ETHICS REVIEW IN
SOCIAL CARE RESEARCH

REPORT FROM THE PLANNING GROUP ON
ETHICS REVIEW IN SOCIAL CARE RESEARCH
TO THE DEPARTMENT OF HEALTH

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SUMMARY OF THE REPORT FROM THE PLANNING GROUP

1.1 This report outlines the recommendations of the Planning Group on Ethics Review in Social Care Research set up by the Department of Health. The Group met three times over 2006-07 and brought together a range of relevant interests, including those of other government departments and devolved administrations (Appendix 1 lists the members).

1.2 The aim of the Planning Group was to make recommendations for a comprehensive system of social care ethics review, following the formal Public Consultation in 2005. A key objective was to ensure that any system covered both children and adult sectors and research that cuts across national boundaries. The remit of the group covered the ethics review of social care research, but not the research governance responsibilities of organisations employing researchers or of research sites.

1.3 The Planning Group spent some time discussing the definition of ‘research’ in the context of social care. It was argued that research ethics review should be limited to ‘studies managed and presented as research’. However, in the field of social care a great variety of studies could come within this definition and the desire to be inclusive had to be balanced against the need to limit the workload on any ethics review system.

1.4 The Warner Review of NHS RECs, accepted by the government, recommended that certain types of research be excluded from the NHS ethics review system, such as surveys or service evaluations. The planning group felt that this would be inappropriate in the social care context. The key issue was seen to be the level of risk involved, not the design or purpose of the research.

1.5 It was agreed that the broad definitions provided by the National Research Ethics Service (NRES) and the Economic and Social Research Council (ESRC) were useful starting points and that a process of risk assessment, using the DH Risk Assessment Tool (see Appendix 4), should be undertaken within the ethics review process, to identify low risk research, requiring less intensive subsequent review.

1.6 Members of the Planning Group were concerned that any system of ethics review should include service users effectively and should support their participation in appropriate ways. Consultations with service users have underlined the contribution which ‘experts by experience’ can make to every stage of research. At the same time service users have made the point that people, having been fully informed, have the right to decide for themselves whether or not to take part in research.

1.7 The Planning Group recognised that much social care research is adequately covered by existing ethics review systems. Research involving the NHS must be reviewed by the research ethics committees (RECs) within the NRES and the equivalent provisions established by the UK Health Departments. Research funded by the ESRC is scrutinised by committees operating under the ESRC Research Ethics Framework (REF). Other social care research undertaken by staff or students within a Higher Education Institution (HEI) may be reviewed by the appropriate committee within the HEI. Some Councils with Social Services Responsibilities (CSSRs) have access to local committees to review ‘own account’ and other research requiring access to service users or staff.

1.8 However, the Group agreed that there is a need for provision of ethics review for research not currently covered by these systems. The volume of this research is not currently known, but it could include some or all of the following research:
• undertaken by researchers not located in or linked to an HEI;
• high-risk research undertaken by local councils and their staff in areas without
research governance systems
• conducted by central government and its regulatory bodies.
• conducted by staff or students within HEIs without access to an internal REC.

1.9 It was suggested that ethics review in social care should operate at two main levels.

• At Level 1 the review of science and ethics of ‘own account’ research will be
undertaken as part of more general research governance systems within local
Councils. These systems may be within a single Council or part of emerging local
governance alliances between Councils. Many will link with existing systems within
universities or the NHS.

• Level 2 will consist of a central Social Care REC (SCREC) to approve cross-national
and/or multi-site research, including that undertaken by collaborating Councils. It is
yet to be decided whether this level will also be responsible for standard setting,
accreditation, training and guidelines for operating at Level I, but it would ideally act
as a source of advice and support for Level 1 review systems.

The task of the Planning Group was to make proposals for the setting up and running of the
SCREC intended for Level 2 of this system.

1.11 The SCREC will be part of the NRES and will receive comparable support, and operate
to the equivalent standards of, other RECs within the NRES. To ensure ownership by the
social care community, it was recommended that the SCREC is located within a social care
body and that this body undertakes the role of the Appointing Authority (AA). The Social
Care Institute for Excellence (SCIE) was suggested as a possible body. The AA and the
SCREC should have comparable resources to AAs and RECs within the NRES.

1.12 The SCREC will operate as a flagged committee within the NRES, so that eligible
multi-site proposals, specific to the social care context, which are submitted to the NRES
could be re-directed to it. However, most social care research has no connection with the
NHS. The SCREC will expect to receive proposals directly from many other sources, such
as central and local government, non-university-based researchers, charities and the
independent sector. The SCREC should be approved as an Appropriate Body under the
Mental Capacity Act.

1.13 The SCREC should be subject to standard operating procedures that reflect and
respect the social care context, while being comparable to those applying elsewhere in the
NRES. The Planning Group stressed that it was important that the membership and
composition of the AA and the SCREC should command the confidence of the social care
community. The application process will need to take account of social science designs and
methods, as will the documentation required of applicants.

1.14 It will be essential that research proposals do not have to go through more than one
ethics review system. In order to avoid such duplication, it will be important to manage
actively the interface between the different systems of ethics review. The NRES will make
appropriate links with the review systems in the devolved administrations.

1.15 The next stage will be to identify the financial resources necessary for the proposed
system, since SCIE is not currently funded to take on either the AA or the SCREC. The
Planning Group received a Briefing Note and Proposals from the ADASS which will provide
a broader context for future discussions.
2 BACKGROUND

2.1 The DH Research Governance Framework (RGF) specified that health and social care organisations should have systems in place for ensuring that all research proposals gain independent ethical approval (Department of Health, 2001a and 2005). In the NHS there is a well established system, now placed within the National Research Ethics Service (NRES). Wales and Scotland have developed their own systems for research governance, but were represented at the meetings of the Planning Group, in recognition of the support for increased cooperation in this field (Scottish Executive Health Department, 2006; Wales Office of Research and Development for Health and Social Care, 2001).

