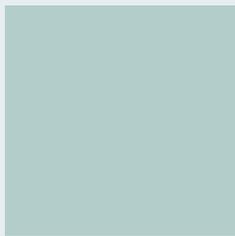*Research Governance Framework*

# Resource Pack for Social Care

2nd Edition - April 2010

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## Foreword from the Department of Health (England)

This second edition[1] of the Resource Pack is designed to support the implementation in social care of the DH Research Governance Framework (RGF). Developed in consultation with a wide range of partners, the Pack summarises the main responsibilities and benefits for social care bodies and provides information about the resources available to help develop governance systems.

The RGF (DH, 2001 and 2005) aimed to cover both health and social care, but the specific characteristics of the social care research sector - in particular its underdeveloped infrastructure - required a separate approach. A subsequent **Social Care Implementation Plan** (DH, 2004) was drawn up, setting out the role of all participants, especially local Councils, in the collective task of developing good research governance.

The Implementation Plan provides an intentionally inclusive definition of research: in effect, any activity that defines and presents itself as research will need to be subject to proper governance. The Plan does however differentiate between externally funded research studies and Councils' in-house or 'own account' research activity in terms of the responsibilities involved.

While all externally funded studies will be covered by the RGF, it is ultimately for Councils themselves to decide what aspects of their internal research should be included, and how. In making this decision, they will need to balance the potential risks to research participants against the importance of supporting good quality research. As with national review systems, proportionality of approach will be key.

Establishing basic standards of research governance is vital to social care bodies. It will ensure transparency and accountability and help prevent any unnecessary duplication of resources. It will also enable more effective knowledge-sharing between social care bodies and encourage active collaboration in areas of mutual interest. Most importantly, of course, good governance will help social care bodies protect those for whom they have a duty of care from any possible harm arising from participation in research.

But good governance will also help to raise and sustain the quality of social care research. Despite its intellectual vibrancy, social care research has suffered from limited resources and uneven capacity. Part of the reason for this is that the role of local Councils, as hosts and as providers of quality research, has been underplayed. The Social Care RGF Implementation Plan places this role centre stage. In turn, Councils need to develop their role in research from the passive 'recipient or host' to the more active role of 'partner or commissioner'. We hope that the information provided in this Pack will assist them in this important task.

*Dr Carol Lupton,*
*Social Care R&D Lead, Department of Health (England)*
*March 2010*

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[1] This edition of the Pack revises the draft second edition issued in limited quantities in the summer of 2008.

## Foreword from ADASS

ADASS, representing Directors of Adult Social Services, welcomes the opportunity to support the second edition of this pack, which gives good practice advice to councils and all involved in social care research. This revised edition offers an opportunity to review developments since the first edition of 2005, which our predecessor organisation also supported.

First, there seems to have been welcome progress in developing the distinctive features of research governance within many individual councils and consortia of councils, often supported by ADASS regions. If this has seemed like making bricks with very little straw, in the way of resources, there are tangible achievements to show nonetheless.

For its part, ADASS has tried to help those interested in research in our field to look at research governance in a wider context. The **Briefing Note and Proposals** we produced in 2007, and which is included in the Pack, has renewed significance this year. ADASS is not currently pursuing the detailed proposals, given the changes since 2007 mentioned below and described in this edition of the Pack. Nevertheless councils are expected increasingly to be able to give good quality evidence on the impact of their services: and good quality research is an essential means to this end. Poor quality research, by contrast, serves no-one well, still less at a time of economic constraint. This reminds us that research governance must be able to assure everyone involved, including our service users, that the ethics and methods of research are sound – including the research and evaluations conducted by councils themselves.

Since 2005 significant NHS resources have been channelled into a revised national, regional and local research infrastructure system. Similarly, the revamped but non-statutory National Research Ethics Service (NRES) enjoys a level of resources and systems of support which local councils can both envy and draw lessons from. ADASS has consistently argued that the distinctive aspects of social care research, and therefore governance of research, need to be recognised and adapted to. So it welcomes the development of greater service user involvement with the NHS research governance system, as it has previously welcomed such involvement in social care and research governance. These threads continue to be illustrated in this new edition of the Pack.

The other obvious change since 2005 has been the administrative separation of children's and families' social care services from those for adults. This second edition of the Pack rightly exemplifies the continuities and links as far as good social care research and governance are concerned.

For its own part, ADASS has refreshed its own national advice system for Directors, in relation to defined multi-site projects seeking support. It offers researchers skilled appraisals of proposals, as distinct from formal ethics and methods reviews. The system is referred to in this Pack, and on the ADASS website.

ADASS has also contributed to thinking about the distinctive role of the national Social Care Research Ethics Committee, established in 2009 as part of the National Research Ethics Service (NRES) and administered by the Social Care Institute for Excellence (SCIE). This presents challenges of accountability as well as opportunities, especially in relation to research involving questions of mental capacity, a legal change not yet widely appreciated among researchers. It provides a chance to see what a small national investment can do to support research quality.

Naturally, we also urge users of this Pack to support and invest locally and regionally in research governance, as a way to ensure the best quality of research in the distinctive range of services making up social care for people in England and beyond.

*Sarah Norman & Paul Najsarek, Co-Chairs, ADASS Standards and Policy Network.*
*January 2010*

## Social Services Research Group Foreword

SSRG is pleased to support this second edition of the Research Governance Framework Resource Pack for Social Care. SSRG has always been committed to promoting good research practice and research standards in social care, and we see research governance as part of that commitment.

Good quality research and evaluation is increasingly important in a climate of constantly changing ideas, approaches and structures for providing social care services. Such endeavour provides a means of putting users' views and preferences at the heart of social care practice and service delivery. The division of responsibility for children's and adult social care services, made since the first edition of this pack was published, is of particular importance in this respect. It is therefore extremely heartening to see the support expressed for research governance (and this document) by the Department for Children Schools and Families, and the Association of Directors of Children's Services. This will help ensure consistency of approach across these two related fields.

The changes in performance management approaches from simply measuring basic inputs and outputs, to capturing outcomes as a means to determine what impact services actually make on people's lives, enhances the need for more sophisticated research and evaluation methods. The movement to provide evidence about overall wellbeing within areas, across all sectors, places further demands for sound research approaches within the specialised area of social care, to ensure that the experiences and voices of people using these services are properly represented in this overall picture. Finally, gaining users' perspectives on what works for them is becoming increasingly prominent, and research activity, through questionnaires and surveys, is capturing important messages to help bring about service improvements. All these factors make the gathering of evidence and the place of research in social care increasingly important today

Good progress has been made by many local authorities in developing research governance processes, with very little direct financial help; although this has been difficult for some to prioritise. However, several general supports have been provided by the Department of Health, including the development of the Research Register for Social Care, a Social Care Ethics Committee (both of which are described in this new edition) and three series of workshops for local authority staff. SSRG members have contributed to all of these initiatives and will continue to work with the Department of Health and the Department for Education to support development in this area.

Research governance is a key element of an overall strategy to enhance the evidence supporting developments in social care. It is helping to redefine and re-establish good research practice in local authority, academic and government settings. It also provides a relevant and useful quality assurance approach and helps safeguard research participants, researchers and those who commission and oversee research activity. At SSRG we think research governance is an important starting point in a new era of research, and we hope you find the second edition of the Resource Pack helpful in taking forward the responsibilities you carry for good, ethically sound and useful research to help bring about service improvements. I am sure that this Resource Pack will provide valuable information and guidance to support research governance in local authorities and be of value to researchers seeking to secure research governance approvals.

*Martin Stevens, Chair SSRG*
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*King's College London*
*March 2010*

# Acknowledgements and Authorship

This pack has been produced by members of the DH External Advisory Group for implementing research governance in social care, in collaboration with members of the Association of Directors of Adult Social Services Research Sub-Group:

- Paul Dolan, Adults and Communities Directorate, Birmingham City Council;

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- Deborah Rutter, Social Care Institute for Excellence;

- Martin Stevens, Social Care Workforce Research Unit, King's College London;

- John Woolham, Department of Social and Community Studies, Coventry University;

- Sue Williams, Kent Adult Social Services Directorate, Kent County Council.

Many thanks are also due to other members of the DH External Advisory Group for implementing research governance in social care, who co-authored the original Resource Pack; and to those who contributed to the regional and national seminars in 2008, at which the draft version of this pack was distributed for comment.

## Intro:     Who is this Pack for?

This Pack contains information, guidance, and a range of resources for supporting research governance. It is aimed primarily at those involved in setting up and running governance systems in local authorities or for people who take part in the review of relevant research. However it also will have value for other research stakeholders, including:

- *senior local authority personnel*, who will find discussion of the wider benefits of research governance for local authorities, and information about the main tasks involved;

- *researchers from all sectors* (in-house, academic, independent and from service user-led organisations), who will find useful information about the overall aims of research governance and how to negotiate the process;

- *research commissioners and funders*, who will find discussion of the implications of research governance for funding and commissioning different kinds of research in a range of contexts;

- *service users and carers*, who will find details of the research governance system, and of the role they can play in it, as well as information relevant to their participation in individual research studies;

- *regulators*, such as the new Care Quality Commission, which will find information relevant to developing the interface between research governance and regulatory scrutiny;

- *organisations and networks* involved in promoting the use of research evidence to develop policy and practice (Social Care Institute for Excellence; Research in Practice; Research in Practice for Adults; Making Research Count, among others) will also find the Pack useful for their role.

## Intro: What is in the Pack?

### Part 1: Introducing Research Governance

This first part of the Resource Pack introduces the **DH Research Governance Framework** and its implications for local authorities.

*Chapter 1* gives an overall description of research governance along with a brief history and an outline of why it is necessary. Several key issues are also set out in terms of the kinds of research covered and the need for balancing risk to participants against the benefits of good quality research.

Specific information about what local councils need to do in order to establish good research governance is given in *Chapter 2*. More general 'tips' for implementing governance follow in *Chapter 3*, presented in a question and answer format. These have been developed over five years by members of the Department of Health's External Advisory Group for implementing research governance in social care (see Annex 1) and through feedback from a series of regional workshops held in 2005-6, funded by the Department's Policy Research Programme.

### Part 2: Doing Research Governance

*Part Two* of the Resource Pack provides more details on the central processes of research governance. *Chapter 4* focuses on approving research proposals, including who should approve, and how. *Chapter 5* provides guidance on reviewing research, covering issues raised by the five key areas or domains of research governance: ethics; science; information; health & safety and finance. Guidance is also provided here about the participation of service users and the public in the reviewing process.

*Chapter 6* provides details of research governance systems in five local authorities, showing how different approaches have been developed in practice.

### Part 3: The Wider Context

In *Part Three*, the wider context is described, beginning with a summary of the main points of the Social Care RGF Implementation Plan in *Chapter 7*. This Chapter also provides information on two new national developments designed to support good governance: the new national **Social Care Research Ethics Committee** and the **Research Register for Social Care**.

*Chapter 8* provides details on the relevant legislative context, including on the Data Protection Act 1998 (amended 2000) the Freedom of Information Act 2000 and the Mental Capacity Act 2005. The role of Caldicott Guardians is also discussed.

## Annexes

- ***Annex 1*** identifies the individuals who have played a role in national research governance advice and planning.

- ***Annex 2*** gives relevant organisation contact details.

- ***Annex 3*** gives specific details of INVOLVE.

- ***Annex 4*** is a Risk Assessment tool, intended to help in this aspect of research review processes.

- ***Annex 5*** is a Briefing Note from ADASS, making suggestions for improvement in research governance quality.

- ***Annex 6*** is the text of an agreement between the Economic and Social Research Council, the National Research Ethics Service, the Association of Directors of Adult Social Services and the Association of Research Ethics Committees, in what has become known as the 'Ethics Approval Route Map' for social care researchers (Annex 6 reproduces this in full).

Introduction

## Chapter 1: Background

### 1.1 What is research governance?

Research governance is the process by which the quality of research can be assured and the rights, dignity and safety of those involved can be protected. Published in 2001 and updated in 2005, the DH *Research Governance Framework for Health and Social Care* (RGF) covers the conduct of research in the NHS and adult social care. It aims to protect participants by ensuring there are clear arrangements to identify and manage any risks associated with a study. It calls for explicit agreement about roles and responsibilities, and draws attention to the law and good practice.

The RGF sets out basic standards for every party involved in research, in five key areas: ethics; science; information; health and safety; and finance. Ensuring that research meets these standards is the central role of research governance systems. While all research is expected to meet the same standards of governance, it is recognised that there are important differences between the health and social care contexts.

This recognition resulted in a separate *Implementation Plan for Social Care* [available from the Department of Health website, www.dh.gov.uk: see also Part Three for detailed extracts from the Implementation Plan].

The Plan gives a key role in governance to Councils with Social Services Responsibilities (CSSRs). It is vital that this role is effectively supported by local and central government, researchers, service users and carers. The Implementation Plan gives councils three central responsibilities:

- ensuring the dignity, rights, safety and well-being of researchers and service users, carers and staff participating in research;
- helping to safeguard the integrity of the research, and upholding standards for ethical review and scientific quality;
- establishing transparent systems to approve, record and monitor all research activity.

## 1.2 Why is it needed in social care?

All research carries an element of risk, which varies in type and severity according to the areas of research undertaken and the characteristics of participants, including researchers. Balancing these risks against the likely benefits of high quality research is a major objective of good governance.

Initially, the RGF was developed in response to concerns about specific examples of unethical practice in clinical research. These risks are unlikely to be as great in social care research. But social care research can involve vulnerable people in difficult situations. It can potentially be experienced as intrusive or distressing and even adversely affect participants' health or well-being.

Social care research has relatively limited funding and capacity, compared with other research sectors (Marsh and Fisher, 2005). This means that social care researchers are often operating under pressure to undertake research with tight resources and/or deadlines and this in itself can generate risks.

So research governance is necessary as a means of assessing that research is carried out:

- only on useful topics;
- with sound methods;
- with sufficient resources and expertise;
- in ways that respect the dignity and self-determination of participants.

In addition, for local authorities, developing systems to assess, record and monitor research activity will provide the following benefits:

- helping to ensure that decision-making is informed by better quality research;
- making it easier to prevent unnecessary duplication of research activity and enabling collaboration;
- ensuring public accountability and transparency for any research in which they are involved;
- helping to protect those for whom they have a duty of care from any possible harm arising from participation in research.

## 1.3 What does research governance cover?

For the purposes of research governance, 'research' means the systematic application of established research methods and techniques to gather information on human participants in an explicitly planned way.[2] This is a deliberately broad definition, designed to cover a wide range of data-gathering activity. An important but not conclusive test is whether the study is designed, managed and presented as research.

Councils with Social Services Responsibilities (CSSRs) are the main care bodies involved in the process, but research in organisations providing services under contract to local councils is also covered by the RGF. Formally, the RGF extends only to adult social care services, although local authorities are encouraged to apply the same principles to research involving children's services and other research activity involving human participants and many are beginning, or continuing, to do so.

All research under the above definition, whether undertaken by external researchers or those employed in local authorities, needs to be subject to good governance procedures. Although the primary focus is on externally funded research, councils are encouraged to develop basic systems for **all** research studies to assess the risks presented and how they may be dealt with. Those judged to be of low risk, such as those dealing with secondary source data, may not need the level of subsequent scrutiny required by those of higher potential risk.

These actions must take into account the need for proportionality. The Social Care RGF Implementation Plan (DH, 2004) aimed '… *to protect participants by ensuring there are clear arrangements to identify and manage any risks associated with a study*'. In trying to reduce the risks from poor quality research, the Department of Health does not wish to encourage the growth of cumbersome and overly bureaucratic procedures at a local level. This is for two reasons: first because councils do not have the resources to develop complex and time-consuming mechanisms for governance; second because councils also have a role to support and encourage, as well as scrutinise, social care research activity. Proportionality in research ethics review is one of five principles agreed by the main organisations in the field[3] as part of what has become known as the 'Ethics Approval Route Map' for social care researchers (Annex 6 reproduces this in full).

It is important to stress that research has much to contribute to the development of better social care services. It is also important to recognise that this is a field in which the research base is very fragile, in terms of the funds available, the research infrastructure and the numbers and security of research workers. Many professional social care researchers are likely to be on short-term contracts, with uncertain career prospects and relatively few funding bodies to which they can apply for grants.

Any system of research governance should seek to support and encourage research and researchers, rather than to deter them from working in this field. The aim should be to be as 'light touch' as possible, consistent with assuring good quality. The key task is to devise systems that will achieve safeguards for those who take part in research, while continuing support for research as an activity that can make an important contribution to the future of social care and to the well-being of service users.

### References

Marsh, P. and Fisher, M. (2005) ***Developing the evidence base for social work and social care practice,*** Social Care Institute for Excellence.
www.scie.org.uk/publications/reports/report10.pdf

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[2] The definition of research used in the DH RGF is the 'attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods'. The statement used here is based on this definition.
[3] The Economic and Social Research Council; the National Research Ethics Service; the Association of Directors of Adult Social Services and the Association of Research Ethics Committees.

## Chapter 2: What Councils Should do to Establish Good Research Governance

### 2.1 Key decisions

There is no single best way of setting up research governance systems. Approaches have varied across the country. Three basic decisions shape the development of a research governance system in a local authority: how far research governance will extend to internal research and information-gathering activity; which part of the authority will be covered; and whether systems are internal only or developed in collaboration with external partners. Chapter 6 has details of five local authority processes which illustrate some of these issues.

#### • *Internal and external research?*

As indicated, the basic requirement for good research governance is to ensure that all research being conducted by those not employed by the authority is subject to independent checks for its ethics and scientific quality, and a record made locally. This is a minimum level of governance, however, and councils will need to consider if this provides sufficient protection for its service users and staff from any risks associated with their wider research activity. It is anticipated that most councils will wish to ensure that most, if not all, of their own-account research is also able to benefit from sound governance. It is also strongly recommended that records of locally approved research are submitted to the Research Register for Social Care (www.researchregister.org.uk).

#### • *Adults' and children's social care?*

While the minimum requirement is for research governance to cover research and related activities in adults' social care, many local authorities have implemented the approach in children's services as well. Some of these introduced governance systems prior to the administrative separation of social care services for children from those for adults, and as recommended by the Department of Health in 2004. Given that governance issues in the children's sector will be very similar to those for adult social care, a combined approach would be cost- and resource-effective.

#### • *Across the local authority?*

A second approach has been to set up a research governance system for all research undertaken in a single authority. This would also be more resource-effective than operating different systems for different areas of activity. By increasing organisational research awareness, such an approach would also enable better co-ordination and greater use of any research investment being made by the organisation.

#### • *In collaboration with other local authorities and/or other bodies?*

A further variation is to set up a consortium of local authorities to share systems and resources (e.g. South East Consortium – see Chapter 6) to help each authority meet its obligations under the RGF. This approach has been encouraged by the allocation of small RGF Alliance grants by the DH, and has enabled the development of partnerships between groups of councils, or between Councils and universities or NHS Trusts (see Chapter 6 for examples). In addition to the benefits of collaboration described above, such approaches provide a wider source of expertise for reviewing proposals and also help develop research partnerships more generally. The manual commissioned by the Midlands and SEARIG research governance consortia is a valuable resource for training.

## 2.2   Specific Tasks

### • *Appoint a RGF Lead*

The first and most important task for Councils is to appoint an individual, or individuals, who will act as the lead for social care research governance within the authority: **the RGF Lead**. This person should be at an appropriately senior level, given the responsibilities involved, and should have professional research expertise and experience. The main responsibilities of the RGF Lead will be to undertake an initial screening of all written social care proposals received by the council from external researchers and to manage the subsequent reviewing, recording and monitoring process. Sufficient time and resources should be allocated to enable the efficient discharge of this responsibility.

### • *Secure senior management support*

Senior managers, whose support is vital in order to develop effective systems, do not always see research governance as a priority. Such key figures need to be convinced about the advantages of research governance, many of which are described below. Engaging their support is an early task for those responsible for setting up local systems. At the outset, therefore, it is worth the RGF lead spending time to:

- identify research governance champions in senior management;
- establish a steering group including senior manager(s);
- lobby for regular slots on research and research governance at senior management meetings.

In turn, senior managers should recognise their own responsibility to support and encourage compliance with their research governance system, as a matter of good practice and in the interests of the council.

### • *Identify current volume of research activity*

In order to inform initial decisions about coverage, it will be important to assess the volume of research activity likely to be covered by a governance system. This may be best achieved by conducting an internal audit of current and planned research activity.

### • *Identify resources needed*

Once the level of research activity is determined, it will be important to identify the resources available, and those needed in addition. As well as time and money, implementation may require the development of research awareness and assessment skills, and access to relevant information. Training for staff – those involved in the process and more generally – may need to be provided.

### • *Design documentation*

The following is a typical set of documents needed to support a research governance system. Remember that many authorities have developed such documentation, and are willing to share, so copying is encouraged:

- information leaflet (describing local RGF contacts and process);
- application form and guidance on applying;
- risk assessment and guidance notes (e.g. The DH Risk Assessment Tool: see Annex 4);
- a specimen approval/referral letter

## • *Promote governance*

Research governance is a new idea, which will require changing the awareness and behaviour of a range of stakeholders, both within and beyond the organisation. Good information and publicity will be necessary to promote awareness of:

- the overall benefits: better quality evidence and better management of risks;

- the value of service user involvement being at the heart of the process;

- the principles and purposes of research governance for current and new staff (build research governance awareness into induction training);

- your local process – how research and service development can join up.

Part 1: Introducing Research Governance

The following questions have been based on individual enquiries made to the Department of Health following the publication of the Social Care Implementation Plan (DH, 2004) and through various public consultation exercises and national training events. Some of the topics covered are addressed in more detail later in the Pack, but it is useful here to provide a summary of some of the main issues involved.

## 3.1 Activities covered by research governance

**Q:** How do we decide what constitutes research for the purposes of research governance?

**A:** For governance purposes, 'research' means the systematic application of established research methods and techniques to gather information on, or from, human participants in an explicitly planned way. This is a broad definition. Any data-gathering activity utilising questionnaires or face-to-face interviews, for example, would potentially be covered by this definition.

In deciding whether or not an activity constitutes 'research', therefore, two key judgements need to be made. First, whether the activity defines itself as research and claims the particular authority accorded to research-based information. Clearly most, if not all, data-collection activity that is supported by external funding bodies, or undertaken by universities and other research providers, would fall into this category. Internal data collection involved in producing management information, such as the recording of units of service (e.g. 'bed-days') is very unlikely to lay claim to the title of 'research'.

Grey areas however may emerge between these two extremes. Some activities badged as 'audit' or 'consultation', for example, may be little different in nature from those that are termed 'research'. A survey of service users' experiences, for instance, utilising methods such as questionnaires, individual or group interviews, is clearly a 'research-like' activity. While we need to guard against drawing all such activity into the governance net, we also need to avoid the situation where work is defined as something other than research specifically to avoid scrutiny of its ethics or methods.

In making this judgement, a second key consideration should be the extent to which the activity presents a potential risk to those involved, particularly if they are vulnerable service users or carers. As the Implementation Plan argues, all research-like activity should involve '…arrangements to identify and manage risks to the dignity, rights, safety or well-being of participants'. It is for councils to establish a process that will enable decisions to be made, on a case-by-case basis, about the nature of the risk posed to those who are the subjects of any data-gathering activity. Externally funded data collection that does not present itself as research, and is thus not claiming to meet the basic standards of rigour implied therein, may need to be treated with particular caution.

Given these complexities in deciding which kinds of internal activity require research governance scrutiny, it is good practice to channel projects that are not purely routine management information collection through the stages of a research governance system, in the first instance. In this way it will be possible to review all elements of such projects that can contribute to risk to participants.

These elements include, to varying degrees, aims, methods, characteristics of prospective participants, access arrangements, consent and equalities issues, researcher/supervisor competence, ethical and legal issues, including data protection and mental capacity aspects, timetabling and proposed dissemination.

## Q: What if the activity is not designed to be scientific or generalisable?

**A:** If data collection activities are not presented as research, there is a danger that the methods involved could be ill thought-out and poorly applied. There have been cases where those seeking user/carer views have argued against inclusion in the RGF because data collection tools have not been designed or applied scientifically, and so cannot technically be considered research. This would be acceptable as long as the survey's findings were not subsequently presented as 'research-based', and their limitations were made very clear. Even so, it would raise questions about the ethics of involving staff and service users in such a study and, indeed, about the extent to which the findings of a badly designed survey would be of much use to anyone.

Arguments have also been made for exclusion of projects from the RGF on the grounds that the resulting information is specific to the local context and thus not generalisable. However it is quite possible for the results of locally-specific research to be generalisable. Much will depend on how well the study has been designed, the topic being researched and the extent to which it is contextually specific. It will also depend on the purpose of the research; that which sets out to generate rather than test hypotheses, for example, is not seeking immediate generalisability. Finally, even if it reflects only a very small or specific slice of reality, locally-based research may reinforce that undertaken by others, in other contexts, thus contributing to the gradual growth of a more generalisable body of knowledge.

