research methodology, who should also comment on the originality and value of the research. It is not the task of the REC or ethics review panel to undertake additional scientific review.

8.8 However, there may be an issue about the provision of advice and support to researchers. Past experience suggests that some ethics review systems have been faced with research proposals where the methods are inappropriate or ill thought through. In other instances unanticipated ethical issues may arise in the course of carrying out research. In the NHS assistance can be given to less experienced researchers by members of funded R&D Support units. These have been developed in response to the Research Governance Framework and have reduced the amount of time that ethics committees spend on methodological issues and on inappropriate applications. They can also give advice when ethical issues during a project. Is there a need for an equivalent for social care?

8.9 In addition to considering prior scientific review, RECs need to take into account the potential relevance of applicable laws and regulations. It is not the role of ethics reviewers to offer a legal opinion, but they may advise the applicant and the organisation where the research is to take place whenever it is of the opinion that further expert legal advice might be helpful to them.

Requirements for a favourable opinion

8.10 Before giving a favourable opinion, the REC or ethics review panel should be adequately reassured about a number of issues. First among these are the implications of taking part in the research for all those who will be involved. Research participants should not knowingly be exposed to **harm or distress**. However, it was significant that some of the service users who were consulted about ethics review argued that avoiding causing distress might not always be appropriate, since some important topics, which should be researched, were by nature distressing. If this is likely to be the case, researchers should ensure that some support or counselling is available if a research participant becomes distressed.

8.11 The issue of **informed consent** is a significant one in social care research, where many of those involved are likely to be vulnerable on the grounds of their youth or old age, or because of their disabilities.

8.12 Social care ethics reviewers should expect to receive a full description of the process for obtaining informed consent, including the identification of those responsible for obtaining consent, the time-frame in which it will occur, and the process for ensuring consent has not been withdrawn. They will want to be reassured about the adequacy, completeness and understandability of written and oral information to be given to the research participants, and, when appropriate, their legally acceptable representatives.

8.13 There should be clear justifications for including in the research individuals who cannot consent, and a full account of the arrangements for obtaining consent or authorization for the participation of such individuals.

8.14 Provisions should also be made for receiving and responding to queries and complaints from research participants or their representatives during the course of a research project.

8.15 Respect for **privacy and the maintenance of confidentiality** will be of central concern in the process of ethics review. Reviewers should expect to be told about the measures which will be put in place to ensure the confidentiality and security of personal information concerning research participants. The proposal should include a description of the persons who will have access to the personal data of the participants, information about where the data will be kept and reassurances about procedures for anonymising and protecting the data. This particularly applies when data is to be lodged with the ESRC Data Archive at the University of Essex.

8.16 It may be appropriate to be concerned about contacts with other professionals in the course of the research. For example, do the researchers plan to contact, to consult or to collect data from the research participant's GP, social worker or carer? Are interviews to be carried out with relatives, friends or neighbours of the participant? In this case reviewers may want to be reassured about the processes by which such contacts take place and about the confidentiality of the data collected.

8.17 There may be limits on confidentiality, for example, when a respondent discloses information which a professional has a statutory duty to report. If this might be the case, it is important that those taking part in the research are warned in advance about the limits to the promise of confidentiality.

8.18 The **care to be provided to research participants** during and after the course of the research is also likely to be of concern. This may include making provision for social or psychological support if taking part in the study proves to be distressing for any participant or his or her relatives. Social care research can involve very intimate and sensitive topics, and even when researchers have taken every precaution against causing distress, they may find that particular individuals are vulnerable in unexpected ways.

8.19 It may also be necessary to be concerned about the **welfare of research staff**. Some social care research involves researchers going into homes and areas of cities where they may be at risk. In addition some research participants may respond with aggression to questions which they perceive as intrusive. Consideration should be given to whether any such dangers might occur in the study in question, and if so what steps are being taken to minimise the risk to research staff.

8.20 Concern about the care provided to research participants may extend to any **costs** which they are likely to incur through taking part in the study and any rewards which they are likely to be offered in exchange for their participation. Many of those

who take part in social care research are among the poorest members of society, and yet they are expected to give their services freely, in a way which would never be expected of researchers or care professionals.

8.21 Effective **dissemination of research results** is part of a researcher's responsibility. However, dissemination may also raise ethical issues. What arrangements will be made for dissemination and will participants be invited to take part in dissemination events? It would be relevant to ask about plans to make the results of the study available to the research participants following the research and whether this may involve any issues of confidentiality.