2.2 However, the field of social care is rather different from the NHS. (See Appendix 3 for a summary of some key differences in resources and staffing). Recognising this, the Department of Health (DH) initiated a process of information gathering, mapping and consultation in England before issuing an Implementation Plan for the RGF in social care (DH, 2004). The consultations involved professional and academic organisations in the social care field, researchers and research funders, groups representing service users and carers, relevant statutory and voluntary organisations in the social care field, and others.

Initiatives to support research governance in social care

2.3 Between 2001 and 2006 a series of initiatives was undertaken in England to provide a firm base for implementing the RGF in social care. These included:

- Two Baseline Surveys of Research Governance in Social Care, undertaken in 2002 and 2005. These mapped the types of research going on within Councils with Social Services Responsibilities (CSSRs), collected information about systems for ethics review and other aspects of research governance, and documented the changes between 2002 and 2005. The 2005 survey showed that 39 per cent of CSSRs had a system in place for the independent review of ethics, while another 32 per cent had plans for a system by 2006 (Pahl, 2002 and 2006).

- A Mapping Exercise on Social Care Research, which looked in detail at all the research studies taking place within eight local authorities (LA). It showed that only 20 per cent of the research projects taking place were funded externally; most were being carried out by internal research staff or by social care professionals as part of their jobs (Boddy and Warman, 2003).

- Consultations about research governance in Social Care, which began the process of discussing the RGF with those who work in and for social care and those who do research in that field. The result was the 2004 Implementation Plan for Social Care, which set targets for the dates by which different parts of the RGF were to be in place (Department of Health, 2004).

- Consultations with service users and carers about the ethics of research, about the forms which ethics review should take, and about supports for the participations of service users and carers. Many of these consultations were set up by INVOLVE or by the Learning Disability Research Network (INVOLVE, 2005).

- A Consultation on Systems of Ethics Review. This offered four options for different systems for ethics review in social care and set out some operating procedures. The different systems were costed and comments were invited on the options put forward (Pahl, 2004).
• A report on the Consultation on Systems of Ethics Review (Pahl, 2005). Around 50 responses, from both health and social care, were received to the consultation, with strong representation from all the main organisations in the social care field.

• Setting up of a Planning Group for a Central Social Care Research Ethics Committee. This report summarises the discussions which took place at the first three meetings of the Planning Group, and draws on the ideas and information coming from the other initiatives listed above.

2.4 The Department of Health also funded a series of initiatives aimed at advising and supporting those who would be responsible for managing research governance and ethics review at local levels in CSSRs. These initiatives included:

• Work by the Research Governance in Social Care Advisory Group (RGSCAG), which was set up by DH, and which draws together representatives from a range of different organisations in social care, including the Social Services Research Group (SSRG), the Association of Directors of Adult Social Services (ADASS), the Association of Directors of Children's Services (ADCS) and research active CSSRs.

• Production of an RGF Resource Pack (SSRG, DH and ADSS, 2005). This was the result of work by the RGSCAG, and its aim was to help research leads within local authorities (LAs) to implement the RGF in social care. It is available both in hard copy and as a CD (SSRG, 2005).

• The provision of Start-up Grants for CSSRs (DH, 2005). These were funded by DH and were for LAs and groups of LAs to help with the costs of setting up systems for research governance.

• A series of nine regional Training Workshops (SSRG, 2005). The workshops aimed to inform research leads within LAs about the RGF and to help them to implement the RGF in their own area.

Consultation on a system for ethics review

2.5 The aim of the 2005 Consultation was to invite views on an Option Appraisal of systems for the ethics review of social care research. Four models for the ethics review of social care research were presented and respondents were asked to identify their preferred option. The options were:

Model 1: A national system of social care Research Ethics Committees 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 Committees (now NRES);

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

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

2.6 The choice of system reflected the sector from which the responses came. Responses from the field of social care and the voluntary sector overwhelmingly opted for Models 3 and 4. Responses from the universities tended to favour Models 3 and 4, but some of those
coming from health-linked university departments opted for Model 2. Responses from the NHS tended to favour Models 1 and 2, which proposed a system similar to the NHS system of the time.

2.7 Several respondents argued for a system of ethics review which would combine the best features of Models 3 and 4 above. ‘Model 3/4’ was a three tier system: it would consist of a central ethical committee to approve national and multi-site research, regional consortia to approve high-risk and inter-authority research, and research governance systems within CSSRs to approve the majority of the work which takes place within local authorities. It was pointed out that many of the structures which would be necessary for this system are already in place, though additional funding would be essential at every level. Standard setting, accreditation, and training would be done at the national level.

2.8 Some respondents suggested using the ethics review systems already in existence in universities, arguing that they would provide independent expertise and impartiality in a way which systems embedded within the health service or the social services could not.

2.9 Desirable qualities in a system of ethics review were seen as: the ability to deal efficiently and equitably with a large number of research proposals; the involvement of a range of stakeholders with appropriate expertise, including service users; the use of different levels of scrutiny depending on the level of risk of the research; the ability to deal with multi-agency and multi-site research; and the existence of a central function to collate information about research and provide for standard setting, accreditation and training.

2.10 There were concerns about: supporting service users and carers in their role in ethics review; balancing any central function with the need to be locally responsive; creating a system which would be of similar standing to the NHS system; the use of electronic forms of communication; the assessment of risk in social care research; appropriate scientific scrutiny of research methods and financing the system.

2.11 Many respondents feared that a complex and bureaucratic system of ethics review could destroy the capacity of research to contribute to the development of better social services. They argued that social care researchers already face considerable barriers in terms of inadequate funding, short term contracts and lack of a career structure. A clear view was that any system of ethics review should support, and not deter, social care researchers and research.