## Q: Should non-financial audit be covered by the RGF?

**A:** There are clear differences between research and non-financial audit. In particular, the latter tends to involve only secondary analysis of previously recorded information, which means that service users or staff are not usually contacted directly. It is also much more likely to be undertaken by staff employed by the care organisation itself. Non-financial audit also differs from research in the following ways:

- scope of application: audit produces findings of less general applicability;
- types of question: audit focuses exclusively on questions about whether organisations are doing what is prescribed in terms of meeting standards;
- variety of methods used: audit uses fewer methods and tends to use single methods within a particular project.

However, non-financial audit can share many features with research. Both, for example:

- can involve the collection and analysis of personally sensitive information for the purposes of answering specific questions;
- can be carried out prospectively or retrospectively;

- should involve recorded decision-making about potential risks, specific ethical issues, sample frames/techniques and rigorous analysis;
- should be led professionally, with clearly defined, though possibly adjustable, aims, objectives and methods and explicit lines of accountability.

Given the similarities in the type of activity involved, non-financial audit may need to be subject to the same basic safeguards as more formal research projects. In particular, consideration should be given to any ethical issues arising and the ways in which these will be addressed. If the audit is being undertaken as part of internal case assessment or performance management activity, it may be useful to submit a written plan of work to the research governance process. This may be particularly beneficial if the audit involves direct access to service users or their carers or staff, rather than the analysis of recorded data.

If persons not employed within the council are undertaking the work, it will need to be subject to the same checks as external research and a written plan of work obtained. As with more formal research, however, proportionality is the key. In particular, care must be taken not to impose too great a degree of additional scrutiny (as opposed to basic recording and monitoring activity) on work that has already received independent appraisal of its methods and ethics.

## Q: What about consultations?

**A:** Consultation is intended to solicit people's opinions on a topic/service in order to influence policy or organisational decisions. Central government has attempted to clarify the purposes of consultation and ensure that it is worthwhile. The central government code of practice is available from the Cabinet Office website: www.cabinetoffice.gov.uk/regulation/consultation/code. Some local councils will have their own equivalent.

Consultation activity differs from research in that it:
- is typically directive (from organisations) and conducted over short time-scales: e.g. central government consultations usually have a time limit of 12 weeks, or less;
- usually addresses a narrower group of questions, often seeking expression of a preference for/ endorsement of a change or modifications to a service;
- may be more arbitrary and less systematic, because generalisability is considered less important;
- uses a smaller range of methods e.g. surveys or group events are used more often than 1:1 interviews;
- usually requires implicit consent (e.g. returning questionnaires or attending events) rather than formal written consent.

However, consultation shares the similarities with research already set out for audit above. In addition, any attempt to go beyond the answers provided to specific questions, and understand their underlying meaning, will inevitably move the work towards the research end of the data-gathering spectrum. Consultation can include formal research elements, particularly if there is an aspiration to generalisability. There may also be ethical issues involved if, for example, consultations are used to justify decisions that have already been made or are biased in their selection of respondents. The lines of accountability for consultation activity, moreover, can be unclear.

Again, differentiation may need to be made between external and internal consultation exercises. In the case of the latter, it will be good practice to make a formal record of any user/carer consultation and assess the potential risks involved. Research governance systems could be helpful in advising on cases involving particularly vulnerable populations or sensitive information. Externally instigated consultation processes, however, that involve direct access to service users/carers or staff, should be reviewed by local research governance mechanisms, if only to ensure that central recording and monitoring of the activity takes place.

**Q:** **What about market-research type activities carried out as part of recognised procurement practice?**

**A:** Provided this kind of information gathering is not by staff employed outside the council or its contracted agencies, and does not collect personal information directly or indirectly on individual service users, carers or staff, it is unlikely to warrant research governance scrutiny. If service users are to be approached directly, even by employees of the council, CSSRs should, at the very least, review and document procedures around consent and confidentiality.

**Q:** **What about research conducted by students?**

**A:** Ethical review of students' research should normally have been undertaken by their supervisors or, preferably, by, an ethics committee within their academic institution. Similarly, supervisors should check the quality of the methods and instruments chosen. The CSSR should request proof that such checks on ethics and methods have been made and require submission of both the documentation reviewed and the response made by supervisors or university ethics committees. There may however be particular ethical issues involved in enabling access to service user and carer populations by untrained researchers, especially on research topics of a sensitive nature. It is therefore recommended that student research should not normally address these issues, unless a good case can be made. Councils are encouraged to work with local universities to develop mutually acceptable practice in this area.

## 3.2    Organisational limits of research governance

**Q: Does the RGF extend to Wales?**

**A:** While most of the content of this document is applicable to Wales, and is considered to be best practice, the Wales Office of Research and Development for Health and Social Care (WORD) is developing a version of the resource pack that will take into account the Welsh context. This work is being undertaken in line with the development of the National Institute for Social Care and Health Research (NISCHR) and implementation of the recommendations stemming from the recent Social Care Research Review in Wales.

**Q:** **What is the situation for non-statutory organisations providing social care services?**

**A:** If the social care organisation is providing services for people under contract to the local Council, then the Research Governance Framework should cover any research involving those receiving (or staff delivering) the contracted services. Councils are encouraged to consider whether this requirement should be clearly set out in all future contracts with independent providers. It is recognised, however, that this process may take some time.

If researchers not employed by the council are undertaking the research, it should be referred by the contractor to the council for approval. If the research is being conducted by the CSSR's own researchers, the agency will need to assure itself that the work presents no risks to its service users or staff and has been signed off by the council's research governance process. This will also help to protect contracted agencies from the resource risk of participating in poorly designed research.

In cases where the independent agency (e.g. a privately run residential care home) is also providing services to people who are paying privately, any research involving those people would have to be negotiated in the normal way with the individual and the agency concerned. It would not be covered by the council's research governance process. However, those managing independent services may judge that all service users, irrespective of whether they are state or privately funded, would benefit from the protection provided by the research governance process.

**Q:** **What if an independent agency wished to evaluate its own services?**

**A:** If those using the services of an independent agency (say a preventative intervention for parents) were self-referring, or referred by professionals not working in the NHS or social services (say teachers) then the evaluation would not be covered by the RGF. Particularly if researchers employed by an external agency are undertaking the evaluation, however, it is hoped that the principles of the RGF would be considered as a guide to good practice.

If the agency were itself funded, fully or in part, by a local council with social services responsibilities, or the NHS, then research on any of its service users would be covered by the RGF. If the agency receives no funding from the CSSR or NHS, but the care of some of the users of its services is the responsibility of NHS or social services professionals, then the RGF would apply to any research involving those particular users. In such cases, it may make sense to apply the RGF to the whole research population.

**Q:** **Does the RGF cover research on children's social care?**

**A:** The coverage of the RGF applies only to those service user/carer/staff populations that are the responsibility of the Secretary of State for Health via the Department of Health (England). In respect of social services departments within local councils, this means that it formally covers

only adult social care services. Children's social care is now the responsibility of the Department for Education. However, councils may wish to consider adopting the RGF for research in children's social care. It is to be hoped that this will provide researchers with a standardised set of procedures for all social care research within or involving councils.

Where services for children are provided on a multi-agency basis, such as by a children's trust for example, the situation is more complicated. Research involving children receiving services provided by NHS staff, or by these staff working in collaboration with education or social care staff, will be covered by the RGF. This will also be the case if the local council has extended the RGF to cover its children's services. Research undertaken by NHS staff in these circumstances may also be covered by local authority research governance even if NHS ethical approval is not required. Where the RGF only extends to adult social care, however, and no NHS staff are involved, research on children's social care services will not be covered. Again, to save confusion and uncertainty on the part of research communities, it may be sensible for multi-agency bodies to implement the RGF across the full range of their services.

**Q:** **Should Councils be developing the RGF on a corporate basis?**

**A:** This decision remains with local councils. There are a number of advantages to working across the whole council in terms of the 'value-added' by shared systems and pooled resources. There are also considerable advantages to the research community of a uniform and coherent set of research governance procedures.

Some councils (e.g. Kent, see Chapter 6) have already developed a corporate approach to research governance and are applying the RGF across the full range of their activities. Other councils where research governance has been implemented across a traditional social services department have included children's services as a natural part of the remit. These approaches are very much to be encouraged.

**Q:** **Can a Local Authority act as sponsor for research undertaken by another agency?**

**A:** The Social Care RG Implementation Plan (DH, 2004: see Chapter 7) recommends that all social care research has an identified sponsor. This is one of the basic checks that councils have to make of external research. The role of the sponsor is to ensure, through a named individual, that all parties involved in the research process (funder, researcher, care organisation and research employer) are aware of their respective responsibilities under the RGF and are willing to discharge them.

Written agreements will need to be made to this effect, especially where there is more than one agency performing a particular role (several care organisations, for example, or research teams from more than one university). It is therefore possible for a local authority to act as a sponsor for research undertaken by another agency, as long as all parties to the research are in agreement and their respective responsibilities are clearly set out.

It is assumed that, in the majority of cases, the sponsor role will be performed by a named officer of the research employer or the organisation funding the research. Named officers from individual

councils will have to act as sponsors for their own in-house research. In some cases, such as multi-site studies funded by a collaboration of councils/CSSRs, one council could helpfully agree to perform the role of sponsor on behalf of the others. Where a local council feels it lacks the expertise or the confidence to assume the role, a council with more a robust research governance system may be willing to act as sponsor. Some councils may be willing to do this on a case-by-case basis (if approached by another body); others may be willing to offer to act in this role more generally. In all these variations, the sponsor needs to be a named individual from the sponsoring organisation.

## 3.3 Links with other research approval processes

**Q:** **What if research has already been given independent ethical and/or scientific approval?**

**A:** For all externally funded research, councils should seek evidence of any formal independent review and favourable opinions of science and ethics previously obtained. Such favourable opinions and the evidence for them should be given due weight within the council's local governance process. Mutual respect between review and governance systems is important to help avoid unnecessary delays to the research. This is a key principle adopted in the document "Securing Ethics Approval: A Route Map for Social Care Researchers", to which the National Research Ethics Service, the Association of Directors of Adult Social Services, the Economic and Social Research Council and the Association of Research Ethics Committees have all signed up (see Annex 6). The experience of some councils (see Chapter 6) suggests that it may be worth investing the time to establish good links with other bodies, such as local universities or the NHS, to develop collaborative arrangements. Such links could help establish common standards for ethics review. One example is to ensure that supporting documentation (information sheets and questionnaires, etc.) is considered by research ethics committees, in addition to research proposals.

Many councils have developed systems that go beyond the minimum, in order to ensure that the particular needs and circumstances of their service users or potential staff participants are understood by the research team, and that the proposed study will be of value to these users and/or to the council. Access to particular service user populations may raise important issues other than those already considered by an independent review process, particularly if those involved in that process are unfamiliar with the social care sector/social science methods. Such councils often request further information from researchers on these issues; ultimately councils are entitled to refuse access to any research about which they have continuing significant concerns.

Councils should, however, seek to avoid the dangers of a two-tier system emerging which becomes overly bureaucratic. It can be very disheartening for researchers to be subject to two or more, possibly very different, sets of review criteria. Particularly if the information requirements are very different, multiple reviews will also serve to slow down the progress of research, which may cause funding difficulties or even the termination of the work. Councils should be careful not to establish local systems that may inadvertently hinder the progress of good quality social care research.

**Q:** **What happens in the case of multi-site research?**

**A:** It is likely that most significant external multi-site projects (those involving more than one local authority) will have received independent ethics approval and will have been reviewed for the quality of methods, and the comments above will therefore apply. To supplement existing sources of ethics review, the new **Social Care Research Ethics Committee** was established in June 2009, with the Social Care Institute for Excellence as the Appointing Authority (see Chapter 8). This committee operates within the National Research Ethics Service (NRES) but is distinctively social care in approach and culture and is well placed to review and approve funded multi-site research.

Multi-site research studies involving the participation of four or more local authorities and meeting its criteria should also be submitted to the Association of Directors of Adult Social Services (ADASS) multi-site approval process (see www.ADASS.org.uk for details). This is not an ethics and methods review process; rather, it aims to ensure that research is relevant to social services' main concerns, and that it is of an acceptable quality. Areas covered are therefore:

- relevance and value to Social Services' key current and future priorities;
- the time staff would be expected to contribute;
- ethical issues;
- the likelihood of the project being brought to a successful conclusion;
- plans for publication and dissemination of results.

Directors are encouraged not to support relevant projects that fail to apply for, or secure, ADASS approval. However, such approval, though significant, does not obviate the need for researchers to negotiate access with individual councils, through their RG system in the first instance.

In respect of local research governance approval, however, it is suggested that multi-site studies identify a **lead local council** which is willing to act by agreement on behalf of the identified others. This council will take responsibility for undertaking the relevant checks and for recording and monitoring the research, including sending information to the Research Register for Social Care, as well as for disseminating copies of that information to other participating councils. This process will save duplication of effort on the part of local councils as well as the research team involved. Researchers are advised to contact local authority RG leads early in the development of such studies, in order to make these arrangements.

## 3.4 Minimum requirements

**Q:** **So what is the minimum local Councils must do to secure effective research governance?**

**A:** At a minimum there are two basic requirements for local councils to fulfil. Firstly, checks need to be made on all **external research** requiring access to service user, carer or staff populations, or their personal data, in respect of whether proposed study has:

- received independent ethics approval;
- been independently reviewed (favourably) for the quality of its methods;

- an identified sponsor who is prepared to accept research governance responsibilities for the proposal (normally the researcher's employer);
- sound arrangements for the management of the project, including financial management.

For most **internal** or **'own account'** research activity that matches the local definition of research, and for external research that has not sought or received prior independent review, the local council should undertake some formal review of methods and ethics before the research proceeds (Annex 4 provides a Risk Assessment Tool which may assist this activity).

Secondly, a record of all applications/assessments and their outcomes (covering both internal and external research) needs to be made, and details kept on a local research register. Information about all approved research should also be sent to the **Research Register for Social Care** (RRSC, www.researchregister.org.uk). Further details are contained in Chapter 7.

**Responsibilities and Processes**

## 4.1 Introduction

This Chapter discusses an overall approach to research governance in local authorities. It identifies different possible arrangements and key sets of activities that are required to provide a minimum level of governance, and highlights approaches that can improve on basic reviewing and approval processes. It also sets out the different approaches and tasks that are required for 'own account' and externally commissioned research studies.

Local authorities have a responsibility to assess both the ethics and the methods of proposals, to form a judgement about risks presented in these areas. They can do this internally, with help and advice from external bodies, such as other local authorities or universities, if needed. Alternatively, they can require researchers to submit to external processes such as scrutiny by a research ethics committee in the National Research Ethics Service (NRES)[4] or a university research ethics committee. Many external research proposals should already have been approved by such bodies. Such approvals may have been required in order to comply with statutory requirements, for example in relation to mental capacity issues. In addition, some will also have been independently reviewed for design and methods by research funders. Once checks and verification are made, with acceptable results, any further review should not repeat the work of other committees, but should focus on local implementation issues, risks, and the appropriateness of the whole project to local circumstances. In all cases, proportionality to levels of risk should be a key principle.

Adopting such an approach is in accord with 'Securing Ethics Approval: A Route Map for Social Care Researchers' (see Annex 6) which has been agreed by key stakeholders, such as the Economic and Social Research Council, the Association of Directors of Adult Social Services, NRES and the Association of University Research Ethics Councils. One basic principle is to avoid double-handling – that is, subjecting the same proposal and documentation to two independent research ethics review systems. This is to avoid conflicts and unnecessary delays arising because of the different requirements of two different ethics review systems.

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[4] The National Research Ethics Service (NRES) includes all the former NHS Research Ethics Committees and the new Social Care Research Ethics Committee.

## 4.2   Who reviews and approves

### 4.2.1  RGF leads

As a minimum standard, the task could be allocated to a single member of staff, typically the RGF lead, where this post exists. Certainly it will be possible for this individual to administer and review proposals that may be claimed as presenting low levels of risk. It is inadvisable however for a single individual to carry the responsibility unaided, or to review potentially more complex or risky research without consultation.

In setting up a RGF system it is strongly recommended that the RGF lead makes contact with other authorities and organisations such as universities. Learning from others who have established review systems is often the best way to get started. It is also likely that other authorities may have paperwork and procedures that can be transferred and adapted locally, to avoid having to start from scratch.

### 4.2.2  Single authority panels

Where possible, it is advisable to establish a group or panel to review and approve proposals. Such panels can operate in different ways. One approach is for all proposals to be considered by all members of the panel, after an initial risk assessment by the RGF Lead. This is the approach taken in Essex, as described in Chapter 6. Another is to nominate a 'lead reviewer' for each proposal who makes an initial judgement about its acceptability, and its need for further review. In some systems a lead reviewer is able to make a final decision about whether or not to approve a proposal, while in others they can only make recommendations to the panel.

### 4.2.3  Multi-authority panels

In some areas, a group of local authorities have set up a joint panel, which is used to approve proposals that carry higher levels of risk or are particularly complex. The 'Southern Consortium' has developed such an approach, which is also described in the Chapter 6. Such arrangements have been developed partly as a result of the research governance Alliance Grants (offered between 2005-6, as mentioned earlier), and partly by investment from the authorities taking part.

## 4.3   Reviewing Research Proposals

The process of reviewing proposals includes a number of elements:

- assessing the appropriateness of the proposal to local needs and circumstances;

- checking documentation, including research plans, participant information sheets, research instruments;

- checking for evidence of necessary prior approval from ADASS's or ADCS's research advisory systems (for multi-site studies). It is to be remembered that these systems provide advice on whether such studies are likely to be of benefit and whether the demands presented are reasonable. They are not a substitute for ethics and methods reviews and approvals;

- ensuring that the proposal has been subjected to appropriate review of ethics and has received a favourable opinion from an in-house (for most internal research) or from an independent research ethics committee (for most external research);

- ensuring that the proposed design and methods have been subjected to appropriate independent review and approval, either in house (for most internal research) or by the research funder, using a peer review system (for much external research);

- making other research governance checks (for identified sponsors; legal compliance, as with the Data Protection Act 1998 and Mental Capacity Act 2005; financial management; information dissemination; and health and safety).

### 4.3.1 Local needs and circumstances

Whether it is appropriate for a study to be conducted at a particular time or place will depend on specific local circumstances. For example, research may not be appropriate at a time of significant change in the way local services are provided. The research proposal should be discussed with internal commissioners and relevant managers in the authority in addition to the research governance lead, to establish whether it is appropriate for local circumstances. For external research, such discussions may often need to be facilitated by the research governance lead within an authority. This approach could be equally valuable in assessing the appropriateness of externally and internally commissioned studies and can be undertaken in parallel with the main research governance process.

Councils should also consider assessing and making explicit the costs that they estimate they will incur for hosting the research process (e.g. staff time). Where research has received external funding, it is often reasonable to ask whether the research team can make some contribution towards these costs. In turn, researchers may need to ask research commissioners to recognise these costs in the funding they provide.

### 4.3.2 Checking documentation and approvals

Full proposals can be submitted using local council application forms (where available) such as those used within authorities' systems described in Chapter 6. However, it is recommended that local authorities accept forms and accompanying documentation submitted by researchers for ethical/methodological reviews completed elsewhere if they are consistent in coverage – for example, full IRAS documents submitted to NRES. This will help reduce practical burdens on researchers (see prior approvals below). Once material is received, the following checks will need to be made:

**(i)    Paperwork and documents**

It is important to begin by checking if all the relevant information has been supplied in addition to research plans or protocols. A copy of an ADASS/ADCS support letter should be supplied for proposals intending to involve four or more local authorities. Participant information sheets/consent forms and questionnaires or interview guides should also be required, as considered appropriate by the council. Evidence that researchers have been CRB-checked, where this is required by the nature of the research, will also need to be provided before work can commence. Again, these checks are required for both internally commissioned and externally funded research.

**(ii)    Prior approvals**

- Ethics

It is important to check whether the proposal and associated documentation have been approved by a suitably qualified and authorised body, such as the national Social Care Research Ethics

Committee, a university research ethics committee, or through another local authority's research governance approval process. Much significant externally funded research will have been submitted to one of such bodies. Evidence of the approval should be provided, including any amendments required.

Where previous approvals have been secured by researchers, including from other local authorities, it is recommended that research governance leads and panels request and study all the documents that accompanied previous applications (including information sheets and research instruments). This should usually be instead of requiring further or updated application forms. In general, the amount and type of information required with applications can be agreed by the RG lead with researchers when they make contact for the first time. See Chapter Five for more detailed advice on ethical issues.

Any research potentially involving participants who may possibly lack capacity, as defined by the Mental Capacity Act, 2005, must have received ethical approval from an approved body. Currently only certain research ethics committees within NRES are authorised to approve such studies, including the Social Care Research Ethics Committee (see Section 7.5).

- Methods review

It should also be ascertained if the methods proposed have been independently reviewed for scientific quality. This review needs to have been carried out by suitably qualified individuals with experience of similar kinds of studies. Again, most significant externally funded research will have been subject to some form of peer review of methods. Researchers will need to provide evidence of the review and its outcome. For students, academic supervisors are responsible for ensuring independent review has taken place. See Chapter Five, Section 5.2 for detailed advice on reviewing methods for in-house research activity.

- Local authority research governance checks

In the case of multi-site studies (involving the participation of more than one local authority) it is good practice to consider whether additional applications are necessary, and in how much detail, if other councils within the study have already given local research governance approval. Where further review is felt to be necessary, the burden on researchers can be greatly reduced if local authorities are prepared to accept application forms completed for other sites. Standard regional templates, such as those operating in Midlands authorities, can be of help here. See Chapter 6 for contact details.

### 4.3.3  Reviewing ethics and methods

Reviewing a study for its ethics and methods is often the most time-consuming and potentially problematic aspect of research governance. The Social Care Implementation Plan for research governance (DH, 2004) proposes a minimum approach on the part of councils and other care bodies. An edited and amended version of the Implementation Plan is included as Ch 7.1 in this Resource Pack. A number of authorities, however, undertake more detailed reviews, either as part of a generally more extensive system, or for certain projects, after establishing that the minimum requirements are met. Again, Chapter 6 gives some examples of different kinds of approach in local authorities.

### (i)   Minimum requirements

For **externally funded research**, once it is established that  the study has been approved by an appropriate ethics committee and has received a favourable independent review of its design and methods, further checks are only required in relation to the other issues set out below in Section iv.

For  most **'own account'** research that matches the local definition of research, and for **externally funded  research that has no access to or has not used a prior independent review system**, the local council should undertake some formal review of methods and ethics before the research proceeds. Judgements about the level of review needed can be assisted by some of the issues identified in the Risk Assessment Tool (see below and Annex 4). The Tool may also be used formally as an aid to judgement. Occasionally, it may be hard to make a judgement about the acceptability of a particular study. In these cases, further advice can be sought from other local authorities or local university staff (although payment may be required if this becomes a regular occurrence). Alternatively, some local councils have combined to form RGF alliances that are able to provide a source of collective – and more independent - expertise and advice on ethics review (see Chapter 6).

### (ii)   More intensive review

Where there are strong concerns about an externally funded proposal, which has been reviewed favourably, further checks may be undertaken, using:

- the full response from the original ethics committee/ and review of methods, including any amendments required;
- the documentation submitted to the ethics committee and funding body (application forms, research instruments and information sheets/consent forms);
- the peer review comments and the researcher's responses to these.

Such checks can provide a valuable safeguard and be a way to identify issues that may have been previously missed. However, where extra scrutiny is felt to be necessary, it is important to take fully into account any prior approvals obtained before requiring further amendments, particularly for multi-site proposals that may already have been subject to several review processes. Occasionally, it may be hard to make a judgement about the local acceptability of a particular study. In these cases, further advice may be available from other local authorities or local university staff, prior to a decision to agree or refuse to support the study.

### (iii)   The Risk Assessment Tool

The Risk Assessment Tool (see Annex 4) can be a valuable support for reviewing research proposals. It can be used to help identify any potential risks of harm that could result from the research and to assess whether researchers have developed a satisfactory approach to addressing these issues. This process can guide decisions on approval and help identify necessary amendments.

It is valuable for those involved in the research governance process to have an awareness of the risks that can arise; how they relate to possible harm and the kinds of approaches researchers and councils can take to minimise identified risks. Chapter 5 outlines some of the important issues for assessing ethical implications and the quality of methods. Also, the South East/Midlands research governance consortia have commissioned a training manual for reviewers in local councils undertaking research governance reviews, concentrating on issues of methods.