8.22 From a **legal perspective** it may be appropriate to consider whether there is provision, in proportion to the risk, for compensation in the case of injury/harm suffered by a research participant attributable to participation in the research; this may involve insurance and indemnity arrangements

Decision-making

8.23 In making decisions on applications, a social care REC or reviewer should take the following into consideration:

- a member should withdraw from the meeting, or refuse to undertake ethics review, for an application where there may be a conflict of interest
- an REC should not review an application in which one of its own members is a named researcher; such applications should be submitted to another REC
- decisions should only be made at meetings where a quorum is present
- the documents required for a full review of the application shall be complete before a decision is made
- there should be a pre-determined method for arriving at a decision; it is recommended that decisions be arrived at through consensus where possible; where a consensus is not achievable, the REC should vote.
- the Chair may have a casting vote.
- advice that is not binding may be appended to the decision.
- in cases of conditional decisions, clear suggestions for revision and the procedure for having the application re-reviewed should be specified.
- the rejection of an application should be supported by clearly stated reasons.

8.24 When decisions are being made by an expert review panel many of the above considerations are relevant. Proposals should not be sent to reviewers who may have some association with the research team or where there may be some conflict of interest.

9 SUBMITTING AN APPLICATION

9.1 The application shall be submitted by the ‘chief investigator’ who is the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study. It follows that the applicant should be of adequate qualifications and expertise to fulfil this important role.

9.2 Where a potential applicant is inexperienced, there should be an identified supervisor of adequate quality and experience who will counter-sign the application form, and then share the responsibility for the ethics and scientific conduct of the research. In this case a current CV of the supervisor should be submitted with the application.

9.3 Any ethics review system should ensure that the requirements for submitting an application for review are described in an application procedure that is readily available to prospective applicants.

9.4 Research to be undertaken by students primarily for educational purposes shall be considered according to the same ethics and operational standards as are applied to other research. However, given the numbers of such projects in the social care field, it may be appropriate for there to be a sift stage in the process of applying for ethics approval. This would make the option of a tiered system attractive. COREC currently has a Working Group concerned with Student Research, and the report from this group is very relevant to the debate about student research in social care (Doyal, 2004).

The documentation

9.5 All documentation required for a review of the ethics of the proposed research should be submitted by the applicant. This should normally include a:

- signed and dated application form
- the proposal for the planned research, together with supporting documents and references and details of any scientific peer review
- description of the ethical considerations involved in the research
- the applicant’s current curriculum vitae
- description of the process to obtain informed consent
- an account of arrangements for data anonymity, storage and protection
- statement describing any compensation for study participation to be given to research participants
- description of the arrangements for indemnity and for insurance coverage for research participants, if applicable
- statement of agreement to comply with ethical principles set out in relevant professional guidelines, and the identity of such guidelines
- commitment to making the results available to research participants
- commitment to producing a final report and relevant publications

GLOSSARY

Clarification is given here of the meaning of some of the terms as used in this document, and as used in the *Research Governance Framework for Health and Social Care*.

Appointing authority - the body responsible for setting up and running the system of ethics review. These may be based in the Offices for Research Ethics Committees set up by COREC, in a regional Government Office, in one or more social care organisations, or in a partnership between a university and social care organisations.

Approval – a term in common usage which merely affirms that the REC has given a favourable opinion. It should be noted that, by itself, such approval by a REC does not entitle a researcher to proceed with the research. All research taking place within a care organisation will additionally require the approval of that organisation.

Care organisation - the organisation(s) responsible for providing care to those participating in the study.

Employing organisation(s) - the organisation(s) employing the chief investigator and/or other researchers. The organisation employing the chief investigator will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funder(s) are responsible for the management of the funds provided, for promoting a quality research culture and for ensuring that researchers understand and discharge their responsibilities.

Ethics review panel - a panel of individuals, chosen for their expertise in the relevant academic disciplines, in social care professions and policy making, or as service users and their relatives. They can be called on to review specific research proposals and communicate their views to the administrator and/or chair of the panel.

Funding bodies - organisation(s) providing funding for research through contracts, grants or donations to an authorised member of either the employing and/or care organisation.

Participants - those taking part in the research as interviewees, respondents, members of focus groups, and so on, or allowing information about themselves to be used for the purposes of research. In some legal and regulatory documents the term “subject” is used instead.

Chief investigator - the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of the study and for seeking research ethics committee approval.

Research Ethics Committee – the committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations

and professionals on the extent to which proposals for the study comply with recognised ethics standards.

Researchers - those conducting the study at individual sites. Key responsibilities of researchers include conducting research according to the agreed proposal, adhering to ethical and legal requirements, and ensuring participant welfare in respect of the conduct of the research.

Care professional - the professional responsible for the care of the participants while they are taking part in the study. Key responsibilities include ensuring that a REC has approved the study and retaining responsibility for research participants' well-being.

LIST OF ACRONYMS

ADSS	Association of Directors of Social Services
CSSR	Council with Social Services Responsibilities
COREC	Central Office for Research Ethics Committees
DoH	Department of Health
GAFREC	Governance Arrangements for Research Ethics Committees
HR	Human Resources
IT	Information Technology
LREC	Local Research Ethics Committee
MREC	Multi-centre Research Ethics Committee
NI	National Insurance
OREC	Office of Research Ethics Committees
NHS	National Health Service
REC	Research Ethics Committee
RGF	Research Governance Framework

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