Planning Group for a Central Social Care REC

2.12 The Planning Group had three main aims, which were:

- to bring together representatives of organisations and interest groups concerned with ethics review in social care, together with those of other government departments and devolved administrations
- to make recommendations for a comprehensive system of social care ethics review, following the public consultation which took place in 2005
- to ensure that any system would cover both children and adult sectors of social care and would operate across national boundaries.

2.13 The Planning Group met three times between October 2006 and January 2007. The members of the Group are listed in Appendix 1. This report summarises the results of their discussions.
3 KEY DEFINITIONS AND PRINCIPLES

3.1 A number of key terms and principles have been the subject of extensive discussion. It is important to begin by clarifying these in order to provide a firm basis for future planning for an ethics review system in social care.

Definitions of research

3.2 Many different definitions of research have been put forward in the course of debates about the implementation of the RGF in Health and Social Care. A clear distinction can be made between definitions which focus on the:

- aims and methods of the study;
- contractual position of the researchers;
- degree of potential risk posed by the study.

A suggestion that ethics review should be limited to ‘studies managed and presented as research’ would face the problem that in the social care field a great variety of studies, from ad-hoc surveys by service users to small evaluations of their service by professionals, are likely to be presented as ‘research’. By the same token, studies which did not describe themselves as ‘research’ might be so in all but name, such as ‘surveys’, and raise ethical issues which were just as significant as other studies described as ‘research’.

3.3 Various definitions of research were discussed by the Planning Group; in addition, a paper on this topic was prepared by the Association of Directors of Adult Social Services (Dolan and Woolham, 2007). This paper outlined some relevant research issues within CSSRs, before considering definitions of research offered by ESRC and COREC (now NRES).

3.4 Within CSSRs, as elsewhere, decisions must be made about whether a particular activity or project, designed to obtain information or knowledge of some kind, should be described as research, or as something different, such as audit or evaluation, service development, routine or non-routine management information; consultation or review.

3.5 Projects which may appear very similar can be differently classified, as audit or evaluation or consultation rather than research, possibly to evade formal RGF requirements. Some authorities restrict the possibilities for evasion by throwing the net very widely and having a similar accountability system for audit and consultation activity.

3.6 However, throwing the net widely, and drawing a wide range of activity into the RGF procedures would produce an enormous workload to be sifted. Equally importantly, it could require RECs to consider types of risk that lie outside their proper remit and expertise. In addition, there could be compliance issues for those CSSRs with complex and wide ranging RGF arrangements.

3.7 It should be noted that for CSSRs research governance is an administrative requirement, not a standard, though it is partly backed by statutory instruments in respect of clinical trials and human tissue research. However, the Human Rights Act, the Data Protection Act and the Mental Capacity Act apply in social care, as they do in other settings. Also, like other research sites, a CSSR may be liable for negligent harm if it is responsible for the person who caused the harm and owes a duty of care to the person harmed. Even non-negligent harm could prompt claims of maladministration.
The paper from the ADSS posed some questions about the relevance of different definitions of research in the social care field, recognising that much social care is outside the statutory sector; and neither research governance nor human rights safeguards have much purchase (Dolan and Woolham, 2007). These questions were:

1. Is the definition too constraining or too wide in the social care context?
2. What extra guidance would be necessary to refine or support the definition to meet the particular needs of CSSRs?
3. What would be the impact on researchers, including student and in-house CSSR researchers?
4. What would be the impact on research participants in terms of safeguards from risk?
5. What would be the impact on research quality?

With these considerations in mind, we turn to the definitions of research put forward by COREC and by the ESRC.

The COREC definition was drawn from the DH Research Governance Framework. It focused on the aims and methods of research and made a distinction between research, audit and evaluation, with research defined as follows:

Research is the attempt to derive new knowledge, including studies which aim to generate hypotheses, as well as studies that aim to test them. It addresses clearly defined questions, aims and objectives…and…and usually involves collecting data that are additional to those for routine care.

By contrast, clinical audit and service evaluation are defined in terms of producing information to inform the delivery of care or to judge current care. It is not considered necessary to submit audit and service evaluation to REC review since it is assumed that there is no element of risk (COREC, 2006a). The Warner Review argued that the remit of NHS RECs should not include ‘surveys and other non-research activity if they present no material ethical issues for human participants’ (COREC, 2006b). This was accepted by the government.

The COREC definition of research is relatively narrow, however, and in the social care context would mean that many activities involving the collection of information from service users or staff, using standard research methods, would not come within the RGF. There is also a danger in confusing design (i.e. survey) with purpose (i.e. evaluation). Those who work in social care have argued that it is impossible to ‘read off’ the level of risk from the design or purpose of the study. Simply because a study is described as a ‘survey’ or an ‘evaluation’, it does not necessarily have lower levels of risk or other ethical problems, compared with a study described as ‘research’ (a RCT is an evaluation, after all).

However, the COREC definition does limit the workload and resource implications of ethics review, by excluding other types of risk that fall within the wider management responsibilities of organisations commissioning or providing social and health care.

By contrast the Economic and Social Research Council (ESRC) in its Research Ethics Framework adopted a very broad definition:

Research is any form of disciplined enquiry that aims to contribute to a body of knowledge (ESRC, 2005, 7)
This definition is extremely wide and would cover activities such as non-financial audit, user consultation and service evaluation. However it could arguably also capture other activities, such as journalism or desk research, which would lie outside the remit of the RGF.

3.13 In social care there has been a continuing debate between two points of view. On the one hand, some argue that ethics review should be undertaken for any enquiry which involves access to service users, their relatives, or members of staff. On the other hand, there are those who point to the workload that this would generate, to the costs of ethics review and to the delays that would occur in carrying out research, if RECs’ time were dominated by reviewing a wide range of information-gathering activities outside their remit.