### 4.3.4 Other research governance checks

For all research proposals, a number of further checks are needed, to establish that:

- a sponsor has been identified who is willing to take overall responsibility for confirming that everything is ready for the research to begin. Local authorities will need to act as sponsor for 'own account' studies and should identify a named individual to take on the role. Usually the research employer takes on this role for externally funded research, although other arrangements are also acceptable (see Chapter 7);

- appropriate arrangements have been made for proper financial management of research, including the ownership and exploitation of intellectual property;

- information about the research findings, once these have been subjected to appropriate scientific review, will be freely available in accessible formats to the host organisation and its user populations;

- health and safety regulations will be observed.

As previously indicated, where a proposal has received comprehensive research governance approval from other local authorities, further checking should be kept to a minimum to reduce unnecessary delays.

### 4.3.5 Post-Review Actions

Research governance reviews can result in proposals being: approved outright; approved with conditions; or rejected. A number of further tasks are necessary for each of these outcomes:

**(i)  If the proposal has been approved:**

- record the decision and establish arrangements for monitoring;

- inform researchers about the approval and make arrangements for further reporting, including requesting final/progress reports for dissemination as appropriate;

- inform relevant managers/other relevant staff about the approved research, the start date and any other relevant issues;

- submit information about the study to the Research Register for Social Care (see Chapter 7).

**(ii)  If conditionally approved:**

- log decision and amendments required;

- inform researchers and request resubmission with amendments.

**(iii)  If a proposal is rejected or withdrawn (for example if it is felt that no improvements can be made in terms of the methods or ethics of the plan in the time available):**

- record decision and reasons;

- inform researchers in writing and explain decision, providing details of reasoning.

**Key elements of research governance decision-making**

Figure 1, overleaf, represents in schematic form the main elements of research governance decision-making. These aspects are particularly relevant for externally funded research with a

significant academic input and rigorous formal processes in place. Other types of project (including in-house studies) require a similar sequence of decision-making or checks, which are especially important where these processes are not externally assured.

**Figure 4.1: Key elements of research governance decision-making**

```
Approach from              Outline proposal
externally funded   ───►   invited/received
researchers

                    │                    │
                    ▼                    ▼

         Not appropriate          Possibly
REJECT ◄── for local              appropriate
           circumstances          for local
                                  circumstances

                                         │
                                         ▼

                    Full proposal   ◄───  Need for internally
                    invited/received      funded research
                                          identified

                                         │
                                         ▼

Request more details,  ───►  Check documentation
and prior approvals          and prior approvals

                                         │
                                         ▼

                    Undertake internal   ◄──►  Seek external
                    review where necessary     advice, if required
                                               (e.g. for high risk
                                               studies)

                                         │
                                         ▼

                    Undertake other
                    RG checks

                                         │
                                         ▼

Log and submit to     ◄───  APPROVE
Research Register for
Social Care; inform         CONDITIONALLY  ───►  Request
relevant internal           APPROVE              resubmission with
personnel & researchers                          changes

                            REJECT        ───►  Log and inform
                                                 researchers
```

## Chapter 5: Reviewing Research Proposals and their Implementation

This chapter sets out some key issues that should guide the review of research, across the five 'domains' of research governance:

- ethics
- science
- information
- health and safety
- finance (and value for money).

It also discusses the involvement of service users, carers and the public.

By outlining some of the ethical and methodological issues and identifying other important aspects of the research process, the chapter aims to inform those directly involved in reviewing research proposals about important issues on which to focus. This information may also be of value to researchers in developing good proposals, and in deciding what information to submit to research governance and other vetting and approval processes.

## 5.1 Ethics

### 5.1.1 Introduction

A vast literature exists on ethics and it is impossible to review it all here. However, it is valuable to start this section with a brief outline of some common ideas about this topic. Ethics can be thought of as the study of moral or good conduct and of the grounds for making judgements about what is good conduct (Trusted, 1987; Birch et al., 2002). Approaches to ethics are commonly identified in one of two broad groups (Betros, 1994).

One view is that ethical values have a separate existence and that they can generate rules that people should choose to follow, whatever the consequences (a 'deontological' approach). There is another view that actions are judged on the basis of their consequences for the general good (a 'utilitarian' approach). These approaches underpin sets of principles to be followed or rights to be upheld, either because of an appeal to abstract values, good in themselves, or because of their overall benefits to the greatest number.

Such principles are commonly quoted as important in discussion of research ethics. One code developed for social work and social care research ethics by Butler (2002) was based on four principles:

- respecting people's right to make choices about their lives, including whether to take part in research ('autonomy');
- acting to maximise positive consequences ('beneficence');
- acting to minimise negative consequences ('non-maleficence');
- honest and fair dealing ('justice').

These principles reflect both the approaches outlined above. For example, the principle of maximising positive consequences may be respected as a generally good thing in its own right

or because it benefits society as a whole. Such approaches reflect Western and rationalistic ethics (Birch et al., 2002) and not the reflexive or emotional aspects of ethical conduct, which are important in making decisions about relationships and interactions. Individual situations usually involve tensions between such principles and require an element of judgement and compromise.

In the Economic and Social Research Council (ESRC) *Research Ethics Framework* (ESRC, 2006) 'Research ethics' is defined as:

> …*moral principles guiding research, from its inception through to completion, and publication of results and beyond.* (ESRC, 2006: 7)

The ethical principles outlined above can be mapped on to a set of issues that are commonly identified as important research principles.

| Research principles | ETHICAL PRINCIPLES | | | |
|---|---|---|---|---|
| | Autonomy | Beneficence | Non-Maleficence | Justice |
| Conduct research with objectivity, integrity and impartiality | | ✓ | ✓ | |
| Consider carefully the consequences of the study for human beings | | ✓ | ✓ | ✓ |
| Respect dignity and minimise harm | | | ✓ | |
| Recruit participants carefully and respectfully | ✓ | | | ✓ |
| Obtain informed consent | ✓ | | | ✓ |
| Respect privacy and maintain confidentiality | | | ✓ | ✓ |
| Treat participants with equity and do not discriminate against groups | | | ✓ | ✓ |
| Report findings honestly and fully | | ✓ | | ✓ |

### 5.1.2 *Conduct research with objectivity, integrity and impartiality*

Whilst research can never be entirely objective (due to the researcher's own values or a range of other factors imposed, for example, by the commissioning process), researchers should attempt to uphold their professional integrity without fear or favour. In order to follow the principle of treating people honestly and fairly, they should not engage with or collude in selecting methods designed to produce misleading results, or in misrepresenting findings by commission or omission.

When considering alternative methods and procedures, researchers should provide an impartial assessment of respective advantages and disadvantages of alternatives. Ensuring that research is undertaken using the appropriate methods for the aims of the research, and to a high standard, maximises the possibility of positive consequences from producing good evidence, and minimises the possibility of distress or harm without a benefit.

Any obligations to employers or funders need to be clarified in proposals and in communication with potential participants. In particular, researchers should not accept contractual conditions that are contingent upon a particular outcome from a proposed inquiry.

### 5.1.3  Consider carefully the possible consequences of the study for human beings

Research should only be undertaken when there are potential benefits for groups being researched, although these can be long-term benefits of increased understanding, as well as policy or practice change. Ideally, new projects should build on previous work, or should clearly show why duplication is necessary. Without a good case for undertaking new research, the possibility of negative consequences (time-wasting and possible distress) cannot be justified by potential positive consequences.

In planning all phases of research, from design to presentation of findings, the researcher should be sensitive to the possible consequences of his/her work and should as far as possible guard against predictable harmful effects.

All information, however it is collected, can be misconstrued. Researchers will not be in a position to prevent action based on their findings: however, they should attempt to pre-empt likely misinterpretations and counteract them when they occur.

### 5.1.4  Respect dignity and minimise harm

Neither consent from participants, nor any requirement to participate absolves the researcher from an obligation to protect the subject as far as possible against the potentially harmful effects of participating. In the conduct of research it is important to avoid or minimise possible distress, which is not the same as harm, arising from the kinds of questions asked in particular circumstances. However it is sometimes necessary to ask questions about distressing situations as part of research in social care. Researchers therefore need to minimise the likelihood of causing harm or distress, through careful choice and development of questions and planning of data collection.

Where it is likely that distress could be caused, researchers should make this clear when contacting potential research participants. In addition, researchers should work with participants, their relatives, and possibly paid staff to identify suitable sources of support to be available. Finally, interviewers and other research personnel should be well trained and have experience of research in the field, in order to ensure they respond in appropriate ways to individuals in distress.

Special care should be taken where research participants are particularly vulnerable by virtue of factors such as age, social status and powerlessness. Care should be taken not to infringe rights to privacy or to disturb relationships between participants and proxies, who are likely to be carers, either paid or unpaid. Where indications exist or emerge that the participant would object to certain information being disclosed in research, such information should not be sought by proxy. See Chapter 8 on the Mental Capacity Act for advice about the new procedures required for research with people for whom capacity to give consent is in question. (See also *Guidance for Nominating a Consultee for Research Involving Adults who Lack the Capacity to Consent,* DH, 2008.)

### 5.1.5  Recruit participants carefully and respectfully

How people are identified and approached has ethical implications and will need careful consideration with CSSRs, in order to access service users and staff. Potential participants need to be clear about why they are being contacted and not put under any pressure to take part (or not to take part) in research activity.

Any payment offered for involvement with research either as incentive or acknowledgement needs to be approached and managed carefully. This is a controversial issue, and will need to be fully explained in proposals. It may challenge the principle of autonomy, as it could interfere with the free choice to take part, particularly for participants in financial difficulties. Thus the amount and type of incentive/acknowledgement needs to be proportionate. There can also be methodological implications for the project from payments being made.

### 5.1.6  Obtain informed consent

Given the potential risks and also the time involved in taking part in research, taking part should be a voluntary choice, in order to respect the principle of autonomy. However, there may be circumstances where individuals (usually staff) are required to take part in research or related activities, such as the gathering of performance information.

Unless a participant has good, clear and sufficient information about the reasons for the research and consequences of taking part, it is impossible to make a genuine choice about whether to take part. Even in circumstances where individuals are compelled to take part, they should be given as much information as possible about the project.

In general, those asked to take part in studies should be given information in appropriate and accessible formats about:

- the nature and purpose of the research;
- what taking part involves;
- the level of anonymity or confidentiality possible;
- their entitlement to refuse to take part at any stage without giving a reason, and to withdraw any supplied data.

Where possible, participants should be approached directly for consent. The Mental Capacity Act (2005) introduced new requirements for approaching and gaining consent to undertake research with people who are unable to give consent on their own behalf. Chapter 8 gives some information about establishing whether a person is able to consent to research and how to work with carers, family members or paid staff to obtain consent on behalf of the individual, where this is unavoidable.

### 5.1.7  Respecting privacy and maintaining confidentiality

Research often involves sensitive information about individuals, which could be harmful or distressing if made public. Only personal information that is necessary for the study to achieve its purpose should be requested and recorded (as required by the Data Protection Act: see Chapter 8). Keeping this information as confidential as possible is therefore required in order to avoid negative consequences.

The identities and records of co-operating participants should be kept confidential, whether or not confidentiality has been explicitly promised. Individuals should not be identified either in the analysis or presentation of results. The identity and research records of those participating in the research should be kept in a secure manner disclosed only to authorised personnel and disposed of securely and as soon as possible after the study is complete. Occasionally, participants have been known to request that their names are used in reports. While this is acceptable, provided all agree, it is very much the exception.

However it is sometimes impossible to ensure total anonymity, particularly if reporting quotes or narratives gathered as part of the research, and which is seen as good research practice. In such circumstances, it is important to be honest with participants about the possibility of being identified, before they agree to take part (to treat people fairly and honestly). Sometimes a researcher is obliged to break confidentiality, for example in situations where a participant reveals someone is being harmed, or that they themselves have abused a child or adult. Again, it is important to make this potential obligation clear to participants before they agree to take part.

### 5.1.8 Treat participants with equity and do not discriminate against groups

In order to minimise potential harm and to treat people fairly, the design of the study should not discriminate against research workers or participants on the basis of age, gender, race, ethnic origin, religion, sexual orientation or disability. Participation in the study, in either capacity, should be on the basis of equal opportunity. Consideration should be given to issues likely to act as a barrier to participation, and reasonable steps taken to address these.

Involving service users in all aspects of research is often a powerful way of ensuring that research respects dignity and treats people fairly.

### 5.1.9 Report findings honestly and fully

In reporting research, researchers have a responsibility to alert potential users of their data to any limits in their reliability and validity. Researchers are advised to avoid overstating or understating the validity or the degree to which the data can be generalised from. Without acknowledging the strengths of the research, potential benefits may not be achieved. If limitations are not acknowledged, potential harm may be caused if research users place too much confidence in the evidence produced.

In order to assess the quality of research, and therefore maximise its value, methods and procedures should be open to public scrutiny and assessment. This will also provide useful information for future researchers, and generate further potential benefits.

## Resources

### Economic and Social Research Council (ESRC): ESRC (2006) Research Ethics Framework (REF)

This document sets out what the ESRC requires by way of ethical approval for the research it is asked to support, and sees as good practice for all social science research. The REF is mandatory for ESRC-funded research and is available for use by other funders if they wish. www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Images/ESRC_Re_Ethics_Frame_tcm6-11291.pdf

### ESRC National Centre for Research Methods (NCSRM): 'Informed Consent in Social Research: A Literature Review'

This review provides useful background information about the need for informed consent and different ways of obtaining it. http://eprints.ncrm.ac.uk/85/1/MethodsReviewPaperNCRM-001.pdf

### Government Social Research Unit Professional Guidance: 'Ethical Assurance for Social Research in Government'

This document sets out the key principles to be upheld in the conduct of social research for government. The principles reflect the standards accepted by the wider profession, but take particular account of the responsibilities of those conducting social research for government. http://www.gsr.gov.uk/professional_guidance/ethical_assurance.asp

### Social Research Association Ethical Guidelines

These are a very useful guide to research ethics issues. www.the-sra.org.uk/ethical.htm

### The Respect Project

The RESPECT project was funded by the European Commission's Information Society Technologies (IST) Programme, to draw up professional and ethical guidelines for the conduct of socio-economic research. www.respectproject.org

### National Research Ethics Service (NRES)

NRES aims to support ethical and good quality research in the NHS. It provides support and guidance to NHS Research Ethics Committees. www.nres.npsa.nhs.uk/

### British Sociological Association (BSA): 'British Sociological Association (BSA) Ethical Guidelines'

While focused on sociological research, this statement contains a useful statement of ethical issues that may arise throughout the research process. It encourages researchers to take responsibility for their own ethical practice. www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm

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## 5.2   Science

There is an ethical requirement to undertake research for good reasons, in order to develop knowledge with the potential to improve services and outcomes. Using sound methods and operating to high standards when undertaking research is also an ethical concern. Both of these issues also make up the idea of good social science, which needs to underpin research activity in this area.

As with ethics, there is a huge literature about methods: this introduction can only point to some of the major issues and identify some resources for those wanting to follow these up. To satisfy standards of science, research needs to have:

### 5.2.1   Sound reasons for doing the research

Well thought-out proposals need to show why research activity is being undertaken, showing how it links to previous work or is a particular policy or performance imperative in a local context. It should be possible to construct a good reason for undertaking any project falling within the definition of research covered by research governance.

### 5.2.2   Specific aims and objectives

In addition to identifying a general reason, specific aims and objectives are needed in order to be clear about what researchers are trying to investigate, the hypothesis they are testing or the specific area of performance they are measuring. This shows that the researchers have a clear reason for the specific methods to be employed in the research.

### 5.2.3   An appropriate research design

A clear description of the research design or plan for the study is essential. This demonstrates how the methods and approach selected will fully achieve the aims and objectives of the project. The following illustrates how different designs can be used for different purposes:

**(i)   To test the impact of a new service or development:**

- Randomised control trial – in which participants are randomly allocated to an 'intervention' group receiving a new or different service or a 'control' group which receives traditional services or occasionally no input.

- Quasi-experimental design – in which participants are allocated to an intervention or control group by non-random means. For example, introducing a new approach for users of one day service and comparing results with those of a similar group of service users of another day service.

- Before and after testing – in which the impact of a new approach is measured through the difference in relevant scores (perhaps on a well-being or quality of life measure) before and after receiving the service.

**(ii)  To describe opinion or characteristics:**

- One-off surveys – postal, online questionnaires or face to face, structured interviews sent out or undertaken at one time can identify opinion or describe the characteristics of a group or population.

- Repeated surveys – in a similar way, repeated surveys or interview studies can investigate changes in opinions or characteristics over time.

**(iii)  To explore and understand meaning and experience:**

- Phenomenological – in which the overall aim is to understand the lived experience of a group or individual. In-depth approaches such as interviews are usually employed.

- Ethnographic – in which the aim is to understand a culture or set of social relationships, which could be linked, for example, to ethnicity, the world of a school or social work team. Observation is often a key part of such studies.

- Grounded theory – in which the aim, for example, is to uncover and explain the social-psychological processes within a particular setting. Examples could be examining the processes of induction of staff or understanding the key elements of assessment. The key characteristic of grounded theory approaches is a sequential approach to selecting participants, fieldwork and analysis. After the first round of fieldwork, with participants selected on the basis of a preliminary understanding of the topic, initial analysis guides further selection of participants and fieldwork, until a final analysis is reached where no new insights appear to be coming from fieldwork. The ultimate goal is to develop a theory to explain the topic that clearly emerges from empirical data collected.

### 5.2.4  Sound methods

In addition to using an appropriate design, methods need to be chosen and developed with care. Researchers need to be able to show how and why they have selected particular methods. Research instruments (e.g. questionnaires) need to be developed according to the needs of the research design and the aim of the research. Questionnaires or interview guides must be tested in order to identify problems and improve the wording of questions or the structure and format of questionnaires.

The use of questionnaires and measures developed for other studies needs to be explained and justified. How the different instruments to be used have been or will be tested is also very important, and should be described. Research instruments will need to be accessible to participants and chosen with knowledge of the particular needs of participants in terms of literacy and language, for example.

Practical issues also need to be addressed. Will there be access to quiet rooms for interviews? Will potential online survey respondents be able to access the internet?

### 5.2.5  A clearly set out strategy to select participants

Occasionally it is possible to include everybody in a study within a population of interest, perhaps in a study to investigate service user views of a small service. More commonly, it is necessary to select a group of participants, either to represent a larger population, or who have a particular set of experiences or characteristics that are relevant to the aims of a study. For large scale quantitative projects it is useful to randomly select a sample of people from a population. For example, to investigate satisfaction with care management or social work, a random sample could be selected from the database of all service users. Studies aiming to explore an issue in more depth will often need to select individuals on the basis of their experiences or particular characteristics relevant to the topic. It is important to be clear about how and why participants will be selected, as well as how they will be recruited to the study.

### 5.2.6  A planned and clearly set out approach to data analysis

In addition to setting out the methods used, how data are to be analysed is also of central importance, as one way of justifying its collection. It also shows how a particular research project or activity will meet the objectives set out. Methods of analysis to be used, including overall approaches to statistical analysis or to working with qualitative data need to be explained and justified in relation to the aims of the study and the kinds of data anticipated.

### 5.2.7  A planned approach to reporting and dissemination

Finally, how a study is to be reported and disseminated is a key part of the quality of the science as well as being an ethical issue. Without reporting the research activity in appropriate forms, the aims cannot be achieved. Different kinds of reports and presentations are needed for different audiences. Having a plan for this element at the start of a study is one indication of its quality. Of course, it is important that researchers accept their obligation to produce and submit reports as a condition of research governance approval. Checking that such reports have been produced is also part of the research governance process.

## Resources

**Intute**
Intute is a free online service providing you with access to Web resources for education and research. The service is created by a network of UK universities and partners. This is the link to the social science section, which includes information on many good research methods. www.intute.ac.uk/socialsciences/researchtools

**The Research Mindedness Virtual Learning Resource**
This has been funded by the Social Care Institute for Excellence (SCIE), to help students and practitioners of social care and social work make greater and more effective use of research in their studies and in practice. Although no longer being updated, this is still a good resource. www.resmind.swap.ac.uk

**ESRC Guide to research methods training in the social sciences**
This brief guide is designed to provide some pointers to the rapidly growing availability of training provision in social science methods. It is being updated and can be downloaded from www.ccsr.ac.uk/methods/courses

**RD info**
RD info is a web resource set up to support health and social care researchers. It contains advice for researchers as well as funding and training opportunities. www.rdinfo.org.uk

## 5.3  Information

The RGF makes it clear that social care research is conducted for the benefit of service users, care professionals, and the public in general. Free access to information, both on research being conducted and on the findings of the research – positive or negative - is therefore necessary once these have been subject to appropriate scientific review. This is also a requirement of the Freedom of Information Act (see Chapter 8). This information should be presented in a format understandable to the public. Reports need to be comprehensible, and take language and other needs into account.

The RGF also makes it clear that, in addition to publicising the findings of research, all those conducting health and social care research must open their work to critical review through accepted scientific and professional channels. Within local authorities, therefore, it is important to establish an approach to checking the findings of in-house studies before they are used as evidence to support or challenge policy.

Once findings are established they must be made accessible to those participating, and to all those who could benefit from them. This may be through publication and/or other means appropriate to the type of research. Data relevant to findings should also be accessible.

## 5.4  Safety

The RGF makes it clear that the safety of participants and of research and other staff should be a priority at all times. All research should comply with national and local regulations on health and safety. Research is carried out as a professional activity and therefore researchers are entitled to the protections of the Health and Safety at Work Act. Further, much research also involves service users and staff in the course of their work.

Issues for service users in terms of health and safety are perhaps more subtle in respect of social care research than for medical research, for example. However risks connected with researchers visiting the homes of people in vulnerable situations need to be assessed. And if participants are asked to come to a venue to take part in research their safety must be considered, including issues of transport and access to the building/room.

Typically issues of researcher safety arise in relation to the risks associated with lone working, particularly where visits to service users' homes are concerned. Good practice in terms of identifying relevant information about potential risks is essential. It is also important to arrange for pairs of researchers to visit or to set up call-back systems, in which the researcher informs a colleague or manager of lone visits and calls in to confirm their wellbeing after the visit. Researchers need to be aware of these issues and address them in their work plans.

## 5.5  Finance and value for money

Many of the requirements set out above, particularly in relation to the reasons for undertaking the activity, and choice of appropriate designs and methods, are indicators that research planning will be of good quality. However it is also important to check that budgets are reasonable, in terms of monetary investment and time resources for paid staff, particularly for in-house activity. The arrangements for financial management of the project also require scrutiny.

External funders and research organisations can be expected to undertake financial management of research, although it is useful to ask for confirmation of the relevant agreements. A further issue is to establish who may be responsible for compensation should anyone be harmed through the negligence of the researchers. Usually this will be an external research organisation or funder, who may well have indemnity arrangements. For in-house research, workers are usually covered by authorities' compensation schemes, although again the arrangements need to be confirmed before research can be approved.

## 5.6  Involving service users

### 5.6.1  Why have service user or carer involvement within research governance?

The majority of social care research projects can benefit from the active involvement of service users and carers. Similarly, service users and informal carers can bring a different perspective to bear when reviewing research proposals, which can complement that of social care professionals, researchers, and academics.

Service users and carers have personal experience from being at the receiving end of service provision, and of dealing with a range of issues, such as physical or learning disabilities, mental health problems or the public child care system and, frequently, the social stigmas associated with them. Along with other members of the research governance panel, they can look at research proposals in terms of how they would benefit service users and help ensure that the needs of service user participants have been fully considered in the research proposals.

### 5.6.2  Recruitment

Service users and informal carer reviewers can sometimes be recruited through other service user participation and planning forums operating within the local authority. Within Essex adult social care, for example, the Participation Networks Forum brings together representatives from fifteen local organisations for service users and informal carers (see Chapter 6).

Service user satisfaction surveys conducted by the local authority can provide an opportunity to identify respondents who may be interested in participating in research governance activity. Links with local voluntary sector networks may also be fruitful in identifying service user and carer groups, which may have been active in other forums. A conversation with your local Community Voluntary Services information officer might be a useful start. When the time comes, be prepared to meet service users and carer groups in their own organisations and forums.

The criteria for accepting a service user or informal carer on to the research governance panel should be no different from those for any other member, in that they should have some but not necessarily all of the following attributes:

- a sound understanding of research methodology;
- knowledge of ethical research principles and standards;
- experience of conducting research;
- experience of being researched;
- service user or unpaid carer experience;
- experience or a sound understanding of social care practice;
- knowledge of the organisation's aims, policies and strategic direction;
- understanding of the Data Protection and Freedom of Information Acts;
- understanding of staff development needs and processes.