3.14 The Implementation Plan for Social Care tried to resolve the issue in a different way. It adopted a deliberately broad definition of research that included: ‘...the systematic collection of data using recognised research methods and techniques’. However, in recognition of the resource implications, it proposed that the RGF should be implemented fully, but in stages, with the first stage being concerned only with:

All research that involves access to service user, carer or staff populations, including volunteers, by researchers who are not employees of the local Council or its contracted agencies (Department of Health, 2004, 4)

Thus the definition of research to be covered by the RGF was couched, not just in terms of the methods of the study being undertaken, as in the NRES and ESRC definitions, but also in terms of the contractual position of the researchers with regard to the local council.

3.15 The Plan proposed that at a second stage the scope of ethics review should be extended to all studies undertaken within Councils with Social Services Responsibilities (CSSRs). However, in order to reduce the workload, it was suggested that care organisations should develop internal mechanisms for assessing the risk to participants, whether they be users, carers or staff. Low risk research studies would not need the same level of scrutiny as those of higher potential risk. This led to the development by RGSCAG of the RGF Risk Assessment Tool for social care research (Social Services Research Group, DH and ADSS, 2005).

The RGF Risk Assessment Tool

3.16 The Risk Assessment Tool aims to help those appraising a research proposal to assess both the likelihood of harm to participants and the overall level of risk. The Tool assesses risk under a number of different headings: subject/participant characteristics, researcher competence, nature of information being sought, methods being used, the relationship between the investigator and the participants, and the external sensitivity of the study. Each dimension is assessed in terms of the likelihood of harm. (See Appendix 4).

3.17 The Risk Assessment Tool can also help to ensure that the level of scrutiny given to a research proposal is proportionate to the likely degree of risk to the participants. It can be used to separate out and ‘fast track’ research projects in which the degree of risk to the dignity, rights, safety or well-being of research participants is low and where a more rigorous ethics review may be unnecessary. More potentially risky research can receive more detailed scrutiny or the attention of specialist advisers. Significantly the ESRC also advocates that proposals should be considered in the context of risk to the researched and the researchers (ESRC, 2005, 21).

3.18 There are some dissenting voices in the debate about risk in research. Experienced social researchers continue to argue that it is difficult to judge in advance whether a
particular project poses risks to participants. They support the concerns of the RGF about ensuring the dignity, rights, safety and well-being of research participants. However, they argue that many projects that might be considered risky by a REC prove in practice not to be so, while other, apparently uncontroversial projects can throw up unexpected ethical dilemmas. Consultations with service users have also made the point that they should be able to decide for themselves if the degree of risk is acceptable: the decision about taking part should not be made for them by a REC.

3.19 The Planning Group considered these issues and concluded that assessment of the level of risk is key to the ethics review of research. It advocated the use of the DH RGF Risk Assessment Tool, both at local and central levels.

Representation of service users and ‘lay’ members

3.20 Members of the Planning Group were concerned that the central Social Care REC should meaningfully include service users and lay members. The distinction between ‘lay’ members and service users was outlined in a paper by Steel (2006). The ‘lay’ role is that of counterbalancing the potential institutional biases of health and social care experts and is therefore essential. However, it is not the same as the kind of contribution that people from the ‘researched’ community, with substantial experience of using health and social care services, can give. This contribution is specific, as has been shown in many other areas of health and social care provision and research. Given that this group of people most often includes those whom health and social care ethics review seeks to safeguard, their perspectives would seem to be an essential ingredient in the process of ethics review.

3.21 It was proposed that the central Social Care REC should have ‘professional’, ‘lay’ and ‘service user/carer’ categories of membership. The proportion of members of each type requires further debate. In the NHS system it is specified that at least a third of the members of each REC should be ‘lay’ (Department of Health, 2001b). For a central Social Care REC this minimum might be divided into a portion of service user/carers and a portion of ‘lay’ members. However, it is probably more helpful to state that the perspectives of all three categories should be adequately involved than to talk about this in terms of membership proportions alone. The involvement of service users is just as much a matter of good chairing skills, a supportive ethos, inclusive practice and documentation, and informed working processes, as it is a matter getting the comparative numbers ‘right’ (Steel, 2006).

3.22 The diagram below demonstrates these different kinds of input:
3.23 To underpin this structure a network of expert individuals and organisations on which the Social Care REC can draw would be very desirable considering some of the responsibilities it would have to face. However, the network should also specifically include ‘expert’ service users/carers as well as ‘expert’ advocates from the organisations that support them. It is particularly important that this wider network also includes experts associated with groups who are traditionally marginalised, such as children and young people, older people, disabled people, learning disabled people, ethnic minorities, and families.

3.24 Further underpinning for a central Social Care REC would be provided by training. This should include bespoke operational training and guidance for all REC members, drawing where possible on NRES materials and other sources, suitably adapted for social care. Training, support and guidance should draw on service user and carer constituencies, in order to equip members with a broader awareness of the issues for groups in social care which are often the subject of research. This training, guidance and support might also be made available to other research ethics review bodies, whether local authority, university, or NHS based.

3.25 The working arrangements for the SCREC should reflect the need for good chairing skills, inclusive practice and documentation, and an informed group process towards effective decision-making that supports all REC members.

Conclusion

3.26 The Planning Group spent some time discussing the issues outlined above. Some, but not all, members of the Group argued that it was not appropriate to exclude certain types of research activity apriori (such as ‘surveys’ or ‘evaluations’) since the key issue was the level of risk involved to study populations. However, the need to be inclusive had to be balanced against workload implications and ensuring that the REC did not consider work that was outside its remit. It was agreed that the broad definitions provided by the NRES and the ESRC were useful starting-points and that a process of risk assessment, possibly using the
DH Risk Assessment Tool (see Appendix 4), should be undertaken to identify low risk studies requiring less intensive, or minimal subsequent ethics review.