### 5.6.3 Reimbursement

As with all work involving service users or carers, the question of reimbursement is key. The general principle should be that service users should be reimbursed for work they are providing, unless a strong case can be made for not doing so. Care must be taken in setting rates and so on, in terms of benefit entitlements, although this should not be used as an excuse not to pay for the time and expertise provided. At the very least expenses for travel, subsistence and any additional care costs need to be reimbursed.

For further free guidance in this area see the section on INVOLVE (Annex 3) or visit www.invo.org.uk.

# Chapter 6:  Examples of Local RGF Systems

This Chapter gives some practical examples of the different kinds of approach taken by local councils, reflecting different circumstances and resources. Five different descriptions of an approach to implementing research governance in social care are given, each written by the local research governance lead.

## 6.1    Adult social care only

### Example:  Essex Social Care Research Governance Framework

#### 6.1.1    Coverage

This framework covers research about or within social care only. It operates within a county council with joint working multi-agency partnerships and a children's trust.

#### 6.1.2    Context

Essex Adult Social Care is part of a directorate including libraries and adult learning, while children's social care is part of the Schools, Children and Families Directorate.

A small in-house research capacity based within the Policy Development team manages the research governance service and advises and supports those wishing to undertake or commission social care research. The research governance approach was built upon a pre-existing research steering group in response to the Department of Health's Framework for Research Governance in Health and Social Care, published in 2001.

#### 6.1.3    Participants

The Essex RGF applies to researchers working within and outside Essex County Council who want to undertake research within or about Essex Social Care Services. It is for everyone in all professional groups, no matter the grade or level.

#### 6.1.4    Definition of research

For the purposes of research governance the definition of research is necessarily broad and includes activities that are not traditionally labelled research, such as audits, reviews and consultation.

The following three questions are posed in order to decide what constitutes research and is therefore subject to scrutiny through the framework:

- Are you attempting to discover new knowledge by addressing clearly defined questions with systematic and rigorous methods?

- Will this be additional information to that routinely obtained from Essex Social Care service users, carers, staff, volunteers and stakeholders, to plan individual services (for example via survey, interview, focus group etc)?

- Will you require access to existing information (anonymised or named) held by the Essex Social Care service groups for reasons other than to monitor performance and plan individual service(s)?

### 6.1.5 *Process: the whole process is managed electronically*

Researchers complete an application form that acts as a checklist to assist them in providing all the information the Research Governance Group (RGG) require to make a decision. They must also submit where appropriate the proposed instruments, including participant information and consent forms.

Applications are submitted via email to a central point, the research governance co-ordinator, where they are vetted and any necessary remedial action taken before circulation onward to the panel. Responses from the panel are usually received within two to three weeks and a final decision is taken by the research governance co-ordinator and chair.

The research governance co-ordinator will then feed back to the applicant by email, following up with an official letter of approval from the Chair. Details of the proposed research are entered onto the Research Register for Social Care.

Monitoring and reviewing the research as it progresses are the responsibility of the sponsor (or line manager). They must take action if there are any untoward or unexpected incidents and report these to the RGG together with any major changes to the agreed research methodology.

When the research is completed, researchers provide a copy of the findings to the RGG who decide whether they should be disseminated more widely. If approval is given the report is added to the local register and submitted to the central Research Register for Social Care.

### 6.1.6 *Scrutiny:*

- **The model combines three scrutiny functions in one committee**

  The RGG are empowered by the local authority to give final approval for research studies to commence and for dissemination of research results. The RGG scrutinises each proposal and research report to assess methodology, ethical standards and value in terms of research and development to the organisation.

- **Reciprocal research governance arrangements**

  Within Essex the Social Care RGG has reciprocal arrangements with other local research ethics committees. With the local PCT Ethics Committee, for example, each acts as a peer reviewer for research that involves both social care and health participants. A slightly different arrangement exists with the University. Here we each field a representative as an active member of our respective ethics and research governance panels.

### 6.1.7 *Guidance:*

- **The approach has been accepted as policy**

  A guidance document is available to potential applicants based heavily on the DH framework. It sets out the reasons for having a research governance system and explains what information the RGG need in addition to the application template, alongside outlines for providing participant information and gaining informed consent. Two appendices cover research standards and ethical principles. An advice and consultancy service is also offered to assist would-be researchers in designing their projects and to assist with completing the application.

### 6.1.8    Expertise:

The RGG is made up of managers and representatives from internal operations, business support and organisational development. External members include service users and carers, lay members, health and university representatives.

The RGG members have a mix of skills and expertise that enable the group to address the three areas for review – scientific, ethical, research and development.

No specific research governance training is provided for the group – its operation relies on the existing expertise and judgement of the members

### 6.1.9    Resourcing:

The Research Governance Group does not have a budget, and scrutiny tasks are fitted around the members' usual work. Service users, carers and other lay members are not paid; however, any reasonable expenses would be reimbursed.

### 6.1.10   Throughput:

Approximately 30 to 40 proposals and 15 reports per year.

### 6.1.11   Benefits:

- *simple* – managing research governance electronically simplifies the process in comparison with some other ethical reviews;
- *fast* - able to turn round an application within a month – sometimes when it is urgent, within a week;
- *helpful* - provides a useful checklist and ensures projects are properly thought through.

### 6.1.12   Possible Disadvantages:

- Reliant on one central manager to co-ordinate and administer.
- Depends on availability of group members to respond via email.

**Contact**: Gay Leggett,
Senior Q and D Officer,
Essex Social Care Services
tel: 01245 434765
email: gay.leggett@essexcc.gov.uk

**Fig 6.1: Essex Research application flowchart**

Research need or idea identified and outline brief prepared

↓

Initial contact to commission or discuss and get agreement to proceed further subject to Research Governance approval

↓

Full proposal/RG application and associated instruments submitted

↓

Application vetted and remedial action taken

↓

Submitted to Panel

↓

APPROVED?

NO → (back to Application vetted and remedial action taken)

Abandon

YES ↓

Respond to researcher and add to Research Register for Social Care

## 6.2    Corporate implementation

**Example:  Kent County Council Research Governance Framework**

### 6.2.1    *Guidance*:

The Research Governance Framework (RGF) covers all aspects of Social Care, including Adult Social Services, Children's Social Services, Youth Offending Services, Asylum Services and Drug and Alcohol Services. Other units within Kent County Council also use the Framework.

### 6.2.2    *Context*:

Kent County Council (KCC) is the largest local authority in the country, with four directorates and a Chief Executive's department.

Three directorates within Kent County Council share responsibility for the delivery of Social Care. These directorates are: Adult Social Services; Children, Families, Health and Education; and Communities. In addition to these, related work is undertaken by teams such as Supporting Independence and Public Health. These teams all fall under the remit of the Chief Executive's department. In order to inform and improve services and working practices, a great deal of research, consultation and evaluative work takes place within these directorates/teams.

Kent appointed a research manager to oversee the implementation of research governance, ensure adherence to the guidance, promote research within the directorate and work in partnership with other organisations. The Research Manager advises and supports colleagues who wish to undertake consultations or research, in addition to commissioning and overseeing research and evaluation for the council.

Kent County Council's approach to research governance is based on the SEARIG (a regional consortium of local authorities in the South East of England) regional model that was developed in response to the Department of Health's 'Framework for research governance in Health and Social Care', published in 2001.

### 6.2.3    *To whom does research governance apply?*

The Research Governance Framework applies to researchers working within and external to Kent County Council who want to undertake research or use data relating to those for whom the directors have a duty of care. This includes service users and carers, their data, and council staff. The Governance Framework covers services provided in-house and those contracted out to other agencies. No matter what grade or level the researcher is, they must adhere to the procedure.

### 6.2.4    *Definition of Research:*

Kent County Council uses the definition of research provided in the Department of Health's Research Governance Implementation Plan for Social Care (DH, 2004). The definition of research adopted in the RGF is 'the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods'.

This deliberately inclusive definition covers most forms of disciplined enquiry involving the systematic collection of data and using explicit research methods and techniques. The RGF

does not assume that research activity is more risky than other ways of collecting information that is not directly related to the provision of care. Other research-like activity undertaken on or by social care agencies, including non-financial audit, may raise similar legal or ethical issues. These activities may also call for arrangements to identify and manage risks to the dignity, rights, safety or well-being of participants and can be included in the approval process.

This definition is broad and includes activities such as non-financial audits, reviews, consultations and evaluations but does not include management information.

### 6.2.5    The Research Approval Group:

Within Kent County Council a 'Kent Research Approvals Group' (KRAG) has been established. This group currently consists of about 35 members who are representative of the social care spectrum and have different areas of expertise. Members include the manager responsible for Data Protection and Freedom of Information, operational staff, policy staff and ethics specialists. The approval group also has academic members from local universities on the panel to strengthen the research methods expertise. Some members of the approval group also sit on other ethics committees.

When the Research Manager receives a new proposal it is forwarded to 4-5 members of the KRAG for their consideration. When evaluating research the research approvals group considers the scientific design, ethical issues, data protection, timetable, dissemination and the health and safety of participants and researchers.

The Research Manager liaises with other staff to ensure that the directorates have the capacity to host the research as well as checking that the sponsor, funder and all other ethical approval arrangements are in place. The Research Manager also ensures that the researcher holds professional indemnity, public liability insurance and where necessary holds an up-to-date Criminal Records Bureau check.

The approvals process has been in place since 2004 and has already proved successful in ensuring that proposals are more rigorous and ethical. It ensures that work is not duplicated and that clients are not repeatedly surveyed.

### 6.2.6    The Application Process:

- The researcher contacts the department. The request is passed to the Research Manager. The Research Manager sends the researcher a blank application form and the research proposal template guide which outlines the areas that need to be covered within the proposal as well as the accompanying documentation that is required (usually by e-mail).

- Researchers send to the Research Manager a completed application form, their proposal, information sheets, consent forms, questionnaires, details of insurance and any other ethical approval (again by e-mail).

- A signed copy of the application form is submitted, along with CRB checks.

- The Research Manager screens the application to ensure all documents are present before further action is taken.

- The research proposal is logged on the research database and assigned a number.

- All relevant documents are then sent to members of the Research Approval Group by e-mail. This will normally include a member of staff from the specialist area.

- Ten working days are allowed for responses from the research approval group.

- If the research is considered to be high risk it can be passed to a member or members of SEARIG.

- Where there are concerns these are also discussed with a senior manager in the unit involved and appropriate feedback is discussed.

- Responses are collated by the Research Manager and an official letter of approval is sent to the researcher. If there are any conditions or clarifications required then these are noted in the letter.

- The research is monitored and any adverse incidents recorded.

- Any major changes to the research must also be re-submitted to the Group.

- On completion of the research, the researcher forwards a copy of the report to the Research Manager and the KRAG decides whether the findings should be disseminated more widely. This is usually done but there need to be checks to ensure that any student research has been passed by the university.

- It is published on the Research Database and a copy is entered on the Research Register for Social Care.

### 6.2.7   *Monitoring and Review:*

The research supervisor or line manager should undertake monitoring of the research. Interim updates are requested to ensure that the research is keeping to the timetable and that the research has not significantly altered.

### 6.2.8   *Guidance on Research:*

The research proposal template and application form sent to researchers outlines the required outline content of the proposal and documents. Internal staff have access to the Social Services Library and Research Centre, where there is a new section specifically on research theory, ethics and methods. Further guidance is available from the research manager and the internal website.

### 6.2.9   *Resources:*

The Research Approval Group undertakes the scrutiny of proposals within their normal working role. Academic staff are invited to join and in return staff from KCC sit on university ethics committees.

### 6.2.10  *Advantages of the Approach:*

- All proposals are managed electronically, thereby avoiding the need for approval group members or researchers to attend a meeting.

- The process is fast. Low risk proposals can be accelerated through the approval system, sometimes within a day.

- The process adds rigour to proposals and ensures that there is a clear need for the research/ evaluation/consultation to take place. It ensures that all aspects of the process (e.g. analysis)

are thought about in advance, thus minimising time wasted by unnecessary and irrelevant data collection.

• The RGF ensures that all ethical and data protection issues are considered.

• Research is not repeated, thereby saving time and money. The availability of the database ensures that researchers can learn from each other's work.

• Potential participants are not constantly bombarded with surveys but instead these are proportionate to business needs.

### 6.2.11   Disadvantages:

• Relies on the Research Manager to co-ordinate and administer the process.

• Relies on the goodwill and availability of staff on the research approval group.

**Contact:**
Sue Williams
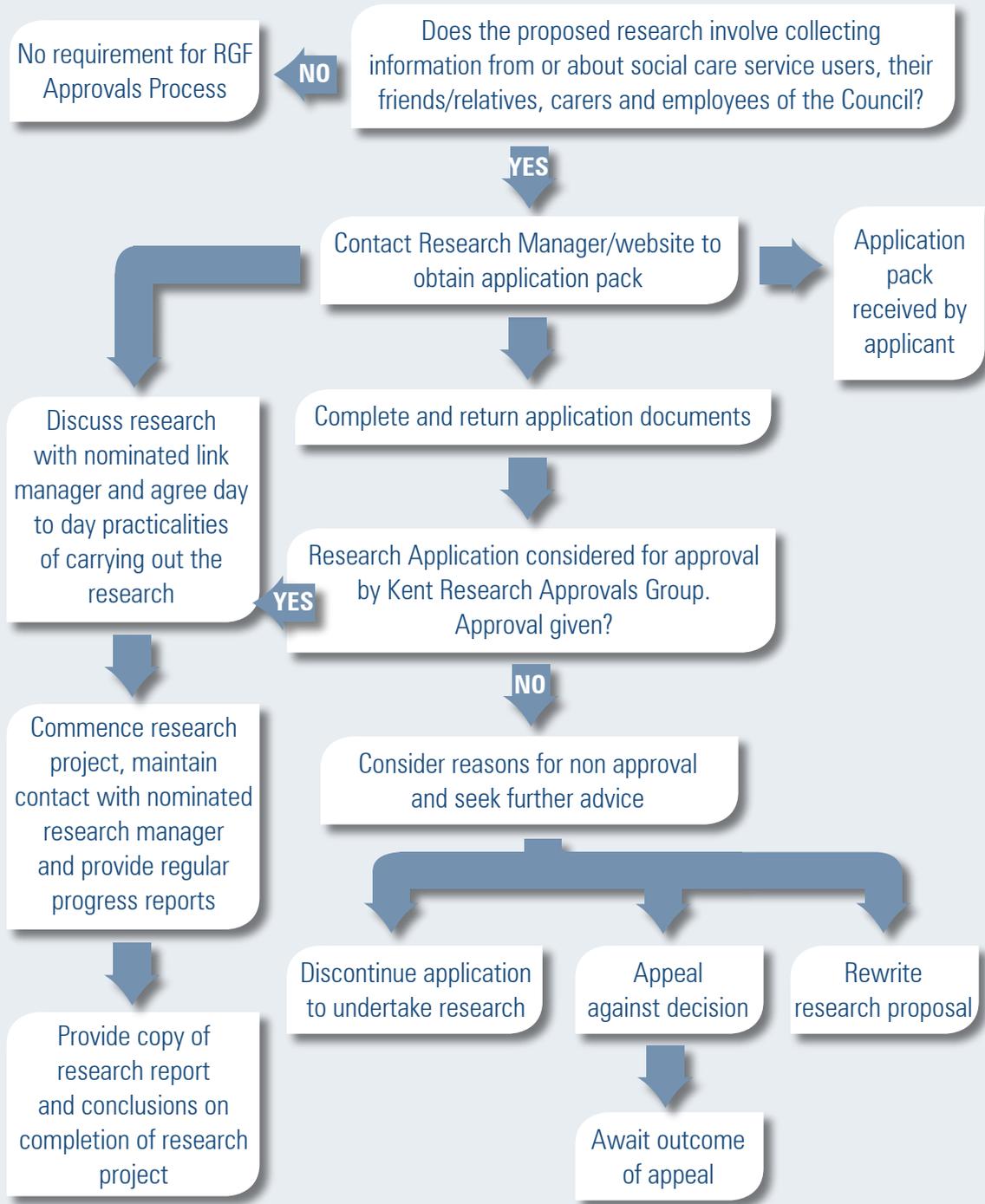Research Manager and Manager of Library and Research Centre
Kent County Council
Social Services Directorate
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email: sue.williams@kent.gov.uk

**Fig 6.2: Kent Research Application Process**



- Does the proposed research involve collecting information from or about social care service users, their friends/relatives, carers and employees of the Council?
  - **NO** → No requirement for RGF Approvals Process
  - **YES** → Contact Research Manager/website to obtain application pack → Application pack received by applicant
- Contact Research Manager/website to obtain application pack → Discuss research with nominated link manager and agree day to day practicalities of carrying out the research
- Complete and return application documents
- Research Application considered for approval by Kent Research Approvals Group. Approval given?
  - **YES** → Discuss research with nominated link manager and agree day to day practicalities of carrying out the research
  - **NO** → Consider reasons for non approval and seek further advice
- Discuss research with nominated link manager... → Commence research project, maintain contact with nominated research manager and provide regular progress reports → Provide copy of research report and conclusions on completion of research project
- Consider reasons for non approval and seek further advice
  - Discontinue application to undertake research
  - Appeal against decision → Await outcome of appeal
  - Rewrite research proposal

## 6.3    CSSR alliances

**Example: South and South East Authorities Research and Information Group**

In this region there is a group of 13 authorities known as SEARIG (South and South East Authorities Research and Information Group). This meets regularly and when research governance was first brought in by the DH a group of authorities pooled finance to employ a consultant to combine the approach across authorities, while still retaining their own unique local flavour.

The consultants were managed by West Sussex and Brighton and Hove, and the work has brought a consistency across the region, as was demonstrated by joint training between East and West Sussex where case studies were evaluated by both sides with a large degree of agreement.

Including the two management authorities there were eight authorities in total, including shire counties and unitaries. Some took the plunge and went corporate from the beginning while others took a slower approach to implementation. Currently there is a range of situations across the area with a corporate perspective, a semi-corporate perspective (where consultation is corporate but not as yet all research), covering both adults and children's services or covering adult services only.

When the DH proposed the RGF 'alliance grant', 13 authorities in the area came together to form the full consortium. Each authority put half of their grant into the joint pot and kept half to develop their own internal systems.

We are lucky to be associated in this joint activity with the Midlands Consortium so that experience and expertise as well as finance can be joined up and utilised to the full. In all this constitutes a group of 28 authorities, so we are approaching 20% of the country in terms of numbers of jointly participating authorities.

The product of this has been a series of regional training events, and the commissioning and production of a reviewer manual for local authorities.

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## 6.4   CSSR and NHS alliances

**Example: Barnsley Health and Social Care Research and Development (R&D) Alliance**

The Barnsley Health and Social Care R&D Alliance is a research partnership between Barnsley Hospital NHS Foundation Trust (BHNFT), Barnsley Primary Care Trust (BPCT) and Barnsley Social Services (BSS). Each organisation contributes financially to support the Alliance, including the continued employment of a Research Fellow (1 WTE) to support research development and capacity, and a part time administrator (2.5 WTE). A unique aspect of Barnsley is the emphasis on partnership; the Alliance encourages and facilitates care pathway research across organisations, rather than restricting research to within organisations.

The Alliance offers a comprehensive approach to managing research governance across the health and social care community. Funding was granted by the Department of Health for an integrated approach to research governance for the three organisations within the Alliance, led by BHNFT because of its longer experience of research governance. A research governance officer and assistant were employed by the Alliance in January 2004.

The functions of the Alliance are to:

• Develop a strategy for R&D.

• Encourage and facilitate research across health and social care.

• Address inter-agency and interface issues covering a range of service areas.

• Develop research governance across health and social care.

• Develop capacity in research for health and social care practitioners.

The Alliance Steering Committee acts as an advisory group, promoting and monitoring research and development within the Alliance. Members of the Committee include senior management team members from the three partner organisations as well as the Director of R&D and the Research Fellow in Primary Care.

Barnsley has four main programmes of research including:

• older people;

• seamless services: pathways of care between and across service providers;

• cardiovascular disease and diabetes;

• cancer.

**Contacts:**

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• Dr Ruth Bacigalupo, Research Fellow. Email: ruth.bacigalupo@nhs.net

• Michael Stanley, Professional Development & Support Manager.
  E-mail: mick.stanley@barnsley.gov.uk

## 6.5 Adults and Children's Social Care CSSR research governance

These two authorities have a similar approach to research governance, helped by their membership of the Midlands Research Governance Group, now covering 16 authorities. This example describes the components common to the two.

### 6.5.1 Coverage

Research, defined as in the RG Implementation Plan: including some forms of consultation, and within both Adults and Children's Social Care services.

### 6.5.2 Staffing

Single RG leads, as indicated at the end of this example, are responsible for publicising and managing their systems and processes, including recruiting and supporting advisory committee/panel members, who review research proposals and outcomes.

### 6.5.3 Application Process

Guidance to prospective researchers is included within council procedures and posted externally through council websites or other media.

Local universities are especially encouraged to draw the attention of students to the application process as early as possible within dissertation timetables.

Informal enquiries are encouraged by the RG leads, from within or outside the councils, to clarify whether any proposed project requires or might benefit from review within the RG framework. For significant multi-site projects, with a responsible sponsor and ADASS/ADCS support, potential capacity for the Council to participate is explored through internal management sources, before any formal RG processes start.

All applications, external or own account, are submitted in writing using a standard Midlands Regional template, and requiring copies of supporting documents, such as participant information sheets and questionnaires. For projects to be undertaken jointly with the NHS, these supporting documents would include copies of previously submitted NRES application material and favourable opinion letters. The template is adapted from good practice models in other English authorities, slightly modified in the light of experience. A key feature is that the application form for projects is a part of a general electronic information and application pack. This is so that prospective researchers and sponsors can have a clear understanding of research standards, and sign up to their commitment to these.

The process and documentation expected from researchers covers material relevant to both ethics and methods, and includes compliance with legal and other research governance requirements.

The application process is handled electronically, and information is displayed on the Councils' websites. Midlands Regional leaflets and posters, giving a general introduction and contact details, have also been disseminated in-house, among staff, and to local universities.

### 6.5.4 Sifting of Applications

The standard application format, and the requirement to produce copies of relevant supporting documentation – questionnaires, information sheets, consent forms, evidence of independent ethics review and reviews of methods, evidence of CRB checks if necessary – are consistent with NHS research governance processes.

These requirements can represent a challenge to less experienced researchers, such as students or some in-house staff. It is not unusual for project planning in these groups to be inadequate, in the light of available time commitments and organisational realities – such as the need to allow for appropriate response times for requests. In some cases researchers may be counselled at an early stage to rethink the scale of their proposal, as an alternative to abandoning it.

The sifting for all projects is handled by the RG lead, for example ensuring that all documents relevant to a risk assessment (if necessary) and review have been provided.

### 6.5.5 Scrutiny

With rare exceptions, after any **initial concerns** identified in the sifting process have been conveyed and responded to, core project documentation, as revised, is submitted electronically to an advisory panel (in Birmingham, committee). This documentation may be accompanied by a copy of the initial concerns letter, if applicable; and any indication of previous ethics or methods review outcomes, as provided by the researcher.

For projects where risks are initially judged to be low, or where previous independent review processes have been positive, consideration by the advisory panels is completed within 7-10 days. Risks here cover both ethical and methods concerns.

If a project is judged high or medium risk, and/or previous reviews appear to have been inadequate, the application may, exceptionally, be reviewed at a meeting of the panel/committee. Such meetings are approximately quarterly. Accordingly, most projects are reviewed more swiftly than this, and electronically rather than in committee meetings. The process applies to in-house projects, where previous reviews are not likely to have been undertaken independently or at all.

### 6.5.6 Expertise

The panels supporting the RG process are made up of unpaid volunteers: staff; service users; and members of staff from social work departments of local universities. The latter sometimes act as supervisors for student projects, so do not review these if there is a conflict of interest.

Membership is for fixed periods and is renewable. The panels are advisory, not executive. They do not have a fixed number of members, but about a dozen people can be called on.

Conditions for membership apply, such as treating material in confidence. There may also be a test of expertise prior to full committee membership being granted. Generally criteria follow those indicated in Chapter 5 of this Pack.

### 6.5.7    Initial outcomes of research governance

The facilitative process, plus comprehensive requirements, means that very few projects are advised to be rejected. However, many are amended voluntarily at early stages, and a few are abandoned when it is clear that they were devised without sufficient awareness of research issues, or the resources/capacity to undertake them successfully.

A formal **favourable opinion letter** is sent, which may include observations and suggestions, or conditions to be met in the form of clarifications or commitments. Overall, the aspiration is to provide constructive feedback on all proposals, even those not approved.

### 6.5.8    Subsequent outcomes

Provision of feedback to participants and to the RG lead is a commitment for researchers undertaking approved projects. Occasionally in practice this has to be pursued by the RG lead, or is provided but in an unacceptable way. Direct feedback to the RG Panel or Committee is therefore provided, thus enabling learning as to whether initial judgments about research merits were justified in practice.

In Birmingham an annual report gives a brief description of projects undertaken in the year, and their findings. In both councils, individual project reports received will be circulated to appropriate staff, and sometimes this leads to requests for presentations.

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## Chapter 7: The Organisational Context

This chapter sets out the key elements of guidance offered by the Department of Health that applies particularly to social care research. The material is derived from the RGF Implementation Plan for Social Care (2004) and is updated to November 2009 unless otherwise indicated.

### 7.1. The Social Care RGF Implementation Plan

The Department of Health's *Research Governance Framework for Health and Social Care*[5] (RGF) sets out the core principles of good research governance, to be secured by the achievement of standards in five domains:

- ethics: ensuring the dignity, rights, safety and well-being of research participants;
- science: ensuring that the design and methods of research are subject to independent review by relevant experts;
- information: ensuring full and free public access to information on the research and its findings;
- health and safety: ensuring at all times the safety of research participants, researchers and other staff;
- finance: ensuring financial probity and compliance with the law in the conduct of research.

These principles apply equally to research in the NHS and social care environments. While all research will meet the same standards of governance, it is recognised that there are important differences in the health and social care contexts. This recognition resulted in the production of a separate Implementation Plan for the RGF in Social Care (DH, 2004).

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[5] Department of Health (2001) Research Governance Framework for Health and Social Care, Department of Health: London. A second edition was published in 2005.

### 7.1.1 The coverage of the RGF

At a minimum, the standards and principles of the RGF apply to all research that relates to the responsibilities of the Secretary of State for Health.[6] This includes any research undertaken by academic or independent bodies/individuals, in or with social care agencies, as well as research undertaken by those agencies themselves.

The focus of the RGF is on all research involving service users/carers, their data or staff, for whom directors of adult social services (or other departments within local councils providing social care) have a duty of care, whether this care is provided directly by the local council or contracted to other agencies in the statutory or independent sectors. For those social care agencies not covered in this way, the RGF is recommended as a model.

The definition of research adopted in the RGF is the "attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods".[7] This deliberately inclusive definition covers most forms of disciplined enquiry involving the systematic collection of data and using explicit research methods and techniques.

The RGF does not assume that research activity is more risky than other ways of collecting information that is not directly related to the provision of care. Other research-like activity undertaken on or by social care agencies, including non-financial audit, may raise similar legal or ethical issues. These activities therefore also call for arrangements to identify and manage risks to the dignity, rights, safety or well-being of participants.

### 7.1.2 Roles of participants

The RGF is based on the explicit allocation of responsibilities amongst the following:

- those funding and/or sponsoring the research;
- the researchers undertaking that research and their employing organisations;
- those involved in providing scientific or ethical review of research proposals; and
- the care organisations in which the research is taking place.

Good governance requires that each of these key agents is clear about, and able to exercise effectively, its responsibilities under the RGF.

#### i)   Research funder

The primary responsibility of the research funder is to ensure that the research it commissions represents a proper use of the funds it controls and is good value for money. The funder therefore has responsibility for assessing the quality of the research, typically by independent expert review, and the adequacy of the research team and research environment involved. If the funder is unable itself to arrange independent expert review, it must require another organisation to do so.

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[6] The Department of Health issued the Research Governance Framework in the context of the Secretary of State for Health's responsibility, with the Welsh Assembly, for health and social care in England and Wales. There are similar research governance frameworks for Scotland and Northern Ireland.
[7] This covers generalisability at a conceptual as well as statistical level and includes studies that aim to generate, rather than test hypotheses.

The main additional action for the research funder is to decide if it is able to take on the role of sponsor for the research it commissions (see Section 4). The research funder will not necessarily be the sponsor. However, it is expected that the funder will consider taking on the responsibilities of sponsorship, alone or with others, if the employer of the lead researcher cannot accept this role.

If a funder does not wish, or is not able, to take on the responsibilities of sponsor, it must identify and collaborate with another organisation that is willing to do so. Potential collaborators include other social care bodies and universities. Care organisations should ascertain whether there is a sponsor who accepts sponsorship responsibilities, before allowing external research access to their service user populations or staff.

## ii)  Research sponsor

All social care research covered by the RGF must have an identified sponsor[8] that accepts the responsibilities set out in the Framework document.[9]

It is a responsibility of sponsorship to confirm that everything is ready for the research to begin and that all other key agents have agreed to their roles. By so doing, the sponsor confirms that these agents accept their respective responsibilities, and areas of accountability, within the research process. These arrangements should be documented.

It is also the sponsor's responsibility to ensure that the study is subject both to appropriate independent scientific review, and to independent ethical review from an appropriately constituted body. Where no appropriate ethics committee exists, it is the responsibility of the sponsor to ensure that ethical review is undertaken by other means (e.g. via peer review). The sponsor will also make it a condition that the relevant CSSR has given its permission before the study commences at any individual site; and for multi-site studies, that the Association of Directors of Adult Social Services has given approval.

It is expected that the organisation funding the research will normally take on the role of sponsor. The role of sponsor may be assumed by the organisation employing the lead researcher, provided it makes arrangements to manage the potential conflicts of interest within that arrangement. For student projects, the academic supervisor, on behalf of the academic institution, will normally undertake the role of sponsor.

The lead organisation providing care (typically the local Council with Social Services Responsibilities - CSSR) may also act as sponsor, if it has the systems to do so, either individually or in conjunction with other care organisations. This will necessarily be the case for research that is undertaken in-house, where there is no external funding body or research employer.

## iii)  Care organisation

Research has a central contribution to make to the role of councils as 'learning organisations' and in the development of evidence based policy and practice. Individual councils play a role in the

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8  An organisation, a group or an individual may take on the responsibilities of sponsorship.
9  Department of Health (2001) Research Governance Framework for Health and Social Care, Department of Health: London. A second edition was published in 2005.

creation of a shared evidence-base. They undertake research themselves and they fund others to do so. For much social care research they are the terrain in which the research takes place.

The distinction between external and internal research is an important one for councils. For research undertaken by, *or in conjunction with*, externally employed researchers, there will be agents willing to assume the role of research funder, sponsor and employer. For in-house or 'own account' research, the council will assume the responsibilities of funder, sponsor and employer. This presents a challenge, given the volume and variety of in-house research. In addition, councils and other social care organisations may wish to consider developing their systems in partnership with others that have, or could build up, the necessary expertise.

In respect of RGF implementation, councils and care organisations need to develop mechanisms for assessing the risk to participants (whether they be users, carers or staff). This will require the identification of a nominated individual (RGF lead) or group, with appropriate authority and expertise. This group or individual should assess written plans for all research studies. Those considered to be of low risk – such as studies dealing entirely with secondary source data, or with organisational behaviour – may not need the significant levels of scrutiny required for those of higher potential risk. The central responsibility for social care organisations under the RGF, however, is to protect the dignity, rights, safety and well-being of any of their service users/carers or staff who are involved in research. The organisation remains responsible for the ongoing care of its service users, whether or not part of that care is provided as part of a research study.

### iv) Research employer and lead researcher

Strengthening research governance in social care will rely on the active participation of the academic and independent research sectors. As employers of researchers they are expected to ensure that their staff are supported in, and held accountable for, the professional conduct of research. Employers have a particular responsibility to ensure that their research staff understand and discharge the responsibilities set out for them in the RGF, and only participate in agreements that allocate research governance responsibilities to those equipped to discharge them.

The lead researcher is responsible for developing proposals that are ethical and for seeking approval from an independent source of ethical review. For social care research involving access to NHS patients, data and/or health care professionals, this will require application to the appropriate NHS Ethics Committee.

For social care research that does not involve the NHS or CSSRs, and is not funded by the Department of Health, or covered by the MCA (2005), independent review may be sought from an ethics committee within the researcher's employing organisation, provided the potential conflicts of interest are addressed. It is recommended that such research is submitted to a research ethics committee that is compliant with the ESRC's Research Ethics Framework (see 'Securing Ethics Approval: A Route Map for Social Care Researchers'). Alternatively, it may be secured by application to the new **Social Care Research Ethics Committee** (see 7.2 below) or locally through a CSSR's RGF system.

It is the responsibility of the researcher to secure independent ethical approval or to inform the research sponsor if no appropriate reviewer can be identified. The lead researcher is also responsible for ensuring that someone with appropriate authority has given written permission on behalf of the care organisation for the study to commence.

## Figure 7.1: Responsibilities of Key Agents in the Research Process

| | |
|---|---|
| **Chief Investigator, Investigators, Researchers** | • Developing proposals that are scientifically sound and ethical.<br>• Seeking independent ethical review.<br>• Conducting research to the agreed protocol (or proposal), in accordance with legal requirements and guidance.<br>• Ensuring participants' welfare while in the study.<br>• Feeding back results of research to participants. |
| **Research Ethics Committee** | • Providing an independent expert opinion on whether the proposed research is ethical and respects the dignity, rights, safety and well-being of participants. |
| **Sponsor** | • Confirming that everything is ready for the research to begin, including:<br>  - putting and keeping in place arrangements for initiation, management and funding of the study;<br>  - satisfying itself the research protocol, research team and research environment have passed appropriate scientific quality assurance;<br>  - satisfying itself the study has ethical approval before it begins;<br>  - satisfying itself that arrangements will be kept in place for monitoring and reporting on the research, including prompt reporting of suspected serious adverse incidents;<br>  - ensuring the research complies with the law. |
| **Main funder** | • Assessing the scientific quality of the research, as proposed.<br>• Establishing the value for money of the research, as proposed.<br>• Considering the suitability of the research environment in which the research will be undertaken, and the experience and expertise of the key researchers involved.<br>• Requiring that a sponsor takes on responsibility before the research begins. |
| **Employing organisation** | • Promoting a quality research culture.<br>• Ensuring researchers understand and discharge their responsibilities.<br>• Ensuring the research is properly designed, submitted for independent review, and that it is well managed, monitored and reported, as agreed with the sponsor.<br>• Taking action if misconduct or fraud is suspected. |
| **Care organisation/ responsible care professional** | • Ensuring that research involving their service users, carers or staff is conducted to the standards set out in the RGF (drawing on the ethical review and sponsor).<br>• Ensuring there is ethical approval for all research for which they have a duty of care, including directly providing reviews of ethics and methods if necessary.<br>• Retaining responsibility for research participants' care. |

## 7.2    Research register for social care (www.researchregister.org.uk)

### 7.2.1  Introduction

The Department of Health has worked with the Social Care Institute for Excellence (SCIE) and other stakeholders to establish a central research register that enables local authorities and other agencies to record details of the social care research they review, commission or carry out. The Register records both current and completed research, and provides links to completed research reports, where these are available.

The Research Register captures research carried out within, or commissioned by, local Councils with Social Services Responsibilities (CSSRs) and which has been approved through a council research governance process. This is in addition to any non-CSSR social care research. Research is defined broadly as any activity that utilises established research methods, such as questionnaires, observation or interviews. Only that which has received favourable independent review of its methods and ethics, including student and practitioner research, is recorded. The Research Register ultimately aims to cover research in both children and adult sectors. Its scope is UK-wide.

The Research Register is easy to use and freely accessible.

### 7.2.2  How does it work?

The website is accessible to anyone, but only registered users can add data. Details of how to register and submit data can be found on the website. Information about a research study can be added incrementally, but it will not appear on the site until all the mandatory fields are completed. Once a record is completed and approved it appears both on the Research Register and on SCIE's Social Care Online website (www.scie-socialcareonline.org.uk).

## 7.3.   Ethics review of social care research

### 7.3.1  The Social Care Research Ethics Committee (SCREC)

The SCREC, which began operation in June 2009, was established to review all adult social care research funded by the Department of Health, and multi-site cross-national social care studies. It is also a resource for anyone researching in the social care field who does not have access to other sources of independent research ethics review (perhaps because they are not based in a University), and for all social care studies involving adults lacking capacity.

The Committee does not supplant other systems, such as local university research ethics committees, where these are considered sufficiently independent by other research funders. The SCREC operates alongside other committees in the NRES system (e.g. by reviewing non-clinical research in joint NHS/local authority contexts).  As a committee within the NRES, the SCREC is also able to review research studies covered by the Mental Capacity Act 2005, which university research ethics committees are not currently able to do (see Chapter 8).

The SCREC receives the same funding and administrative support as all committees operating under the National Research Ethics Service (NRES). Access to the SCREC is either via NRES or SCIE (contact coordinator Barbara.Cuddon@scie.org.uk, tel. 0207 089 6840). The Committee complements the continuing ADASS national advice system; and clear operational links are expected to be established between the two. Avoidance of duplication will be helpful for the research community. For detailed guidance about pathways to social care research ethics review, see Annex 6.

Everyone involved in implementing research governance and carrying out research needs to be aware of their responsibilities under the following legislation or good practice:

- the Data Protection Act 1998

- the Freedom of Information Act 2000

- the role of Caldicott Guardians

- the Mental Capacity Act 2005

This chapter provides a brief overview of relevant legislation and good practice, and outlines the implications for research governance. Links to further resources are given in each section.

## 8.1   The Data Protection Act 1998 (as amended 2000)

The purpose of the Data Protection Act (DPA) is to protect the rights of individuals by ensuring the ways in which data are obtained, stored, processed and shared by others is strictly governed. The DPA relates to personal data or information held by organisations about individuals.

Failure to comply could result in prosecution.

Under the Act, individuals have a right to:

- see any information held about them;

- challenge organisations if appropriate;

- have inaccurate information changed or deleted;

- claim compensation if appropriate.

The 1998 Act includes '*all structured data in relevant filing systems*'. This includes both electronic and manual files. A relevant filing system may be structured either by reference to individuals or by reference to criteria relating to individuals. It includes manual records: for example structured files in filing cabinets containing personal data.

Personal data include anything that can help identify a living individual, such as their name and address or National Insurance Number. Although the DPA doesn't apply to the records of deceased individuals, it should be noted that the Caldicott Guidelines suggest that the same level of respect for confidentiality should be afforded to the records of those who are deceased as is given to those who are living. Personal data will therefore be considered to apply to data or information from which any individual can be identified. However, once any identifiers linking data to a person have been removed then they no longer constitute 'personal data' and are therefore not covered by the provisions of the 1998 Act. It is therefore worth considering at what point in the research process is the earliest that personal identifiers can be removed from the data.

Sensitive personal data includes any information that an individual feels unwilling to share. Typically (though not exclusively) this includes information concerning racial/ethnic origin, political or religious

beliefs, trade union membership, physical or mental health, details of sexual orientation, criminal record etc. In this case, the data subject must give their explicit consent (informed and written consent) before data can be processed. If consent cannot be given, and no legal guardian or advocate is able to give written consent on behalf of the data subject, processing must only take place where necessary and justifiable.

Organisations that have to process data (such as the NHS or local authorities) will have to appoint a data controller who determines for which reasons and how any personal data can be processed (see section on Caldicott Principles).

### 8.1.1 What are the Data Protection Key Principles?

1. Personal data must be processed fairly and lawfully and can only be processed if ONE of the following conditions apply:

   (i) The individual about whom the data have been collected has given informed consent i.e. they clearly understand the purpose for which the data are being collected and how they will be stored

   (ii) It is necessary for:
   - Performance of contractual duties or in preparation for contracting with the person concerned
   - Compliance with legal obligation
   - Protection of a person's vital interests i.e. their life
   - Administration of justice
   - Crown/public functions
   - Legitimate interests of a data controller/third party.

2. Personal data must only be used in for the purpose(s) for which explicit consent has been obtained from the individual concerned.

3. Personal data shall be adequate, relevant and not excessive.

4. Personal data shall be accurate and where necessary, kept up to date.

5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary.

6. Personal data shall be processed in accordance with the rights of the individuals concerned.

7. Security measures shall be taken to prevent unauthorised or unlawful processing of personal data and to protect against accidental loss or destruction or damage to personal data.

8. Personal data shall not be transferred to a country or territory outside the European Economic Area, unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

The Act also covers any personal data that are obtained from, or used for, the Internet/Intranet; including digitised images on web pages, photographs, email addresses, personal images recorded on CCTV etc.

### 8.1.2 *Implications for research governance*

In order to comply with the DPA, researchers need to establish that the purposes for which data will be used are legitimate and that only data relevant to those purposes will be collected. Further, researchers need to be clear about how they are going to obtain consent from participants to collect and store their data. Researchers also need to be clear about how they are going to store data, so that confidentiality is maintained.

Before giving consent, participants should be made aware by researchers of the possibility that their data may be used for a variety of purposes (for example, for comparison with future studies). Finally, researchers need to state how long they intend to keep data after the study has been completed before they are destroyed. Sometimes, data can be passed to data archives, such as 'Qualidata' (www.esds.ac.uk/qualidata): researchers need to state if this is their intention and obtain explicit consent. When reviewing proposals, it is therefore important to be satisfied with the arrangements for these issues.

## 8.2 Freedom of Information Act 2000

The Freedom of Information Act (FoIA) gives a general right of access to all types of recorded information held by public authorities, including the NHS and local authorities. A time limit of 20 days has been set for requests to be processed. Exemptions from that right are specified within the Act (for example, information relating to personal data, law enforcement, national security and where release of information could result in the premature publication of research). The Act is fully retrospective and came into effect on 1st January 2005, which means that access should be granted to information collected before that date.

Access to personal and patient information is still governed by the Data Protection Act 1998: the Freedom of Information Act gives right of access to non-personal information and amends the DPA to cover all personal information.

Part VII (AMENDMENTS OF DATA PROTECTION ACT 1998) covers amendments relating to personal information held by public authorities, including:

- extension of meaning of 'data' to include all data held by public authorities;

- right of access to unstructured personal data held by public authorities;

- exemptions applicable to certain manual data held by public authorities;

- particulars registrable under Part III of the Data Protection Act 1998, requiring that Data Controllers record that they work for a public authority.

Both the Freedom of Information Act and the Data Protection Act are administered by the Information Commissioner (www.ico.gov.uk).

### 8.2.1 *Implications for research governance*

The FoIA does not cover personal information, which provides some protection for individuals participating in research activities: no one can make a request under the FoIA for the names of people who have taken part in research. However local authorities, as public bodies, need to develop a publication scheme, to be approved by the Information Commissioner. Information about research undertaken within authorities, including external and internal projects, could be open to

requests for information under the FoIA. This provides another incentive to develop good information about local research activity, as required by the RGF. Information about the activity of the research governance panel itself could be subject to FoIA requests, which suggests the value of keeping good records about the numbers of applications and decisions.

## 8.3   Role of Caldicott Guardians

Caldicott Guardians are senior staff in the NHS and local authorities appointed to protect the personal information of service users. They were introduced following the Caldicott Review of Patient-Identifiable Information (1997), which recommended that 'Guardians' of patient information should be created to safeguard and govern the uses made of confidential patient information within NHS settings. Local authorities subsequently adopted the Caldicott principles.

### 8.3.1  Caldicott Standards – General Principles

*Principle 1 - Justify the purpose(s)*
Every proposed use or transfer of personally identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate Guardian.

*Principle 2 - Do not use personally identifiable information unless it is absolutely necessary*
Personally identifiable information items should not be used unless there is no alternative.

*Principle 3 - Use the minimum necessary personally identifiable information*
Where use of personal identifiable information is considered to be essential, each individual item of information should be justified, with the aim of minimising the need to identify individuals.

*Principle 4 - Access to personally identifiable information should be on a strict need-to-know basis*
Only those individuals who need access to personally identifiable information should have access to it, and they should only have access to the information items they need to see.

*Principle 5 - Everyone should be aware of their responsibilities*
Actions should be taken to ensure that those handling personally identifiable information – both practitioner and non-practitioner staff – are aware of their responsibilities and obligations to respect an individual's confidentiality.

*Principle 6 - Understand and comply with the law*
Every use of personally identifiable information must be lawful. Someone in each organisation should be responsible for ensuring that the organisation complies with legal requirements.

### 8.3.2  Implications for Research Governance

Similarly to the Data Protection Act, the Caldicott principles require good research practice in terms of consent, confidentiality and storing data securely. The Caldicott principles emphasise the need for clarity over why personal information should be passed on, the proportionate nature of the information sought and how access is arranged. Having a research governance approval system is a good way to ensure that research activity is carried out in line with Caldicott Principles, as it requires proposals are checked for:

- what personal details are to be passed to researchers and why this is necessary;

- who will have access to personal information;

- when personal details are to be separated from research data (e.g. when survey data are to be anonymised).

### 8.3.3 Social Care Information Governance

Information Governance is a Department of Health initiative, addressing five broad aspects of information processing: how information is Held, Obtained, Recorded, Used and Shared (HORUS). It has four fundamental aims:

- to support the provision of high quality care by promoting the effective and appropriate use of information;

- to encourage staff responsible to work closely together, preventing duplication of effort and enabling more efficient use of resources;

- to develop support arrangements and provide staff with appropriate tools and support to enable them to discharge their responsibilities to consistently high standards;

- to enable organisations to understand their own performance and manage improvement in a systematic and effective way.

Information Governance currently covers the following:

- Data Protection Act 1998

- Freedom of Information Act 2000

- The Confidentiality Code of Practice 2003

- Information security management

- Records management

- Information quality assurance

- Information Governance management

- Specific organisational views, e.g. Councils with Social Services Responsibilities (CSSRs)

Taken from the Department of Health website (www.dh.gov.uk): click on Policy and Guidance, then on Information Policy, then Information for Social Care, then on Social Care Information Governance. www.dh.gov.uk/en/Policyandguidance/Informationpolicy/Informationforsocialcare/DH_4075306.

The 'Social Care Information Governance Toolkit' (www.igt.connectingforhealth.nhs.uk) gives more information about this topic.

**For further information, contact your Data Protection Officer and/or Caldicott Guardian.**

## 8.4   The Mental Capacity Act –  Fact Sheet For Social Scientists

www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@pg/documents/digitalasset/dh_106217.pdf

### 8.4.1  What is the Mental Capacity Act?

(i)   The Mental Capacity Act 2005 (MCA)[10] provides a statutory framework for people who may not be able to make their own decisions, for example because of learning difficulties, brain injury or mental health problems. It sets out who can take decisions, in which situations, and how they should go about this. The Act applies to England and Wales only.

(ii)   The MCA enshrines in statute current best practice and common law principles concerning people who lack mental capacity and those who take decisions on their behalf. Sections 30 to 34 apply these principles to research that seeks to involve people without the capacity to provide informed consent to their participation. Their aim is **to balance the importance of properly conducted research with the need to protect the interests and respect the current or previously expressed wishes of those involved.**

(iii)   To undertake research with those who lack capacity, the MCA requires a researcher to obtain approval from an 'appropriate body'.[11] This body must be satisfied that the research project meets certain requirements set out in the MCA and that arrangements are in place to consult a family member, friend or unpaid carer about the participant's previous attitudes and beliefs relevant to taking part in research of this type.

(iv)   Anyone carrying out research to which the requirements of the MCA apply must act in accordance with the provisions of the Act in order for the research to be lawful.

### 8.4.2  What kinds of research does it cover?

(i)   The MCA applies to research that is defined as 'intrusive', that is, any study that would normally require the consent of a person with capacity in order to be lawful.[12]

(ii)   The definition of 'intrusive' research (see section 30(2) of the MCA) is wide ranging and covers all primary data collection, apart from that which involves the collection of anonymised, or effectively pseudonymised, data where there is no breach of the Data Protection Act (DPA) or the common law duty of confidence. **It is not limited to medical or biomedical research that is physically invasive** (e.g. the collection of tissue samples).

(iii)   However, only research which intends to include people without the capacity to consent is covered by the legislation. The purpose of the MCA is to enable the involvement of such participants, *where it is appropriate to do so*.  While no group should be unreasonably excluded from a research study, the legislation also aims to ensure that people without capacity have the right to be free from unnecessary interference in the name of research.

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[10]  The  MCA Code of Practice can be found at: www.dca.gov.uk/menincap/legis.htm#codeofpractice.
[11]  In England this is a research ethics committee (REC) recognised by the Secretary of Sate; in Wales, this recognition is by the Welsh Assembly Government. (Mental Capacity Act 2005 (Appropriate Body) regulations 2006.) Currently only RECs operating under the National Research Ethics Service (NRES) are so recognised, including the new Social Care REC.
[12]  It does not apply to clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).