3.27 The Planning Group recognised that much social care research is adequately covered by existing ethics review systems. Research also involving the NHS must be reviewed the research ethics committees (RECs) within the NRES and the equivalent provisions established by the UK Health Departments. To meet the requirements of the Mental Capacity Act, 2005 these services are being extended to be fully inclusive of social care research.

3.28 Research funded by the ESRC is scrutinised by committees operating under the ESRC Research Ethics Framework (REF). Social care research undertaken by staff or students within a Higher Education Institution (HEI) may be reviewed by the appropriate committee within the university. Some CSSRs have access to a local or shared ethics committee to review research carried out within the CSSR.

3.29 However, the Group agreed that there is a need for provision of review for research not currently covered by these systems. The volume of this research is not currently known, but it could include social care research:

- undertaken by researchers not located in or linked to an HEI;
- high-risk research undertaken by local councils and their staff in areas without research governance systems;
- conducted by central government and its regulatory bodies.
- conducted by staff or students within HEIs without access to an internal REC.

3.30 After extensive discussions, the Planning Group recommended the establishment of a single, central Social Care Research Ethics Committee (SCREC). In the following chapter some if the implications of this recommendation are explored.
4 A CENTRAL SYSTEM FOR ETHICS REVIEW IN SOCIAL CARE

4.1 The Consultation on Ethics Review in Social Care made it very clear that the social care field wanted a system of ethics review which would specialise in social care and would be located within, and managed by, the social care world (Pahl, 2005). There was widespread support for a central system of ethics review, operating within a tiered system in which many (probably most) projects would be reviewed only at regional or local levels.

4.2 The proposed system would, thus, have two main levels.

- At Level 1 the review of science and ethics of research will be undertaken as part of more general research governance systems within local Councils. These systems may be within a single Council or part of emerging local governance alliances between Councils. Many will link with existing systems within universities or the NHS. For externally funded research, ethics and science review will often have been undertaken before the approach to the Council is made. This should be taken into account, making the process of scrutiny less onerous and time-consuming.

- Level 2 would consist of a central Social Care REC to approve cross-national and/or multi-site research, including that undertaken by collaborating Councils. It is yet to be decided whether this level would also be responsible for standard setting, accreditation, training and guidelines for operating at Level I, but it would ideally act as a source of advice and support for local level review systems. ‘Multi-site’ would be assumed to be defined as five LA sites or more, as in the NHS.

4.3 The task of the Planning Group was to make proposals for the setting up and running of a SCREC intended for Level 2 of this system. This paper reports on the discussions which took place within the Planning Group, as a basis for wider discussions with all those concerned with the process of ethics review in social and health care and in relevant HEIs.

The location of a central Social Care REC

4.4 The Social Care REC Planning Group recommended that the SCREC should be identified with, and ideally located within, a respected social care body. The location of the SCREC should be considered with this in mind, insofar as it also meets researchers’ need for accessibility.

4.5 It was suggested that such a body should have responsibility for both children and adult services, and should be UK-wide in its remit. It should be independent of government and should have developed expertise in supporting service users in a variety of different roles in social care. Appropriate links would have to be made with existing review systems in the devolved administrations and with the new Research Register for Social Care (RRSC). The Planning Group suggested that the Social Care Institute for Excellence (SCIE) would be a suitable location for the central SCREC.

The Appointing Authority

4.6 In the NHS responsibility for establishing and governing RECs lies with the Appointing Authorities (AA). An AA is the body responsible under the Governance Arrangements for NHS Research Ethics Committees (GAfREC) for the establishment and support of an NHS REC (Department of Health, 2001b). The AA sets the annual budget for the system, ensures that adequate resources are available for the RECs and for the running of the system, and ultimately, accepts legal liability. In practice, however, no one has ever sued a REC or an Appointing Authority, let alone won any damages.
4.7 Since 1 April 2007 all NHS RECs in England have been managed together in one National Research Ethics Service (NRES), with some being ‘flagged’ for their specialist expertise. Strategic Health Authorities (SHAs) continue to be the AAs for all RECs in England. The NRES Central Allocation System ensures that proposals go to the most appropriate committee, which may be one with particular experience of reviewing the ethics of research in a specialist field, or one recognised under legislation for the review of certain types of research. Some AA responsibilities, such as training for REC members, are managed on a day to day basis by the NRES head office, but ultimate responsibility and legal liability remain with the AAs. SHAs are reimbursed from the NRES budget.

4.8 In Wales the Local Health Boards act as AAs for RECs, with the exception of those RECs in North Wales, where the NHS is the AA. The Local Health Boards, and the NHS Trust in North Wales, are reimbursed from the Welsh Office of Research and Development for Health and Social Care (WORD). Discussions are currently in progress about future options for research governance in Wales.

4.9 The SCREC Planning Group discussed the question of an Appointing Authority (AA) for a national social care research ethics system. It was agreed that an alternative to SHAs would be preferable in the social care field. It was considered that a social care AA would be more appropriately identified with, and possibly sited within, a respected social care body, such as SCIE. As with AAs of other NRES RECs, the costs of the social care AA would be reimbursed from the NRES budget. The experience accumulated within the NRES could also be drawn on to meet the particular needs and priorities of social care.

4.10 The AA should identify a Named Officer, at a senior level, who will have lead responsibility for liaising with NRES in setting up the central Social Care REC system. In the case of the proposed social care system, this would include not only running the central, Level 2, SCREC but also providing support and advice, where possible within available resources, to Level 1 systems. The Appointing Authority would be responsible for ensuring suitable staffing for the REC and its facilities so that the work of the central SCREC can be undertaken in an efficient, professional and confidential manner.