(iv)   It is thus for the research team to decide if it wishes to include people in their study without the capacity to consent. In making this decision, the team needs to address the following questions:

> **a) is the research related to the 'impairing condition' that causes the lack of capacity, or to the treatment of those with that condition?** [13]

If the answer to this question is 'no' then the study should proceed without involving those who do not have the capacity to consent to participation. If the answer is 'yes' the researchers need to answer a second question:

> **b) could the research be undertaken as effectively with people who do have the capacity to consent to participate?**

If the answer to this question is 'yes' then the study should exclude those without the capacity to consent to participation. If the answer is 'no' then the inclusion of people without capacity in the study can be justified. The research team will still need to decide however - as it would have done prior to the legislation - if it has the time, resources and expertise to ensure the meaningful involvement of people without capacity.

(v)   If, having considered the questions above, the research team decides it is scientifically meaningful and methodologically viable to include people without the capacity to consent, it will need to seek approval for the study from an 'appropriate body'.[14]  To secure approval the research team will need to demonstrate that the study will meet one of the following central requirements:

> • that it will be likely to be of benefit to the person lacking capacity, either directly (i.e. by improving her/his personal circumstances) or indirectly (by improving the quality of treatment or care more generally), and that this benefit is in proportion to any burden on that person caused by taking part;

**OR**

> • that the research will serve to increase knowledge of the cause, treatment or care of people with the same or similar condition and that the risks to participants will be negligible, with no significant interference with their privacy or freedom of action.

Only if one of these two conditions can be effectively established is it likely that the study will be able to proceed under the MCA. The following two case studies illustrate the ways in which these conditions could play out in particular research studies.

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[13]  An 'impairing condition' is defined as being caused by, causing or contributing to an impairment of, or disturbance in, the functioning of the mind or brain. 'Treatment' is not used here in the medical sense and includes the way that people are cared for, or provided with a service more generally. S31 (5)b of the MCA refers to providing knowledge on the care of people affected by an impairing condition.

[14]  Currently only Research Ethics Committees (RECs) operating under the National Research Ethics Service – including the Social Care REC – have been recognised as 'appropriate bodies' for this purpose.

**Case 1:**

A national charity is promoting a scheme in which local schoolchildren visit elderly residents living in the community to help with shopping or other tasks. It has contracted a research team to evaluate the impact of the scheme, from the perspectives of the young adults and the older people involved. The team is worried that some of the older people involved in the scheme could have capacity problems.

The research is not related to the condition causing the incapacity of these individuals, nor to the treatment of those with that condition. Moreover, it would be difficult for the research team to demonstrate that the study could not be as effectively conducted only with those who had the capacity to consent. Given this, the research team would find it difficult to justify including people without capacity to consent in the study.

**Outcome: The study team establishes clearly from the outset that it does not intend to include people without the capacity to consent to participation.**

**Case 2:**

A research team is proposing to investigate the use of physical restraint on older residents of care homes. The researchers consider that the experience of people with dementia is crucial to this work, as they are disproportionately likely to be subject to restraint. For this reason, the team feels that the study could not be as effectively conducted if people with dementia were excluded. The team recognises that many, if not most, of the residents with dementia will lack the capacity to participate actively in the research and have selected non-participant observation as the main method of data collection.

Although observation is not physically invasive, the proposed research is intrusive under the definition given in the MCA and will need approval by an appropriate body. The research team is confident that the research will be enabled under the Act as it is directly relevant to the 'impairing condition' (dementia), and the team is proposing to identify personal or nominated consultees to ascertain the wishes of those without capacity to consent for themselves. It is able to demonstrate that the findings of the study will to be of indirect, if not direct, benefit to the older people involved, and that any research 'burden' on participants would be minimal.

**Outcome: An application for approval of a study on this basis is made to a Research Ethics Committee within the National Research Ethics Service that has been recognised for the purposes of the Mental Capacity Act.**

### 8.4.3 Obtaining Consent

i)  The issue of consent is central to the implementation of the MCA. The requirement for consent is defined in terms of common law or statute. For social scientific research this involves the provisions of the Data Protection Act and the common law duty of confidentiality[15]. **As such, the MCA does not introduce any new requirements in respect of consent that do not already apply to the collection and processing of personal data.**

ii) The research sections of the MCA focus on situations where it is not possible to secure informed consent from the research participant, due to a lack of capacity on his or her

part. They aim to provide a means for such research to proceed, under carefully controlled conditions.

iii) A core principle of the MCA is that capacity should be assumed, unless established otherwise. In research, capacity is normally implied by the act of consenting to participate in a study. However, it is important to avoid the possibility that compliance is wrongly taken to imply consent. Demonstrable steps should be taken to ensure that the respondent is able fully to comprehend or retain information about a research study.

iv) Where it is clear that informed consent cannot be provided by potential participants, the Act sets out the particular conditions under which the study can still proceed, if eligible (see 2.4 – 2.5 above). In the first instance, this requires the researcher to take 'reasonable steps' to identify someone close to the person concerned (not acting in a paid capacity) to advise on whether s/he would want to be involved. This person is a 'personal consultee'.

v) Where a 'personal consultee' cannot be identified, because the person who lacks capacity has no family or friends willing and able to fulfil this role, the Act requires the researcher to nominate someone else who will be able to act in this capacity – a 'nominated consultee'. Guidance has been produced on the principles underpinning this role and the ways in which it can be discharged in different research settings.[16]

vi) The use of *opt-out consent* is common in social research but is problematic under the MCA. It should not be used if the study is planning to involve people without capacity, as consent is being assumed by default, rather than actively established. Moreover, even if it is not the aim to include people without capacity, the use of the opt-out approach increases the possibility that people without capacity will be inadvertently included in a study population.

vii) If the team is clear that it does *not* wish to involve people without capacity, then it should take reasonable steps to prevent their inadvertent inclusion. Approach materials (e.g. survey contact letters) should clearly indicate that the study is not approved under the MCA and that no one should participate on another's behalf. Data collected inadvertently on those without capacity should be destroyed. If a team decides subsequently that it does wish to involve people without capacity, it will need to submit an amended proposal for approval by an 'appropriate body'.

viii) Researchers are rightly concerned about the possibility that people who are able to consent at the outset of a study may lose, or experience fluctuations in this capacity over the course of the research. The MCA makes provisions for such a situation, using a personal or nominated consultee, as set out above. Even where an individual originally gave consent, the research team must take account of any subsequent advice from a consultee that continued involvement would be contrary to his/her wishes or best interests.[17]

ix) Regardless of the views of a particular consultee, any person lacking capacity to consent who at any time does not appear to consent to the research procedures, or actively expresses discomfort or distress, should immediately be withdrawn from the study.

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[15] Unless approval is obtained from the National Information Governance Board (formerly the Patient Information Advisory Group ) to set aside the duty of confidentiality in respect of patient data (under s251 of the NHS Act, 2006).

[16] Guidance for Nominating a Consultee for Research Involving Adults who Lack the Capacity to Consent. DH 2008.

[17] Guidance for Nominating a Consultee for Research Involving Adults who Lack the Capacity to Consent. DH 2008.

**Case 3:**

A government department wants to undertake a postal survey of the experiences and needs of adults with physical disabilities. The research team contracted proposes a random sample of households using an 'opt out' consent approach. The research commissioner is concerned that this approach will unintentionally capture people without the capacity to consent in the sample and that the research team will as a result be acting illegally under the MCA.

The team feels that the research could not be conducted as effectively by excluding people without capacity, as this group is likely to have a distinctive perspective. However, it recognises that it does not have the time or resources necessary to develop robust ways to obtain the views of such participants and reluctantly decides it is not able to include them. This decision is clearly stated in the research proposal which does not have to be submitted to an appropriate body under the MCA.

However, the team is still worried that the use of an 'opt out' consent mechanism could leave it in a difficult situation under the legislation if replies are received on behalf of those without capacity. It is also concerned that the experience of people without capacity will be excluded from the study.

**Outcome:**

**The team marks all approach materials clearly with the statement that the study has not been approved under the MCA for people without capacity to consent for themselves. Any replies received on behalf of someone without capacity will be excluded from the research study. However the scope of the study is expanded to include the views of carers or relatives about their own experiences.**

### 8.4.4 What the MCA means for Social Scientists – Frequently Asked Questions

**Q: Does the Act apply only to research 'in or with' the NHS?**

*A:* The Act applies to any intrusive research within England and Wales, wherever it takes place, except for clinical trials of investigational medicinal products. This may include research in health, social care, criminal justice and many other settings. It is not limited to research undertaken within NHS organisations or other public bodies.

**Q: Do projects that are not classified as research require approval under the Mental Capacity Act?**

*A:* No. The provisions of Sections 30-34 of the Act apply only to studies that are designed and presented as research. It is the responsibility of the researchers' employers or sponsors/funders to determine whether a project should be presented as research.

**Q: I plan to withdraw any participants who lose capacity during the study. Does the study require approval under the Mental Capacity Act?**

*A:* No. However, ethical approval may still be required under other regulations or the policy of the host institution(s) for the research.

**Q: To what extent is it acceptable to assume capacity on the part of participants and should researchers monitor this over the course of a study?**

*A:* A core principle of the Act is that capacity should be assumed unless established otherwise. Section 3 of the Act discusses how a person may be unable to make decisions for him/herself, including possible reasons why s/he may not be able to comprehend or retain information about a research study.

If a participant has properly consented to take part, it may generally be assumed that capacity remains in place, although you should be alert to any changes suggesting that capacity has been lost. There is no need for the researcher to monitor capacity proactively. Where the research involves the administration of postal questionnaires, consent is usually considered to be implied by return of the questionnaire. However, you will need to check that the questionnaire has not been completed by someone other than the selected participant.

**Q: What happens if, during the course of the study, some of my participants lose capacity?**

*A:* Unless you have prepared for this eventuality, and have secured approval from an appropriate body to do so, the research will have to proceed without any further involvement of those losing capacity and any data collected from them so far will need to be anonymised or destroyed. If the study has approval from an appropriate body under the Act it may be able to proceed using personal or nominated consultees.

**Q: Is it illegal to involve people without capacity in the research – even unintentionally – if the research has not been reviewed by an approved committee?**

*A:* You will not be committing a criminal offence, but the research will be unlawful and you could expose yourself and your employer to complaint or the risk of litigation. This risk will be reduced if you take clear and appropriate steps to exclude such people from your study.

**Q: What happens if I am undertaking a survey of, say, local households and someone without the capacity to consent is included in the sample unintentionally?**

*A:* You will need to have taken a decision at the outset of the study whether you will seek to include those without the capacity to consent. If so, not only will the study have to be approved by an appropriate body under the Act, and arrangements for consulting the likely wishes of this group be devised, but you will have to invest time and resources in developing appropriate methods to involve people who will probably also lack the capacity to respond to standard data collection techniques.

If the survey is not related to the condition that caused the lack of capacity, nor to the consequences of being without that capacity, you will not easily be able to justify including such persons in the survey. If your study does not have approval under the MCA and you find that an individual without capacity has been included in the sample unintentionally, you should withdraw this individual from your sample and destroy any data collected from them.

**Q: What steps do I need to take to ensure that I don't include people without capacity in my research study unintentionally?**

**A:** You will need to state clearly in your research proposal and on approach materials that you are not able to include those without capacity. Where possible, use opt-in consent procedures and always ensure you have robust mechanisms for ensuring informed consent. If someone offers to respond on behalf of another who lacks capacity, explain that you are unable to accept their offer. If you find someone has submitted a response on behalf of someone else without capacity, this response should be excluded from your study.

**Q: Does the MCA mean that I can't have fully representative samples?**

**A:** There is concern that excluding people without capacity may make samples less representative, in so far as the experiences of this group may differ in important ways from those with capacity. Provided that the research topic meets the criteria for justifying the inclusion of people without capacity, and the research team has the time and resources to include them there is no reason to exclude such people. However, if people with limited capacity are not included in an effective way, it is likely that the data collected would not be meaningful enough to increase the representativeness of the study in any case.

**Q: Isn't the Act going to make it less likely that researchers will include people with cognitive problems in the research, even where their particular experience could be very relevant?**

**A:** This could be a risk and would be an unintended and unwelcome consequence of the MCA. However, involving people with limited cognitive capacity has always been challenging, and the Act has the virtue of clarifying grey areas for researchers, such as the involvement of 'proxy' respondents. As before, if the experience of people without the capacity to consent is scientifically justifiable, and the team has the necessary expertise and resources to make their inclusion meaningful, every step should be taken to ensure they are included in the study. In such cases, the MCA provides a statutory framework to enable the research to proceed.

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# Annexes

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### Social Services Research Group (SSRG)

SSRG is an independent network of individuals who provide a range of research information, planning and evaluation in adult social care, children's services and health services. SSRG members are drawn from a wide range of professional groups and organisations sharing a common interest in the work of the caring services. *www.ssrg.org.uk*

### Local Authorities Research and Information Association (LARIA)

LARIA was established to promote the role and practice of research within the field of local government and provide a supportive network for those conducting or commissioning research. *www.laria.gov.uk*

### Research in Practice (RiP)

RiP works in collaboration with the Dartington Hall Trust and works with local authorities across England and Wales to promote positive outcomes for children and families through the use of research evidence. *www.rip.org.uk*

### Research in Practice for Adults (RiPfA)

Also based at Dartington Hall, RiPfA is an established research utilisation organisation for adult social care, offering similar services to local authorities as Research in Practice. *www.ripfa.org.uk*

### Making Research Count (MRC)

A collaborative venture between eleven English universities, which offers staff in Local Authority Adult Social Care and Children's Services Departments (and the NHS and voluntary organisations) the opportunity to work in partnership with their academic colleagues to develop evidence-based social work and social care practice, and to improve the dissemination of research. MRC regions provide learning events at national, regional and local levels for several thousand social care practitioners every year. *www.makingresearchcount.org.uk*

### Social Care Institute for Excellence (SCIE)

SCIE's aim is to improve the experience of people who use social care services by developing and promoting knowledge about good practice in the sector. Using knowledge gathered from diverse sources and a broad range of people and organisations, SCIE develops resources and makes them freely available, supporting those working in social care and empowering service users. *www.scie.org.uk*

SCIE produces a range of reports including knowledge reviews, position papers, practice guides and resource guides. *www.scie.org.uk/publications/list.asp#kr*

### Social Care Online

Social Care Online is an extensive free database of social care information. It includes research briefings, reports, government documents, journal articles and websites. *www.scie-socialcareonline.org.uk*

### Research Register for Social Care

The Research Register for Social Care aims to provide a database of social care research activity that has been subject to independent ethical and scientific review. *www.researchregister.org.uk*

### The Social Research Association (SRA)

The SRA is open to social research practitioners and trainees from all sectors, as well as others with an interest in social research. It offers information, guidance and training opportunities for members and non-members. *www.the-sra.org.uk*

### SRA Ethics Guidelines

The SRA developed ethical guidelines in the early 1990s, which were updated in 2003. They provide an overview of ethical issues and approaches, which is relevant to all kinds of social research. *www.the-sra.org.uk/ethical.htm*

### INVOLVE

A national advisory group, funded by the Department of Health, which aims to promote and support active public involvement in NHS, public health and social care research. *www.invo.org.uk*

### The Respect Project

The RESPECT project was funded by the European Commission's Information Society Technologies (IST) Programme, to draw up professional and ethical guidelines for the conduct of socio-economic research. *www.respectproject.org*

### British Sociological Association (BSA)

The BSA provides a network of communication to all who are concerned with the promotion and use of sociology and sociological research. *www.britsoc.co.uk*

While focused more on more academic sociological research, the BSA produces ethical guidelines, which are also of value for social care researchers. *www.britsoc.co.uk/equality/Statement+Ethical+Practice.htm*

### Market Research Society (MRS)

The Market Research Society (MRS) is the professional body for market researchers and provides a range of services for market researchers and for research users. Of particular value is a 'Buyers' Guide' which can help in selecting independent researchers and an online checking service to identify whether market researchers are registered. *www.mrs.org.uk*

## *Local Government organisations*

### Association of Directors of Adult Social Services (ADASS)

ADASS represents all the directors of adult social services in England. It evolved from the former ADSS (Association of Directors of Social Services) when responsibilities for adults and children's services within top tier local authorities were split between two new departments - the one for adults and the other for children. *www.ADASS.org.uk*

## ADASS Research pages

*www.adass.org.uk/index.php?option=com_content&view=article&id=375:research-home&catid=113:organisations&Itemid=348*

## The Association of Directors of Children's Services

The Association of Directors of Children's Services - ADCS - is the national leadership association in England for statutory directors of children's services and other children's services professionals in leadership roles. *www.adcs.org.uk*

## British Association of Social Workers (BASW)

The British Association of Social Workers (BASW) is the largest association representing social work and social workers in the UK. *www.basw.co.uk*

BASW has developed a code of ethics for social workers that covers many issues relating to research ethics. *www.basw.co.uk/about/codeofethics*

## Information for Local Government (info4local)

info4local provides local authorities with quick and easy access to information from more than 50 government departments, agencies and public bodies. *www.info4local.gov.uk*

## Central Government

*www.dh.gov.uk*

Research governance pages (including the Social Care Implementation Plan)
*www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/index.htm*

## Department for Communities and Local Government (DCLG)

Part of the former Office of the Deputy Prime Minister, this English Central Government Department was created in May 2006 with responsibility for community development and local government activity. *www.communities.gov.uk*

## Local Government Research Unit (LARGRU)

The Local and Regional Government Research Unit provides professional social research support and advice on a wide range of local and regional government issues.
*www.communities.gov.uk/localgovernment/localregional/aboutlocal/*

## The Cabinet Office

The Cabinet Office is at the centre of Government, co-ordinating policy and strategy across government departments. This website brings together information from units in the Department. The central government Code of Practice for consultation is available on the website:
*www.cabinetoffice.gov.uk*

## Code of practice for consultations

*www.berr.gov.uk/files/file47158.pdf*

INVOLVE has been working to promote active service user involvement in research since 1996. By 'active involvement' in research, we mean doing research **with** or **by** people who use services, not to or for them. We believe that the active involvement of people who use services related to the area of research improves the way that research is designed, commissioned, undertaken and disseminated. If research reflects the needs and views of people who use services, it is more likely to produce results that can be used to improve practice in social care.

In 2001 the principle of active service user and carer involvement in research became enshrined in policy through the DH Research Governance Framework for Health and Social Care. The second edition (2005) says:

> *Relevant service users and carers or their representative groups should be involved wherever possible in the design, conduct, analysis, and reporting of research.*

INVOLVE believe implementation of active service user involvement in research, and research ethics review, should be achieved in manageable stages, with an ongoing commitment to learn, improve, and build upon it. To support this we have a number of resources available at no cost:

- publications (See list below);

- a website: www.invo.org.uk;

- individual advice via email or telephone;

- presentations and workshops given to groups, organisations and at conferences;

- a quarterly newsletter, which is sent out to our mailing list that you are welcome to join.

## INVOLVE Publications

If you would like any of the following key documents in hard copy you can place an order by emailing admin@invo.org.uk or telephoning 023 80 651 088. Alternatively, all publications are available from the INVOLVE website (www.invo.org.uk). Please contact us if you have difficulty accessing documents or would like publications in alternative formats.

**Involving the Public in NHS, Public Health, and Social Care Research:**
**Briefing Notes for Researchers (2004):**
A booklet of particular use to researchers new to or just starting to involve the public.

**Public Information Pack (PIP) (2007):**
A pack of four booklets for service users and carers, covering the what, why, how, and who of getting involved in research..

**A Guide to Actively Involving Young People in Research:**
**for Researchers, Research Commissioners and Managers (2004) (Perpetua Kirby):**
Developed with a group of young people and older adults who have been involved in research.

**A Guide to Paying Members of the Public who are actively involved in Research (2006):**
Sets out principles of good practice and guidance on deciding payments for expenses, time and expertise.

**Good Practice in Active Public Involvement in Research (2007):**
A quick reference leaflet covering key good practice issues.

**INVOLVE newsletter:**
A quarterly newsletter containing articles and news to keep you up to date with what is happening in the world of public involvement in research. Ask to go on our mailing list.

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## Function of the Tool

The tool offers a way of establishing the likelihood of harm to research participants and the degree to which the potential for harm has been identified and addressed within a given research proposal. It can help to ensure that the level of scrutiny given to a research proposal is proportional to the likely degree of risk to participants. Use of the tool does not remove the need for reviewers to have sight of all documentation normally required for a given study – proposal, information letters or sheets, questionnaires or other instruments etc. intended to be used in the proposed study.

Professional and informed judgements are central to using the Risk Assessment Tool. However, it has been designed with simplicity and ease of use in mind and no claims are therefore made for it being comprehensive in scope.

## How does it work?

The tool helps those independently appraising a research proposal to consider both the likelihood of harm to participants that may arise due to the nature of the proposed research and the overall level of risk.

### Likelihood of harm

The main part of the tool offers a series of statements, presented in rows and columns, against which a given piece of research can be assessed.

The left hand column statements are those representing the highest likelihood of harm to participants. Statements found in the right hand column are those representing the lowest chances of harm occurring. Research proposals can be appraised against each of the statements contained in the rows to form an overall impression of the likelihood of harm to subjects/participants. For example, research proposals in which a large number of the cells in the left hand column appear to best describe the proposal indicate that the study is one in which the chances of harm to participants is likely to be high.

### Risk

Likelihood of harm predisposes research participants to greater levels of risk. However, a predisposition does not mean that this greater risk is inevitable. It is important also to consider the extent to which the research proposal identifies and addresses areas likely to give rise to higher chances of harm. If a research proposal identifies and addresses these effectively, then the overall level of risk will be reduced.

To take account of this, *if the review of a research proposal indicates that, for a given row, there is a high chance of harm, then it is important to consider if there is also a high level of risk.*

At the end of each row there are two cells that describe two logical possibilities if a high chance of harm is identified. For each row, either:

- the concerns or issues relating to the area giving rise to the higher chance of harm have been fully addressed in the research proposal, or

- the issues concerned have not been fully addressed.

The final page of the tool is intended to record the outcome of the review process and offer recommendations to researcher, sponsors or funders where appropriate, to address any concerns that may be identified.

| Extent of likelihood of harm to participants as defined in research proposal | + | Extent to which likelihood of harm to participants has been addressed in research proposal | = | Overall response of those responsible for review of research |
|---|---|---|---|---|

## Who is it for?

The tool can be used in a variety of contexts and settings and by a range of different people. It is primarily designed for use by CSSRs. The way it is used will depend on the local arrangements within which CSSRs respond to the RGF.[18] For example:

- Where concerns about likelihood of harm or risk are identified, the tool may be used to determine the subsequent level of review that may be needed.[19]

- It could be used within the review process itself.

- It might also be used as a self-assessment tool by the researcher or principal investigator – though a formal review process will always be needed to review research proposals.

- It could be used by Quality Assurance staff in some contexts.

In general terms it is envisaged that the tool might be used at an early stage in a defined research application process to decide who might be best placed to review the proposal, or to assist in a decision about whether to approve or not approve any proposed project.

A pre-requisite for use of the tool is that enough information and related documents are provided in support of the specific proposal. Absence of material in the important categories shown below would equate to concerns NOT being fully addressed etc. Thus it is normal, for example, to expect interview schedules or questionnaires to be produced in advance, in order to assess their appropriateness as components of methods.

[18] This document may need to be reproduced in appropriate formats if it is to be used by lay people or service users involved in an ethics review process.
[19] For example, West Sussex CC has well-developed systems for dealing with research applications. The Social Research Unit receives completed proposal forms and consider the likely risk of harm, degree of intrusiveness and other causes for concern, and based on this will route a research proposal to any one of four different review processes.

# The Risk Assessment Tool

| Title of Proposal | | Date | Name of Researcher/Principal Investigator | | Ref No. |
|---|---|---|---|---|---|

| Area | Likelihood of harm (tick boxes to indicate judgement) | | | Areas of high likelihood of harm addressed? |
|---|---|---|---|---|
| | **High** | **Low** | | |
| **Subject/ participant characteristics** | ☐ Informed consent & 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. | ☐ Informed consent & ability to withdraw from study possible with a support to overcome communication barriers e.g. advocates, translators/ interpreters, signers, or technology. | ☐ Informed consent and ability to withdraw from study fully possible. | Concerns about informed consent and communication barriers **are** fully identified/ addressed. / Concerns **are not** fully identified or addressed. |
| **Methods/ nature of data collection** | ☐ High levels of face to face contact and /or interaction between researcher and participant e.g. participant observation or observation study. | ☐ Some face-to-face contact and interaction for limited amounts of time. | ☐ No face to face interaction between investigator and participant. | Possible risks arising from high level of contact **are** identified and fully addressed. / Possible risks **are not** identified or addressed. |

Annex 4

| Area | Likelihood of harm (tick boxes to indicate judgement) | | Areas of high likelihood of harm addressed? |
|---|---|---|---|
| | **High** | **Low** | |
| **Researcher competence** | ☐ Researcher(s) not well qualified, with little or no experience or knowledge of the topic of investigation, the participants or the methods to be used e.g. undergraduate researcher /student project. | ☐ 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. | Any lack of competence by the researcher(s) **is** fully addressed. |
| | | ☐ Researcher(s) well qualified with experience and knowledge of all three of the following factors – topic of investigation, the participants/subjects and the methods to be used. e.g. formal research training and/or qualification and/or experience and knowledge gained from working in an appropriate environment. | Any lack of competence **is not** addressed. |
| **Nature of information being sought** | ☐ The topic and kinds of information being sought are likely to be regarded as highly personal or sensitive by those from whom they are to be collected or about whom they are to be obtained. e.g. criminal records, psychiatric history etc. | ☐ The topic or the kinds of information being sought include items likely to be considered somewhat personal or sensitive by some people e.g. age, ethnicity, income. | The need to collect any personal information **is** fully justified. |
| | | ☐ The topic and kinds of information being sought do not focus on personal information at all e.g. opinions about services received. | The need to collect this information **is not** fully justified. |

| Area | Likelihood of harm (tick boxes to indicate judgement) | | Areas of high likelihood of harm addressed? |
|---|---|---|---|
| | **High** | **Low** | |
| **Appropriateness of method to subject & quality of research design** | ☐ The methods/instruments are not appropriate to the subject of the proposed study or the research questions being asked, the need for the study is not established or the project does not have the resources to properly address the research question(s). | ☐ The methods/instruments 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. | The case for & resources to do the study exist & methods **are** fully appropriate to the subject or main research questions.<br><br>The case for & resources to do study are absent & methods **are not** appropriate to subject or main research questions. |
| **Level of privacy to participant** | ☐ Not confidential. ☐ Confidential. | ☐ Anonymous. | If the study is not anonymous or confidential reasons for this **are** fully justified & conform to Data Protection Act principles.<br><br>Study is not anonymous or confidential and reasons for this **are not** fully justified. |

| Area | Likelihood of harm (tick boxes to indicate judgement) | | Areas of high likelihood of harm addressed? |
| --- | --- | --- | --- |
| | **High** | **Low** | |
| **Relationship between investigator & subjects/participants** | ☐ Subjects/participants are personally known to investigator & investigator may have other duties or responsibilities towards all or some of the research participants which may create potential conflicts of interest. | ☐ Limited information about subjects/participants is provided to the investigator to make the study possible or more reliable. | Conflicts of interest **are** fully described & consideration given to how to minimise possible effects on study. |
| | | ☐ Subjects/participants are unknown to the investigator and cannot be identified. | Conflicts of interest **are not** fully described. Proposal does not adequately consider how to minimise effects on study. |
| **External considerations** | ☐ Study is likely to be extremely sensitive. | ☐ Parts of study may be sensitive. | Sensitivities **have been** fully identified and adequately addressed. |
| | | ☐ No known sensitivities. | Sensitivities **have not been** adequately addressed. |

Annex 4

# Annex 4

| | Comments from review |
|---|---|
| Subject/participant characteristics | |
| Methods/nature of data collection | |
| Researcher competence | |
| Nature of information being sought | |
| Appropriateness of method to subject | |
| Level of privacy to participant | |
| Relationship between investigator & subjects/participants | |
| External considerations | |
| Other comments arising from review e.g. balance of risks & benefits | |

**Overall judgement:**

Acceptable level of risk ☐

Unacceptable level of risk ☐

Require more information ☐

## *Guidance & examples*

Further information about the categories used in the Tool and some examples are presented below. The information is intended to be indicative and not exhaustive.

### Subject/participant characteristics

Some service users may experience particular difficulties in giving informed consent, or in withholding consent, in research which requires such consent. This may be for many reasons, including:

- the age of a child (where the child is very young)

- the incapacity of an adult due to significant learning difficulties, or mental health issues including dementia (see Chapter 5 on the extra requirements for undertaking research with such people introduced by the Mental Capacity Act [2005])

- because of barriers to communication arising from language (for people whose first language is not English) or literacy (if people cannot read or write)

- because of sensory impairments (for example visual impairment, blindness, hearing impairment or deafness)

- because of speech impairments (for example, such as those arising from degenerative illness, or stroke).

The information given to participants to enable them to decide whether to take part should, for example:

- be clearly written so the participant has a full and accurate understanding of exactly what they are consenting to;

- state that they can withdraw from the study at any time without this affecting the services they receive in any way;

- provide information about to whom they may complain, should they need to.

If informed consent is difficult because communication barriers exist, the likelihood of harm to research subjects/participants will be greater unless ways can be identified in the research proposal by which these barriers can be overcome. A research proposal has both to acknowledge the issue as well as offer an account of how any identified barriers will be surmounted.

For example, a research study in which people from ethnic minority groups will form part of the sample should be able to establish the preferred language of those within the sample and ensure that appropriate steps are taken to enable any non-English speakers to take part. This might include the use of translated versions of letters, consent forms and postal questionnaires or ensuring that an interpreter is available for interviews.

If the study involves children or young people, the provision of information about the project (necessary to ensure informed consent) might need to be made available to the parent or guardian as well as the child, and the information provided to the child or young person written in an accessible style.

## Methods/nature of data collection

Methods of data collection that involve:

- high levels of face to face contact or interaction between the investigator and the subject/participant, or

- where the methods are relatively intrusive

may create situations in which one of those concerned may be placed in a vulnerable position of some kind, or one that may compromise the quality of the study. For example, research designs of this kind, in certain contexts, may lead to:

- risks to the researcher – for example if the research involves visits to the homes of people who are to be interviewed;

- the possibility of misconduct or abuse on the part of the researcher, or the possibility that an accusation of misconduct may be made against them;

- a loss of perspective by the researcher arising from a failure to adequately manage fieldwork relationships – for example over-involvement in the research environment;

- stress to those from whom information is being sought – for example through the length of an interview, the timing or location of observations, the number of contacts between the researcher and the persons taking part in the research.

To address potential difficulties of this kind it may be necessary for the proposal to demonstrate how the safety of and respect for participants will be ensured. Where appropriate the proposal should also indicate how field researchers would be supported to manage fieldwork relations properly – a particular issue in any action-research design.

## Researcher competence

There are several dimensions to the issue of competence. A researcher may:

- be generally inexperienced – for example, if they are a student or someone who is not a professional researcher;

- they may lack any real knowledge of the subject under investigation or of the social care context;

- they may possess little or no experience of working with those people from whom information may be collected;

- they may not know about the range of suitable methods to use to achieve the objectives of the proposed study.

Each of these factors increases the likelihood of harm or distress to participants. For example, those who may be asked to take part may be caused distress or inconvenience because a lack of knowledge of their needs might lead the researcher to use inappropriate methods to obtain the information required. The investigator's reputation may also be affected. In addition, a lack of knowledge may also mean that the research funder would be left out of pocket having committed resources to a study that may already have been completed already elsewhere without the researcher knowing about it, or may have sufficient methodological flaws as to be relatively worthless.

If the researcher or researchers to be involved in the study are inexperienced, the research proposal should clearly outline where lack of experience or competence may be an issue and what remedies will be applied, such as through academic supervisor guidance. For example, if the researchers

concerned do not have training in and experience of using the kinds of research methods appropriate to the topic, it may be that they are not the right people to do the study.

If a researcher lacks knowledge of the subject area or topic, they will at the very least need access to those who do have this knowledge, and can share this by offering support and guidance. If the investigator lacks knowledge of a service user group that will be the focus of the proposed study, they may need either to obtain this, or the proposal will need to demonstrate that they have access to sufficient appropriate support to compensate for this gap. Finally, it is very important that any researcher working directly with service users or with case identifiable data has Criminal Records Bureau (CRB) clearance.

**Nature of information being sought**
Some research is likely to require the collection of information that might be highly sensitive or personal – for example:

- data relating to criminal records;

- psychiatric history;

- health status.

Alternatively, the data may be collected as a result of an invasive procedure of some kind such as a new, perhaps untested, therapeutic intervention.

The need to collect sensitive information of this kind should be fully justifiable and explained in the research proposal.

If the collection of sensitive data is not explained, not justified, or is considered unnecessary by those appraising the proposal, the data should not be collected.

If the collection of this information is justifiable, then a range of other issues relating to the level of privacy of the person about whom the data are collected will apply. This will be considered separately below.

**Appropriateness of method to subject, or research questions and the quality of the research design**
It is important that the methods used are the most appropriate for the subject of the study. If they are not, the results of the study may be compromised.

Firstly, the need for research should be established. If there is no need for the study there is little point in doing it.

Secondly, it is important that the proposed study has the resources needed to answer the research questions.

For example, a study requiring interviews with large numbers of service users will normally consume more resources than a postal survey of a group of comparable size. The methods should be appropriate to the subject. For example, using focus group interviews as a method of obtaining information about the use that hundreds of people make of a service will not be very useful if what is being sought is reliable quantitative information – that is, information that accurately reflects the views of all service users.

A better approach would be a postal survey or survey interview using a sample selected in such a way that there can be confidence in the findings. On the other hand, if the purpose of using focus groups is to find out more about the kinds of issues that are important to these service users, a postal survey might be a waste of time as the questions asked might not capture the main issues for users unless the researcher has a detailed prior knowledge of these issues. In this scenario, the method of focus group or unstructured interview could be the more appropriate approach to take.

**Level of privacy to participant**

If the data are not anonymised at the point of collection, the research proposal should explain why it isn't feasible or appropriate to collect the data in this way. The proposal will need to demonstrate that all stages of the data collection process conform to the standards laid down in the Data Protection Act and by the local Caldicott Guardian. The following issues are important in this regard:

- the security of collected data;

- the method of analysis;

- the way that analysed data will be presented;

- the process by which collected data will be disposed of.

How these issues are to be addressed should be described in any research proposal, but this is particularly important if data are not anonymous. Privacy is of the utmost importance if the collected data are of a sensitive or personal kind.

To address concerns about privacy a research proposal should clearly state what level of privacy can be maintained by the study and how this will be explained to subjects/participants. It may be desirable, for example, to state how attempts will be made to minimise the possibility that individuals might be identified, for example by changing names, or selecting data that cannot be attributed to source. A clear account of the following should be included in a research proposal:

- how collected data will be stored;

- who will see the collected data;

- how data will be analysed;

- how long collected data will be kept;

- how data will be disposed of when no longer needed.

**Relationship between investigator & subjects/participants**

There are particular issues that should be carefully considered if the investigator and the subject/participants of a proposed study are known to one another (for example where a member of staff working in a day centre or residential care setting wishes to conduct a study of some kind on attendees/residents). Key issues might, for example, include:

- 'audience effect', in which participants' opinions of, or attitudes toward, the researcher affect their behaviour towards the researcher or their response to questions the researcher may ask;

- an imbalance in power between the researcher and subject/participants may make it very difficult for consent to be withheld;

- there may be a conflict of interest on the part of the researcher, arising from vested interests in securing a particular outcome to the study;

- a researcher's prior knowledge of the subjects/participants may affect what data are collected/ not collected.

To address these concerns any pre-existing relationship between investigator and subjects/ participants should be described. Where appropriate, the proposal might offer remedies for any potential bias that may occur. For example, this might be by ensuring that:

- consent is obtained by someone not known to participants;

- close supervision of the fieldwork process occurs; or

- a third party is used to conduct random 're-tests' to ensure consistency in data collected.

## External considerations

Some research is likely to generate much more interest, and be of a much more sensitive nature than other research, because of heightened media interest, possible implications arising from findings, public concern, or, in local government settings, political agendas.

- There may be a risk that findings may be misinterpreted, by design or by accident.

- There may be pressure to complete the research and publish findings as soon as possible, to satisfy an immediate demand for information or to support important decisions that may need to be made.

- It may be that the findings of a research study, or the area of investigation, are those that key individuals or interest groups may find unpalatable. Alternatively, findings may be exaggerated to suit the agenda of such individuals or groups.

It may not be possible for the researcher or research team to anticipate how a completed study will be received, but an assessment of the policy environment within which the proposed study may be eventually received, and the outcome of research in the same field by others may provide clues. Other ways of addressing external considerations might include the provision of lay summaries of the findings – particularly of complex studies and large reports, and being clear about any assumptions or values that may underpin the proposed study. How the research will be disseminated should be agreed before a study, which will help address these issues.

Please feel to use this tool in reviewing research proposals. If it is to be used in publications, please acknowledge the source by reference to this resource pack.

### *Acknowledgements*

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# Social Work and Social Care[20] research governance: Outline Ideas to Develop a Regional and National Research Ethics and Quality Assurance System

## Summary

This note describes Department of Health guidance for research governance in statutory social care settings and the process of implementing this guidance in local authority settings in England and Wales.

It explores the concerns of sections of the social care research community about the role of NHS research governance systems being extended into the field of social care.

It offers an outline proposal for a system that would operate at national and regional levels

- to support local authority research governance activity in ensuring social care research is of good quality, and ethically sound, whilst

- acknowledging the distinctive nature of some social care research activity and significant differences in research culture, resources, and skills between local authority and NHS settings,

- and helping to streamline accountability for quality in research design and execution. The costs of establishing and maintaining a national forum are discussed schematically.

This is a briefing note and an initial proposal. It offers a starting point for a debate between the ADASS/ADCS and key stakeholders to establish a workable research governance system at national and regional levels. It is produced against a backdrop of NHS changes, establishing a National Research Ethics Service from April 2007, covering non-NHS elements such as social care, and under the auspices of the National Patient Safety Agency.

## Background

In 2001 the Department of Health (DH), as the government policy lead organisation, published its Research Governance Framework (RGF). The RGF was a response to clinical malpractice such as the Alder Hey 'body parts' scandal in the mid 1990s. Originally intended to apply within the NHS only, the framework was extended at a late stage in its preparation to cover research carried out within social care settings. The only statutory element relates to drug trials, stemming from an EU Directive of 2001, and intrusive research in relation to mental capacity issues since the 2005 Mental Capacity Act.

The original proposals met with fierce criticism from the social science and social care research communities, within and outside local government. This led the DH[21] to create a separate

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[20] "Social care" is used here as the general term, and would include "social work" as a discrete professional element, particularly being used to describe a corpus of professional knowledge in university settings. It is also a term that has been largely retained at the present time in Scotland.

Implementation Plan in 2004; and to the creation of a standing national Advisory Group for research governance in social care settings. Any earlier intentions of extending the remit of pre-existing research governance machinery within the DH were not pursued as the degree of hostility to and concern about this amongst the social care research community became clear.[22]

**Progress towards implementation of local Councils' (Councils with Social Services Responsibilities - CSSR) research governance arrangements**
A major concern of the social care research community was that much of social care research is completed to tight deadlines with the minimum of resources, and using a wider range of methodologies than those most frequently associated with clinical research.[23] They viewed the NHS approach to research governance as time consuming; and their experience has been that it often paid little regard to the specific constraints faced by social care researchers.

The DH acknowledged that little was known about social science research carried out in social care agencies rather than academic settings (much of which results in so-called 'grey' or unpublished literature). A study commissioned in 2002 by the DH (Boddy & Warman, 2003) suggested that the volume of research being conducted in non academic settings was significantly greater than had been previously imagined.

This led the DH to recommend to CSSRs a two stage approach to RGF implementation: starting with external research activity, extending the following year (2005) to research carried out 'in-house' within CSSR settings. A resource pack, to support CSSRs in establishing local research governance arrangements, was published jointly by the ADSS, DH and SSRG in 2005. A further survey by Pahl (2006) suggests that now most CSSRs have some kind of arrangement in place for the appraisal of research in their organisations. These activities also served to focus attention on the wider relationship between the quality of research conducted in these settings, and research ethics.[24]

In parallel, the Economic and Social Research Council (ESRC) published in 2005 its Research Ethics Framework. This codifies its expectations of social science research funded by the ESRC, and usually undertaken through universities.

Progress in implementing social care research governance arrangements at a local authority level has been remarkable in a number of respects.

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[21] This has had at its core a two-tiered system of ethics review. NRES, or the Central Office for Research Ethics Committees, co-ordinates and implements national standards. MRECs or Multi – Site Research Ethics Committees operate at regional level and are used if the proposed research is planned to take place in more than 5 different locations. LRECs, or Local Research Ethics Committees, review research at a local level. This structure is in the process of change, within the redesigned National Research Ethics Service (NRES). We have generally retained the older terminology because of its applicability in the recent past. Other aspects of governance concern indemnity insurance, the issue of honorary NHS contracts to non-NHS staff, and Criminal Record Bureau checks.

[22] There were two fundamental areas of concern. The first was about the bureaucratic and time consuming nature of the LREC/MREC process for small scale social care research, in addition to the other governance requirements, which would create great difficulties for many researchers working in the social care field. The second was concern that the research background knowledge and skills of those who reviewed proposals in the NHS were partial, often lacking an understanding, or even acceptance of the legitimacy of, some social care research methodologies.

[23] This is not, of course, to imply that these factors mean that scrutiny should be any less rigorous, but that it should be less time consuming.

[24] The two are not synonymous, but in this respect, local/regional research governance arrangements for social care research could play a central role in improving research quality, especially in relation to research activity carried out by staff working in social care settings.

- There has been no ongoing funding made available from the DH to support the implementation of research governance in the majority of CSSRs.[25]

- The DH advice, and the detailed Implementation Plan (2004) for CSSRs to introduce research governance arrangements, have the status of guidance, and are not mandatory or statutory.[26]

- The Department for Education, while being a major stakeholder and having an interest in the quality of research upon and with children within CSSRs' area of responsibility, has not played an active part in research governance promotion and guidance.

- The research culture and capacity within CSSRs are not at all well developed compared to the status and capacity of research within the NHS.[27]

- The operational definition of what constitutes research is wider than in the NHS.

This progress drew praise from the National Director for Social Care at the DH in a letter sent to Directors in July 2006, though the letter counselled CSSRs to be proportionate in balancing assessment of risks of research against the support of good quality research.

### The need for a nationally co-ordinated approach to ethics review

A need for a national body or set of arrangements to offer guidance and support to CSSRs – to ensure that local research governance procedures are both efficient and effective and based on sound models – was recognised in 2004, when the DH offered four possible models of national ethics review in social care research. The responses to the consultation were analysed (Pahl, 2005). It was hoped that there might be some national consensus from those who replied as to a favoured model. In fact, respondents tended to reflect the sector from which they came, with the academic respondents opting for a system that emphasised the use of local and regional structures, to minimise uncertainty and delay. To surmount this impasse, and to try to secure funding for any future national body, it was proposed to negotiate with the National Research Ethics Service (NRES, formerly COREC) over the creation of a compromise 'nested' social care committee – a separate entity within the NRES structure, but part of this system nonetheless.

A proposal requesting that the ADASS become a component element in this role was presented to the ADASS research subcommittee in mid-2006 (Dolan, 2006). A precondition for the existence of the proposed 'nested' committee within the then NRES system was that the appointing authority (the body with responsibility for establishing and appointing to such a committee) should have or obtain the status of a Strategic Health Authority, accountable to the Secretary of State. The appointing authority would also be required to obtain unlimited insurance indemnity to protect it, in the event of malpractice leading to litigation. In view of these requirements, the ADASS was unable to commit itself to this approach.

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[25] Small amounts of DH funding were provided to support the Implementation Plan referred to, for a programme of basic training for research governance lead staff, and in respect of very small amounts of 'one off' funding (@ £2,500 per CSSR) to support implementation - though this has to be claimed from the DH for approved work completed. In addition, DH funding has also been made available to SCIE to support the development of an Electronic Register for Social Care Research launched in 2006.

[26] NHS research governance systems operate within the same guidance based requirement.

[27] Marsh, P., & Fisher, M., (2005) *Developing the evidence for evidence based practice in social work and social care* London, SCIE, make some trenchant observations about the disparity in resources available to support research activity within CSSRs compared to the NHS.

NRES envisaged (in its Business Plan, November 2006) some modification to its existing national and local system, including "renewing" Local Research Ethics Committee membership from April 2007; and made budget provision of £200k in two successive financial years. This would cover what is described as non-NHS REC activity, though it is not clear whether the focus would be exclusively on social care.

## *Key issues from a social care perspective*

There are five long-established issues, and one emerging issue.

### Wariness of NRES's narrow focus on issues of risk aversion in research, narrowly defined

The traditional review processes have concentrated on issues of risk and informed consent. Other issues of research quality and value, not least for participant groups, are not on the agenda. Swathes of survey or other forms of evaluative research, for example, are not reviewed, despite raising ethical but apparently not safety issues. This continues with the NRES.

### NRES unfamiliarity with social science methodologies

Essentially, sections of the social care research community remain concerned that a NRES-type national committee for social work/social care - if appointed by NRES's successor - will not reflect the realities for social care researchers of tight deadlines and short timescales; that it will fail to acknowledge the validity of research methodologies other than the Randomised Controlled Trial commonly used in clinical research; and as a result will not provide informed guidance and support for local social care research governance groups that have been established.[28] The few examples of local co-operation between CSSRs and Primary Care Trusts have required the demonstration of mutual respect and knowledge.

### Need for support for research capacity and for research conducted from within social care settings

The status of research activity in local authority, and specifically social care settings, differs significantly from that in NHS settings. Far greater resources are spent on research within the NHS, and research culture and funding have deeper roots. Staff who undertake research in local authority settings are less likely to have formal research qualifications; and will have less access to appropriate training and support than those working in the NHS. No career structure exists for researchers working in local authority settings. This is parallel to recent observations on social care and social work research in Higher Education Institutions (Bywaters et al., 2006).

### Need for a more inclusive constituency of reviewers

The NHS tradition has been to engage a specific and prescribed "lay" element within committees dominated by professionals undertaking reviews in paid time. Changes in this tradition are mooted, but have yet to show evidence of achievement in relation to effective service user inclusion. By contrast, some CSSRs are developing systems locally, which engage service users as well as varied groups of professionals. The views of the national organisation for patients, INVOLVE, have found a receptive hearing.

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[28] These concerns are not without foundation. In 2005 a review of NHS ethics committees (The 'O'Higgins Review') established a series of ad-hoc advisory committees to explore different areas of research governance. One of these ad hoc committees reported on social care research. There were no local authority representatives on this committee.

## Need for 'value-added' to be paid for

Ultimately, academic and non-academic research is funded to achieve worthwhile results in an ethically acceptable way. The costs of quality regulation have to be borne by some: and arguably those bodies who commission research in particular should acknowledge that they benefit from rigorous well-regarded systems of accountability. Those bodies, of course, principally include government departments in relation to research within social care.

These factors will have an impact on the local social care research governance arrangements that have now been established. The circular letter sent to CSSRs, praising efforts to implement research governance, also reminded of the need for proportionality. To this must be added the possibility that the quality of reviews of research proposals and of monitoring may vary according to the skills and backgrounds of reviewers.

## The reach of social care research governance

An unknown amount of social care research effectively bypasses both NHS and local authority research governance systems. This is because it takes place in sectors which are to a degree removed from local research governance arrangements, and are 'hard to reach'. Paradoxically, the sectors include some of the most vulnerable people in the country – older people in independent sector residential homes, and other people receiving services privately through a variety of providers. The reach of the Human Rights Act has yet to be conclusively tested in this area.[29]

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[29] Section 3.10.2 of the Research Governance Framework for Health and Social Care (2nd edition, 2005) makes clear the requirement that care providers in such organisations have specific responsibilities: the Guidance states
No health or social care research involving human participants ….may begin before
• An identified sponsor has taken on responsibility for that research
• The study has received a positive ethical opinion
• The allocation of responsibilities is agreed and documented.

# The proposal (as at June 2007 and not currently being pursued)

## Summary

1. This proposal aims to establish a streamlined and authoritative source of guidance for researchers and local councils in relation to social care research (adults and children's' services).

2. It utilises existing expertise at national (England) and regional levels to create a support infrastructure for social work/social care research governance within local CSSRs.

3. It also proposes the development of a new co-ordinating group operating at a national level – possibly facilitated by SCIE – as a NRES-sponsored group, but with the power to appoint its members vested in social care stakeholders.

4. This group could work within modified GAFREC[30] guidance and NRES working definitions of research activity – providing the current guidance and definitions are substantially revised to accommodate the specific nature of social care research activity.

5. To support individual CSSRs and consortia in developing local/regional research governance procedures, the proposal offers an approach that would tap into the skills and experience offered by existing regional ADASS/ADCS groups, local universities and national organisations that support the use of research evidence in CSSRs, such as Making Research Count, Research in Practice, and RiPfA.

This would streamline existing national arrangements, [principally those maintained by ADASS] and support authorities at a regional level, whilst safeguarding standards in relation to safety and the quality of social care research. It would open the possibility of extending the reach of social care research governance standards.

## Purposes

The proposals set out below offer a starting point for discussion and negotiation rather than a detailed blueprint of structure and role. Geographically, it may be advisable to explore the feasibility of a forum based in England and possibly Wales in the first instance, but it would be desirable to aim for a UK-wide forum at a later point. Resource assumptions are critical and are addressed below.