Membership of the central Social Care REC

4.11 The members of the central Social Care REC should:

- include a senior-level Chair and an Administrator;
- be independent and unbiased in their working;
- be selected following a transparent process;
- include members with relevant experience, training and expertise;
- include service users and ‘lay’ members;
- receive induction and on-going training and support;
- maintain confidentiality about their deliberations.

4.12 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 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.

4.13 The Governance Arrangements for Research Ethics Committees specify that members of RECs are not in any way representatives of particular groups, but are appointed in their own right (DH, 2001b, 6.8). The same will be true of the SCREC. However, it will be important that the membership of the SCREC covers the field as widely as possible. The relevant academic disciplines are likely to include social work, social policy, sociology,
psychology, law, economics, politics, anthropology and others, and the relevant Joint
University Committees. It would be useful to have members who have worked
professionally in services for children and services for adults, including services for older
people, those with mental health problems and those with learning disabilities. Relevant
professions are likely to include social work, social care, occupational therapy, youth and
community work, probation, and counselling.

4.14 Service users and their representatives should make up at least one third of the
members of the central Social Care REC. In respect of such experts-through-experience the
aim will be to find people who have experience of a wide a range of services. Provision will
have to be made for help and support to enable all service users to participate fully in the
deliberations of the REC; they will also need to be paid and have their expenses reimbursed.

4.15 As a condition of appointment to the Social Care REC, a member must agree to take
part in initial and continuing training relevant to the process of ethics review of social care
research. Members would be expected to maintain confidentiality regarding meeting
deliberations, applications, research participants, and related matters. Members should be
appointed for fixed terms. Terms of appointment may be renewed, but not normally for more
than two consecutive terms. 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.

4.16 The AA would be responsible for ensuring that the SCREC worked efficiently. Having
a paid Administrator is essential if the work of ethics review is to be conducted efficiently and
without undue delays. The Administrator 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 drafting communications to
researchers. The SCREC should be approved as an Appropriate Body under the Mental
Capacity Act.

Funding of the Social Care REC

4.17 Lack of funding has been a major hurdle in the development of an appropriate
infrastructure for social care research, including for ethics review. Appendix 3 sets out the
disparities between the health service and the social services in terms of the resources
available both for research and for service delivery, despite their similarity in terms of the
numbers of employees. For example, spending on research represents 2.52 per cent of
spending on services in the NHS, but only 0.31 per cent of spending on services for social
care. At the same time, the social care field employs more people than the NHS.

4.18 In the NHS the main resources for ethics review are channelled through NRES. This
had a budget in 2005-06 of £5.175 million, out of a total budget for the National Patient
Safety Agency of £35.154 million (House of Commons, 2006). In 2005-6 up to £0.5 million
was made available by the Department of Health to assist CSSRs in the process of setting
up research governance systems. This money was initially awarded to alliances of two or
more CSSRs (Social Services Research Group, DH and ADSS, 2005). It has helped local
authorities to develop their systems for ethics review and to provide training to their research
officers, but no further funding has been forthcoming to develop a central system which
would take forward and systematise what has been achieved (Pahl, 2006). The Planning
Group for the Social Care REC considered these issues and acknowledged that availability
of resources may determine the scope of the SCREC.

4.19 It is therefore proposed that the central Social Care REC should be funded from the
budget of the National Research Ethics Service. It would be essentially a flagged social care
REC within the NRES system. Proposals for eligible multi-site research, specific to the
social care context, which went in to the NRES system would be able to be re-directed to the cross-national Social Care REC. In this position the committee would be able to draw on the expertise which has been developed within the NRES Central Allocation System, but adapted to the particular requirements and priorities of the social care field. The NRES would also be able to make appropriate links with the ethics review systems in the devolved administrations.

4.20 However, most social care research has no connection with the NHS. The SCREC would also expect to receive proposals directly from other sources, such as central and local government, the voluntary sector, non-university-based researchers, charities and the independent sector. To underline the social care ‘ownership’ of the proposed committee, it will be important that a direct access route for proposals is provided via the AA, in addition to that available through the NRES.

4.21 The principles, requirements and standards of the SCREC will be comparable to those applying elsewhere in the NRES. However, the Planning Group suggested that it is very important that the membership and composition of the SCREC should command the confidence of the social care community. The application process will take account of social care research methods and ethos, as will the documentation required of applicants. It is essential to manage the interface between systems of ethics review to that proposals reviewed by the SCREC do not have to undergo duplicate ethics review by other bodies. Finally the Planning Group acknowledged that availability of resources may determine the scope of the SCREC.
5 CONCLUSION

5.1 Research has a central part to play in developing better services in the fields of social and health care. It is therefore important that ethics review supports, rather than impedes, potentially good quality research in social care. Those responsible for setting up systems should aim to minimise bureaucracy and to make as few demands as necessary on researchers. Time spent on filling in forms for RECs is time and money taken away from research which may improve the quality of services.

5.2 It is essential that the ethics of research proposals do not have to be approved by more than one competent REC. This implies that there must be mutual recognition between different systems for ethics review and an acceptance of the idea that equivalent standards do not mean identical systems, membership rules and operating procedures. Consistency and rigour do not preclude proportionate, constructive review that is sensitive to the spectrum of research approaches, disciplines and participant groups. The variations in academic disciplines, in research methods and in ways of working mean that it is not possible for the NHS system to be applied to social care research without any modifications. The system which is proposed here will enable the same high standards to be maintained, while responding to the concerns of the social care field.

5.3 The current situation is rather different in Wales and Scotland, but discussions within the Planning Group showed that there is support for increased cooperation in terms of research governance systems and procedures.

5.4 The next stage will be to identify an Appointing Authority which will provide an office location for the SCREC and to approve funding arrangements and operating procedures for its work. These should meet the standards of the NRES Standard Operating Procedures (NRES, 2007). The Operating Procedures for the SCREC should cover:

- Appointment of a Lead Officer for the RGF in Social Care
- Establishment of the Appointing Authority
- Appointment of chair, vice-chair and members of the Social Care REC
- Administrative support
- Support for service users
- Initial and continuing training
- System for handling research proposals and documentation
- Assessment of risk in projects
- Requirements for a favourable opinion
- Confidentiality and storage of documents
- Monitoring of research projects in progress

5.5 There will also need to be continuing discussions about standard setting, accreditation and training for ethics review in social care, as well as about the development of guidelines for operating at regional and local levels.

5.6 A crucial next step is to identify the financial resources necessary for the proposed system, since SCIE is not currently funded to take on either the AA or the SCREC. The Planning Group received a Briefing Note and Proposals from the ADASS, outlining ideas for developing a regional and national Research Ethics and Quality Assurance system (ADASS, 2007). These proposals are more wide ranging than the brief of the Planning Group, insofar as they locate decisions about ethics review among other research infrastructure issues. However, the proposals and this report together provide a context for future discussion about the development of research in social care.
APPENDIX 1  MEMBERS OF THE PLANNING GROUP FOR A CENTRAL SOCIAL CARE RESEARCH ETHICS COMMITTEE

Althea Allison, COREC/NRES
Richard Bartholomew, DfES/DCSF
Bill Davidson, Research and Development Directorate, DH, Leeds
Paul Dolan, Birmingham Social Services and ADASS
Christine Holmes, Research and Development Directorate, DH, Leeds
Gay Leggett, Essex Social Services
Carol Lupton, DH, Chair
Jan Pahl, University of Kent
David Stanley, Northumbria University, Northumberland REC and JUC SWEC
Roger Steel, INVOLVE
Martin Stevens, SSRG and Kings College, London
Stephen Struthers, ESRC
Marc Taylor, Research and Development Directorate, DH, Leeds
Caroline Thomas, DfES
Carys Thomas/Alex Newberry, Welsh Office
Janet Wisely, COREC/NRES
John Woolham, Northamptonshire County Council and ADASS

APPENDIX 2  ABBREVIATIONS

AA  Appointing Authority
ADCS  Association of Directors of Children’s Services
ADSS  Association of Directors of Social Services
ADASS  Association of Directors of Adult Social Services
AREC  Association of Research Ethics Committees
COREC  Central Office for Research Ethics Committees (NRES after April 2007)
CSSR  Council with Social Services Responsibilities
DCSF  Department for Children, Schools and Families
DfES  Department for Education and Skills
DH  Department of Health
ESRC  Economic and Social Research Council
GAfREC  Governance Arrangements for NHS Research Ethics Committees
HEFCE  Higher Education Funding Council
HEI  Higher Education Institution
JUC SWEC  Joint University Council Social Work Education Committee
LA  Local Authority
LREC  Local Research Ethics Committee
MREC  Multi site Research Ethics Committee
NRES  National Research Ethics Service (successor of COREC)
REC  Research Ethics Committee
RGF  Research Governance Framework
RGSCAG  Research Governance in Social Care Advisory Group
RRSC  Research Register for Social Care
SCIE  Social Care Institute for Excellence
SCREC  Social Care Research Ethics Committee
SHA  Strategic Health Authority
SOPs  Standard Operating Procedures
SSRG  Social Services Research Group
UREC  University Research Ethics Committee
APPENDIX 3

SPENDING ON RESEARCH IN HEALTH AND SOCIAL SERVICES

R & D EXPENDITURE (£)

<table>
<thead>
<tr>
<th></th>
<th>Health</th>
<th>Social services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceutical</td>
<td>2,375,000,000</td>
<td>-</td>
</tr>
<tr>
<td>NHS levy</td>
<td>442,459,561</td>
<td>-</td>
</tr>
<tr>
<td>DH</td>
<td>534,700,000</td>
<td>5,300,000</td>
</tr>
<tr>
<td>Research councils</td>
<td>359,900,000</td>
<td>2,024,460</td>
</tr>
<tr>
<td>Charities</td>
<td>540,000,000</td>
<td>10,650,730</td>
</tr>
<tr>
<td>HEFC</td>
<td>233,085,666</td>
<td>18,944,125</td>
</tr>
<tr>
<td>Totals</td>
<td>4,485,136,227</td>
<td>36,919,315</td>
</tr>
</tbody>
</table>

SERVICES AND STAFFING

<table>
<thead>
<tr>
<th></th>
<th>Health</th>
<th>Social services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Service expenditure (£)</td>
<td>83,609,543,000</td>
<td>11,830,794,000</td>
</tr>
<tr>
<td>Staff numbers (WTEs)</td>
<td>1,308,233</td>
<td>1,452,500</td>
</tr>
<tr>
<td>GPs/Social workers</td>
<td>36,480</td>
<td>88,007</td>
</tr>
</tbody>
</table>

COMPARATIVE MEASURES

<table>
<thead>
<tr>
<th></th>
<th>Health</th>
<th>Social Services</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall R &amp; D expenditure as % of total service expenditure</td>
<td>5.36%</td>
<td>0.31%</td>
</tr>
<tr>
<td>Government and charity R &amp; D as % of total service expenditure</td>
<td>2.53%</td>
<td>0.31%</td>
</tr>
<tr>
<td>Government direct R &amp; D as % of total service expenditure</td>
<td>0.64%</td>
<td>0.04%</td>
</tr>
<tr>
<td>Overall R &amp; D per head of total staff</td>
<td>£3,428.39</td>
<td>£25.42</td>
</tr>
</tbody>
</table>
This Appendix draws on work done at the Social Care Institute for Excellence, which was published by Marsh and Fisher, with Mathers and Fish (2006).

The report concludes that,

This report has demonstrated the stark inadequacy of the current arrangements for producing research-based knowledge to underpin the modernisation of social care.

The first priority is to generate recognition among policy makers and politicians that the modernisation of social care cannot proceed without an infrastructure for creating the knowledge base.

(Marsh et al., 2005, 26).

REFERENCE

## Appendix 4 The RGF Risk Assessment Tool

<table>
<thead>
<tr>
<th>Area</th>
<th>Likelihood of harm (tick boxes to indicate judgement)</th>
<th>Areas of high likelihood of harm addressed?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td><strong>Subject/participant characteristics</strong></td>
<td>Informed consent &amp; ability to withdraw from study not possible or unlikely due to age of child or incapacity of adult. Communication issues arising from language or literacy issues, sensory or speech impairments.</td>
<td>Informed consent &amp; ability to withdraw from study possible with support to overcome communication barriers e.g. advocates, translators/interpreters, signers, or technology.</td>
</tr>
<tr>
<td><strong>Researcher competence</strong></td>
<td>Researcher(s) not well qualified with little or no experience or knowledge of either the topic of investigation, the participants or the methods to be used e.g. undergraduate researcher/student project.</td>
<td>Researcher(s) reasonably well qualified with experience and knowledge of two out of the three following factors – topic of investigation, the participants/subjects or the methods to be used. e.g. non-researcher who has had formal research training who may work in a professional domain offering relevant experience and knowledge.</td>
</tr>
<tr>
<td>Area</td>
<td>Likelihood of harm (tick boxes to indicate judgement)</td>
<td>Areas of high likelihood of harm addressed?</td>
</tr>
<tr>
<td>------------------------------------------</td>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td><strong>Nature of information being sought</strong></td>
<td>High: The topic and kinds of information being sought are likely to be regarded as highly personal or sensitive by those from whom it is being collected or about whom it is to be obtained. e.g. criminal records, psychiatric history etc.</td>
<td>Low: The need to collect any personal information is <strong>fully justified</strong></td>
</tr>
<tr>
<td></td>
<td>High: The topic or the kinds of information being sought include items likely to be considered slightly personal or sensitive by some people e.g. age, ethnicity, income.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Low: The topic and kinds of information being sought do not focus on personal information at all e.g. opinions about services received.</td>
<td></td>
</tr>
<tr>
<td><strong>Appropriateness of method to subject &amp; quality of research design</strong></td>
<td>High: The methods are neither appropriate to the subject of the proposed study or to the research questions being asked, the need for the study is not established and the project does not have the resources to properly address the research question(s).</td>
<td>Low: The case for &amp; resources to do the study exist &amp; methods are <strong>fully</strong> appropriate to the subject or main research questions</td>
</tr>
<tr>
<td></td>
<td>Low: The methods may not be appropriate either to the subject of the proposed study or to the main research questions, or the need for research is not established, or the project does not have the resources to properly address the research question(s).</td>
<td>Low: The case for &amp; resources to do the study are absent &amp; methods are <strong>not</strong> appropriate to subject or main research questions</td>
</tr>
<tr>
<td></td>
<td>Low: The methods are fully appropriate to the subject of the proposed study and to the research questions being asked, there is a demonstrable need for the study and the resources to carry out the study are sufficient.</td>
<td></td>
</tr>
<tr>
<td>Area</td>
<td>Likelihood of harm (tick boxes to indicate judgement)</td>
<td>Areas of high likelihood of harm addressed?</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-------------------------------------------------------</td>
<td>---------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Possible risks arising from high level of contact are identified and fully addressed</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Possible risks are not identified or addressed</td>
<td></td>
</tr>
<tr>
<td>Methods/ nature of data collection</td>
<td>High levels of face to face contact and/or interaction between investigator and participant e.g. participant observation or observation study</td>
<td>Some face-to-face contact and interaction for limited amounts of time.</td>
</tr>
<tr>
<td></td>
<td>Possible risks are not identified or addressed</td>
<td></td>
</tr>
<tr>
<td>Level of privacy to participant</td>
<td>Not confidential</td>
<td>Confidential.</td>
</tr>
<tr>
<td></td>
<td>If the study is not anonymous or confidential reasons for this are fully justified &amp; conform to Data Protection Act principles.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Study is not anonymous or confidential and reasons for this are not fully justified</td>
<td></td>
</tr>
<tr>
<td>Area</td>
<td>Likelihood of harm (tick boxes to indicate judgement)</td>
<td>Areas of high likelihood of harm addressed?</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>------------------------------------------------------</td>
<td>--------------------------------------------</td>
</tr>
<tr>
<td><strong>High</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Low</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Relationship between investigator &amp; subjects/Participants</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subjects/participants are personally known to investigator &amp; investigator may have other duties or responsibilities towards all or some of the research participants which may create potential conflicts of interest □</td>
<td>Limited information about subjects/participants is provided to the investigator to make the study possible or more reliable. □</td>
<td>Subjects/participants are unknown to the investigator and cannot be identified. □</td>
</tr>
<tr>
<td><strong>External considerations</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Study is likely to be extremely sensitive. □</td>
<td>Parts of study may be sensitive. □</td>
<td>No known sensitivities □</td>
</tr>
</tbody>
</table>

Conflicts of interest are not fully described. Proposal does not adequately consider how to minimise effects on study

Sensitivities have **not** been adequately addressed.
REFERENCES AND WEB LINKS


Department of Health (2001b) Governance Arrangements for NHS Research Ethics Committees, London, DH.


Economic and Social Research Council (2005) Research Ethics Framework, Swindon, ESRC.