The proposed key purposes would be as follows:

1. To provide a national framework for commissioning, supporting or endorsing research in identified areas – broadly defined (similar to the Plain English definition proposed and published by the ESRC[31]), to underpin or assess policy, practice and procedures involving staff and service users and carers within the social work/social care field. This builds on the existing role of the ADASS in appraising the 'worth' of research proposals planned to take place in more than three local authorities. This purpose would not supplant the role of the DH or of regulators in commissioning research activity at a strategic level, but would complement it. It also

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[30] Governance Arrangements for NHS Research Ethics Committees.
[31] http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/Plain%5FEnglish%5FSummaries/research%5Fmethods/

acknowledges that the social work/social care field includes children's and families' social care research and research commissioners.

2. To develop and maintain an independent system for responding to multi-site research applications to CSSRs in England and Wales, operating at a regional level. This would be advisory but also comprehensive and authoritative in relation to quality – covering ethical issues, methods, risk assessment, and checking the clear acceptance of sponsorship responsibilities including those for financial management, allocation of intellectual property rights and ensuring free access to information on research.

3. To enable CSSRs to be confident that worthwhile independent quality checks have been carried out on all research that envisages access to their staff or service users (children and adults) and carers, and that the results are a satisfactory contribution to their own decision-making, and therefore to offer support and guidance to local CSSR research governance arrangements.

4. To enable research sponsors to have the benefit of an authoritative, independent opinion from a system closely attuned to and drawn from social work/social care research and service user/carer expertise.

5. To co-ordinate best practice guidance to local CSSR research governance groups via regional ADASS groups in alliance with universities at local and regional levels.

6. To establish shared operational standards for social work/social care research activity. (Whilst the Research Governance Framework offers a robust and comprehensive framework [the 5 'domains'], its elements are not templates but statements of principle.)

7. To offer the basis for a process to review and advise on decisions about research proposals which have been made at a local or individual level, where there are specific grounds for doing so.

8. To support the quality basis underpinning entries on research projects added to the national Register of Social Care Research, maintained by SCIE,[32] and proposals to develop research infrastructure and capacity in the field of social care.[33] [34]

9. To report on activities annually and on research themes.

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[32] As well as ensuring quality, SCIE are currently looking at the prospect of extending the register to include more types of empirical research than those that require RGF approval, such as practice research undertaken for higher degrees. The Register already includes details of desk research projects. The purpose is to use the Register as a means of identifying possibly overlapping projects, as well as documenting approved projects.

[33] Linkage could extend far beyond this. Dame Denise Platt, Chair of CSCI, reported recently on her Review of the Status of Social Care, commissioned by Ivan Lewis, MP, Parliamentary Under-Secretary of State for Care Services. In this wide-ranging review she calls, inter-alia, for the creation of a Research Centre of Excellence – a proposal she states is being actively considered. Dame Denise states *"The need to strengthen the research infrastructure (of social care) comes from the necessity for social care to become more evidence based and to be a full partner with other health and welfare agencies in addressing social disadvantage. By infrastructure, the department and others mean: the capacity to undertake high quality, applied research particularly research that addresses the need for practice improvement"* (para. 11, April 2007). This proposal would strongly complement those of this note.

[34] Fisher, Francis & Fischer (2007), reporting on a consultation of research capacity in social care, suggest *'…the structure for a UK wide approach should be based on each country having a central structure, possibly an agency, that would develop social care research priorities and would bid for and distribute funding: supported by a UK co-ordinating body with a role to ensure that research priorities are complementary and to address generic infrastructure issues (such as the Research Governance Framework and a research register). This framework, of a country-specific, central structure or agency for social care R&D, supported by a UK-wide co-ordinating body, would offer leadership and structure appropriate to social care'* ( p.21). Although there are nuanced differences between Fisher's conclusions and those of Platt referred to earlier, there is no disagreement on the need to develop, co-ordinate and support social care research activity. The proposals in this note for a national co-ordinating forum are fully consistent with those offered by Platt and Fisher et al.

**Specific initial aims**

1.  To agree and implement arrangements at regional level to review all research applications requiring access to CSSR staff or CSSR service users (adults and children), or personal data on them, of (initially) two or more CSSRs in England and Wales.[35]

2.  To agree and implement at regional level examination of ethical, methodological and risk aspects of proposed research and report an evidence-based opinion on these.

3.  To agree arrangements to check that research sponsors have carried out all their initial responsibilities as required by the RGF, and are aware of their later responsibilities.

4.  To publish the results of all reviewed applications.

**Resources**

Regional ADASS groups would feed into the national Forum and link in with regional and local research governance groups – where these exist. The groups would offer support to local authorities, including the building of links with local academic institutions, to ensure that local authority structures developed to review research proposals reflect professional, academic and lay and service user input.

A central role is envisaged for organisations such as Making Research Count (MRC), Research in Practice (RiP) and Research in Practice for Adults (RiPfA) as well as local universities. The proposed structure (below) recognises the fact that whilst local authorities have the responsibility to implement research governance arrangements, many will need support to do so. This support can best be provided at a regional level by the ADASS and university sector organisations working in collaboration. The third contributory element, service users and carers, would also be encouraged at this level, from existing local or national sources, such as INVOLVE, and from specialist service user bodies with local representation.
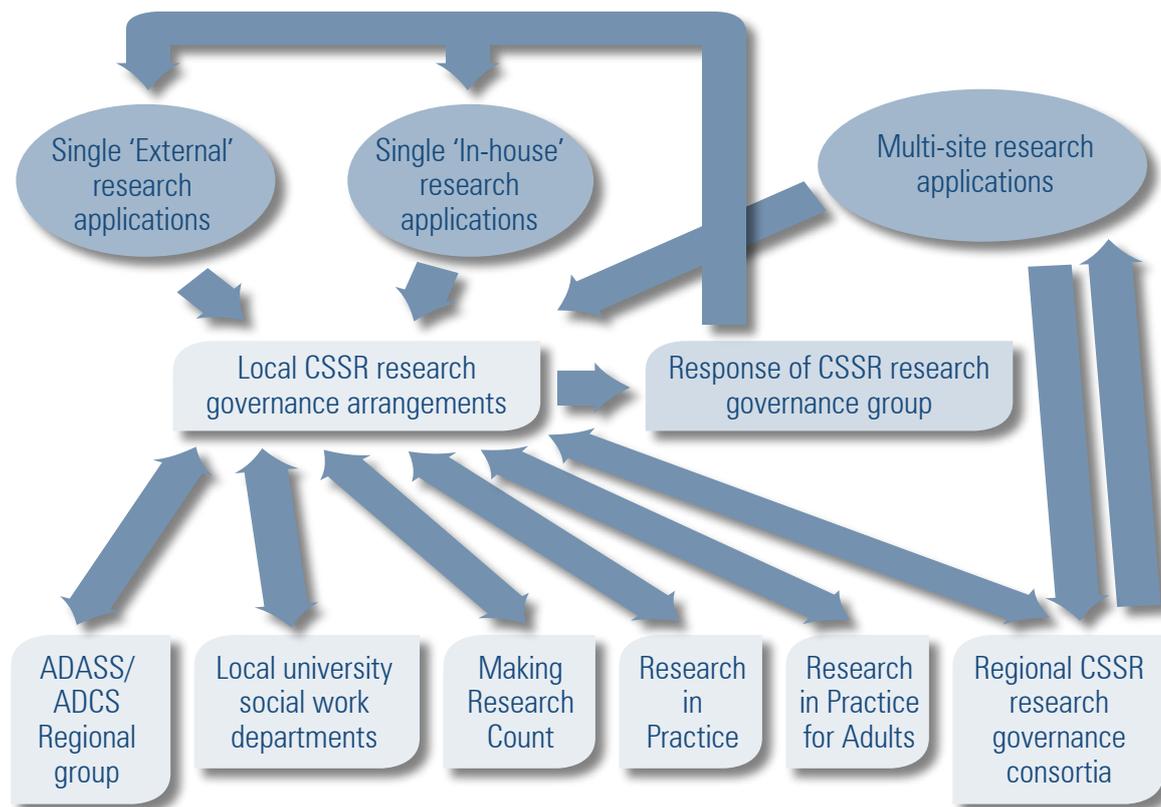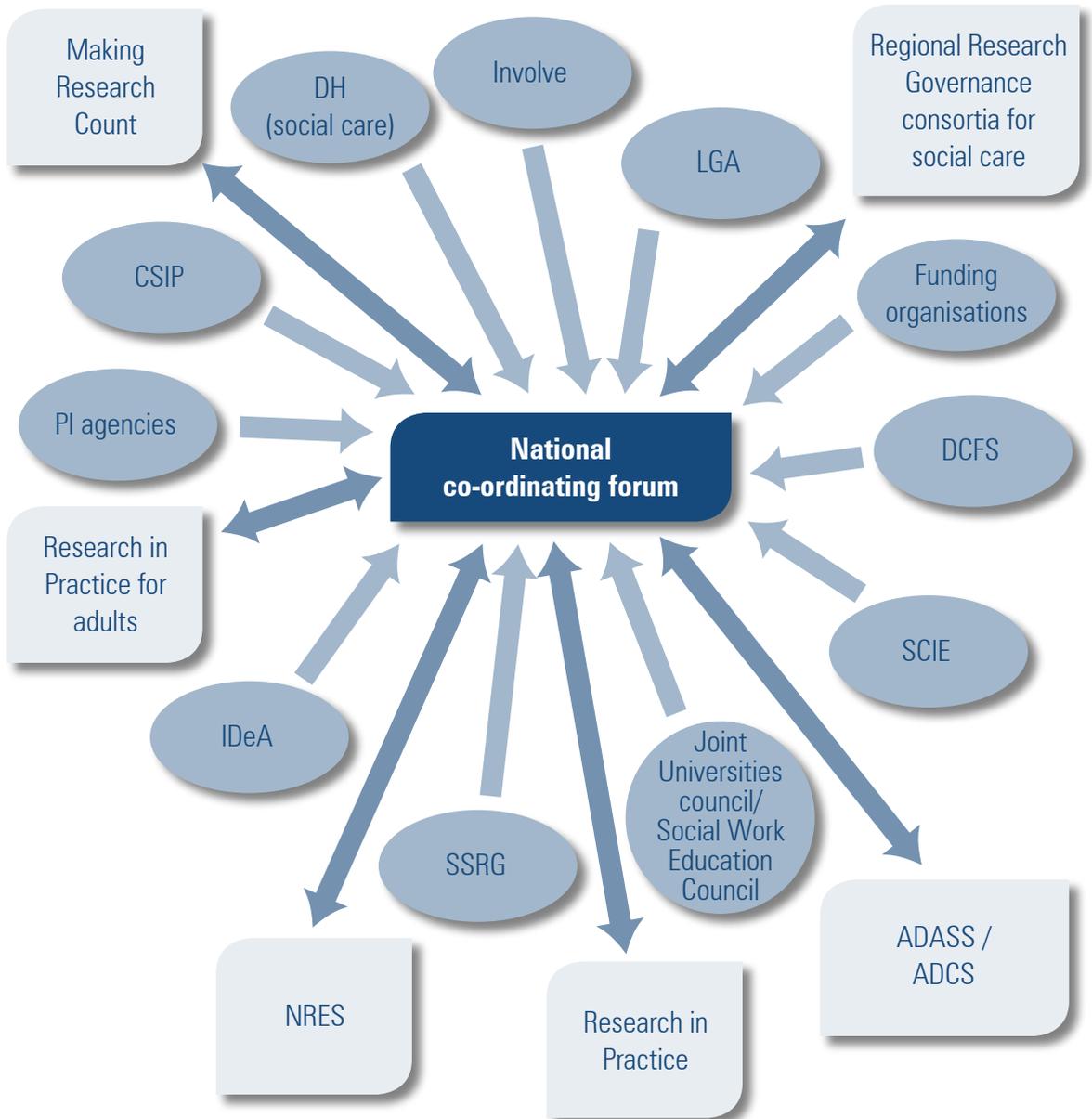
[35] This is a current proposal: it could revert to cover four or more sites if this were appropriate.

**Structure and Roles: Local and Regional**

How the structure might look is represented diagrammatically below.

**Fig A6.1  Schematic outline of relationships between local and regional research governance 'stakeholders'**

Nationally - and especially from the perspective of sponsors of research – there is an increasing prospect of fragmentation and delay should researchers wish to approach CSSRs to take part in their research. This also applies to national government or other national organisations as sponsors, or to CSSRs when conducting research directly, for example, through national surveys. This paper therefore offers a proposal intended an attempt to fill a national gap – not appropriately filled by either the NHS NRES system (as it stands at the present time), by local CSSRs with research governance arrangements, by individual university ethics committees, or by ADASS's advisory system for directors on the priority and potential value of projects. It also provides an opportunity to fill this gap in a facilitative, 'non-traditional' way – for example, with significant service user and carer input into the process. The method of governance for this proposed approach would need to be worked out robustly and agreed by stakeholders.

As well as having a role in appraising national research, the expertise available in such a forum could be focused on:

- the development of operational standards for social care research governance at local and regional levels;

- advice to local and regional groups undertaking review activity;

- assessment of the quality and consistency of project reviews undertaken, including risk analysis; and

- any needs for training such groups may have.

The forum would also be ideally placed to commission the development of training and other appropriate resources and material that could be used by CSSRs to establish maintain and promote internally and externally high quality review processes.

## Activities and Costs

Although these proposed arrangements mostly use existing structures, within ADASS/ADCS and elsewhere, the national co-ordinating function will need to be funded. Ongoing cost areas [after initial set-up] will include:

- Maintenance of a website and material to advise prospective applicants.

- Maintaining a panel of reviewers, to include service users and carers, including initial and periodic training, and covering fees and costs associated with the review activity.

- Advising applicants prospectively and currently.

- Dealing with and processing applications.

- Invoicing for and securing fee payments from researchers.

- Distributing applications and supporting material to regional groups and reviewers and co-ordinating their responses for the forum.

- Contributing to preparation of and discussion of policy and general information about proposed arrangements, including the role of the forum and regional groups.

- Supporting the preparation for and discussions at meetings between forum members, regional ADASS groups and reviewers.

The expectation underlying this proposal is for an annual volume of 500 enquiries and 200-250 completed requests for multi-site (2 local authority sites or more) research review. This estimate is derived from ADASS's current system, and the SCIE national register, plus Council estimates of currently non-compliant research applications appropriate for research governance, which meet the proposed criteria of research applying to two or more local authorities. NRES estimated in 2005 that 1200 applications a year across the UK would be in the social care category, but this figure appears to have been based on every review rather than multi-site applications. An unknown dimension is the volume of research applications that might ultimately emerge from the non-statutory social care sector. It is envisaged that the initial two years' cost would be in the region of £200,000 p.a. Thereafter, annual running costs could be slightly less (or activity expanded as mooted above) and there would be some income stream if there was a policy of charging [at some varied levels] for reviews of submitted research proposals.

- Dr John Woolham, Northamptonshire Community Services

- Paul Dolan, Birmingham Adults & Communities

- Prof. Jill Manthorpe, Social Care Workforce Research Unit, King's College London

- Prof. David Berridge, Dept. Child and Family Welfare, University of Bristol

All the above are members of the ADASS research sub-group. Endorsed by ADASS Research Sub-Group, 29 June 2007.

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# Securing Ethics Approval: A Route Map for Social Care Researchers

This document was agreed by key organisations involved in social care research:

• The Economic and Social Research Council;

• The National Research Ethics Service;

• The Association of Directors of Adult Social Services;

• The Association of Research Ethics Committees.

The document was formally signed off in March 2009. Any factual statements were true at the time this was agreed.

## *8.5 Securing Ethics Approval: A Route Map for Social Care Researchers*

**Key Principles:**

(i) *Reciprocity* – mutual respect between different sources of ethics review is a central principle; this principle should obtain within as well as between ethics review systems that operate to the same standards.

(ii) *Avoidance of 'double-handling'*. No study should normally be required to go to more than one REC and no REC should review a study that has been formally approved by another appropriate body.[36]

(iii) *Proportionality*: to avoid unnecessary bureaucracy and not untowardly hinder the progress of good research, the level or intensity of review must be appropriate to the risks involved. Procedures for expediting low-risk research should be established.

(iv) *Independence*: to avoid any potential conflict of interest, reviewing committees should be independent of the organisations funding the research. Where hosted by the organisation undertaking the research, committees should establish explicit procedures for identifying and managing any potential conflict of interest.[37]

(v) *Researcher-led*: the responsibility for identifying and securing appropriate review lies with the lead researcher, but funders may reserve the right to recommend a particular source of review to their research contractors.

**Definitions and Coverage:**

(vi) The proposed definition of 'research' for university ethics committees is provided by the ESRC in its Research Ethics Framework (REF) document: '…*any form of disciplined enquiry that aims to contribute to a body of knowledge or theory*' (2005:5).[38] The definition used by ethics committees within the National Research Ethics Service (NRES) is provided in the DH Research Governance Framework for Health and Social Care (DH, 2005). Neither definition

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[36] "Exceptionally, a study may need to be submitted elsewhere if a Committee discovers during the review that it is not the appropriate Committee for that type of study.

[37] Independence of the body undertaking the research is a legal requirement for Committees recognised to review clinical trials of investigational medicinal products and for those reviewing research under the MCA.

excludes, a priori, particular designs or methods (i.e. surveys or evaluations) where the study is *designed, managed and presented as research*.

(vii)   The Mental Capacity Act (MCA - 2005) covers '*intrusive research*'. This is defined very broadly as any research that would be unlawful if carried out on, or in relation to, a person who has capacity to consent, but without their consent. This covers all kinds of primary research, including observation or the collection of data about an individual indirectly from another source, except where it involves *only* non-identifiable personal data. This definition is not the same as the (more restricted) definition of 'intrusive research' contained in the ESRC's REF.

(viii)   The proposed definition of '*social care*' is that contained within the DH RGF *Social Care Implementation Plan* (DH, 2004): i.e.: research undertaken 'in or with' bodies (independent or statutory) providing personal social services – the PSS sector. The key to this definition is thus whether access to research populations is being sought via PSS agencies, or the provider organisations contracted by them.

(ix)   Currently, only *adult social care* is formally covered by the DH RGF, although some Councils have chosen to implement corporately and the Department for Education is currently recommending the RGF as good practice. The RGF issued by the Department of Health covers research that falls within the responsibility of the Secretary of State for Health in England. Other UK nations have issued compatible Frameworks.

**Sources of Ethics Review for Social Care Research:**

(x)   The main sources of independent ethics review for adult social care research are:

• committees operating within the national research ethics system (*NRES Committees*), including the new Social Care Research Ethics Committee (SCREC);[39]

• *University-based committees* (URECs), of which many (but not all) are operating under the ESRC's REF. The Association of Research Ethics Committees (AREC) is working to consider ways to encourage greater consistency of UREC operation, including accreditation.[40]

• *other systems*:

   a. some research funders, including many government Departments, do not obtain independent ethical review, but ensure good ethical practice via their research procurement processes. For government Depts., this process is guided by the new GSR '*Ethical Checklist*';[41]

   b. some non-university research institutes (e.g. National Centre for Social Research) have established their own ethics committees, with independent members;

   c. some local councils (CSSRs) have established *local governance committees* that undertake review (science and ethics) of in-house or 'own account' research and provide local governance clearance for externally-funded studies; in a small number of sites, these have grouped into regional research consortia;[42]

   d. the ADASS review process for multi-site studies is not a source of ethics approval.[43]

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[38]   A more detailed definition is provided on the ESRC website: http://www.esrcsocietytoday.ac.uk/ESRCInfoCentre/research/ResearchMethods/

[39]   http://www.nres.npsa.nhs.uk/applicants/apply/applying-for-ethical-review/

[40]   http://www.arec.org.uk/

[41]   http://www.gsr.gov.uk/downloads/professionalguidance/ethical assurance/ethics_guidance.pdf

[42]   These consortia are not connected to ADASS.

[43]   The ADASS review focuses on policy fit and cost/benefits to the sector and is not required but will facilitate (although not guarantee) access to local Council host sites.

(xi) Funders may differ on whether they require ethics approval before a funding decision can be made. Researchers are advised to check the situation with their particular research funder.

**Reciprocity Between and Within Review Systems:**

*(xii) Between URECs and NRES Committees*

- All research undertaken 'in or with' the NHS[44] needs to be reviewed by an appropriate NRES Committee using the Integrated Research Application System (IRAS).[45] URECs must be informed, and may require copies of IRAS applications, but should not undertake additional review.

- All adult social care research that is funded by the DH will be reviewed by the new SCREC and should be handled by URECs in the same way as NHS studies. This will ensure a single approval system for all DH-funded research.

- Non DH-funded social care research may be reviewed by the SCREC or by the relevant UREC. The decision will be made by the lead researcher, in the context of their HEI's internal requirements and any made by funding bodies.

- All 'intrusive' research (see definition at vii) involving people who lack capacity to consent, however funded, must **by law** be approved by a body recognised under the MCA. Currently only Committees operating under the NRES are so recognised.[46] It is intended to recognise the SCREC under the MCA, once its members are appropriately trained.

*(xiii) Within UREC and NRES systems.*

- As required under the ESRC REF, HEIs should make appropriate arrangements to identify a lead UREC to review studies being carried out by a *consortium of HEIs*. This would normally be the UREC in the HEI of the lead researcher of the study. Copies of the study proposal and approval documents should be sent to UREC chairs in all collaborating HEIs.

- NRES should establish clear procedures for the allocation of studies, designed and presented as research, that *involve both NHS and social care sectors*. It is recommended that **multi-site studies** involving both sectors, but without any clinical dimension, should normally be dealt with by the SCREC.

- Access to the SCREC will be via SCIE or NRES routes, using the IRAS. NRES/SCIE coordinators need to agree common standards and definitions in the handling of social care research and IRAS forms should provide a distinctive information route, and guidance, for social care applicants.

*(xiv) Between Local Governance and NRES/UREC systems*

- CSSRs are responsible for ensuring appropriate review of in-house or own-account research. For studies they identify as 'high-risk' they may wish to secure approval by the SCREC, or local UREC (if available). Approval of a recognised committee however is required for any 'own-account' study covered by the MCA.

- For all *externally funded research*, the CSSR is required to check that prior approval of ethics has been undertaken by an appropriate body (NRES Committee, UREC or 'other system':

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[44] A more detailed definition of this condition will be provided in the revised GAfREC document (due shortly).
[45] http://www.myresearchproject.org.uk
[46] All NRES committees are recognised, but not all currently trained, for MCA work.

see x above). Where this is the case, they should not then subject the study to further ethics review. However they will still need to assess, and ultimately decide, whether the work is appropriate for local circumstances/populations.[47]  Councils may indicate changes necessary to enable access (and may, in exceptional circumstances, wish to feed back concerns to the reviewing committee) but should generally avoid requiring any changes to the proposed study that would invalidate the approval already secured.

- Where prior approvals have not been obtained the lead researcher will be required to seek ethics approval from an appropriate body. For NHS and DH-funded social care research, proposals will need to be submitted to the appropriate NRES Committee; for all other studies, review will be provided by the lead researcher's UREC or local UREC/CSSR collaborators, or referred to the SCREC if review cannot be accessed elsewhere.

### (xv)  Within CSSR Local Governance Systems

In the case of multi-site studies, individual participating CSSRs should avoid requiring researchers to submit different documentation. Ideally, a single Council should agree to undertake the necessary checks on behalf of the other partners

**Other Issues:**

### (xvi)  Remit of the SCREC

The SCREC coordinator will be able to provide advice for researchers seeking ethics review, but the Committee is not resourced to provide advice on other aspects of research governance. It is not considered appropriate for the SCREC to produce ethical guidelines for social care researchers. These are already adequately provided by professional societies (e.g. British Sociological Association, British Psychology Society, Market Research Society, Government Social Research, Social Research Association) and by the ESRC.

### (xvii) Risk Assessment

The SCREC will work towards developing a risk assessment approach appropriate to the social care context. This will enable the 'fast-tracking' of proposals judged to be of low risk.  The 'Risk Assessment Tool' produced by the DH SC RGF Working Group or the ESRC's criteria for identifying low risk research (ESRC, 2005: s.1.2.2.) may be useful in this respect.

### (xviii) MCA Training

MCA Training provided by the NRES is designed to cover all types of research. The DH will work with the Government Social Research Unit to produce further guidance for social science researchers working under the MCA.

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[47]  In doing so they will take account of factors such as organisational resources and priorities, impact on local user/carer populations etc. Councils will require sight of REC application forms and decisions and may also require relevant documents (e.g. participant invitation letters, questionnaires), especially if these have not been submitted to the REC. Councils will also check whether independent review of the science of the study has taken place and whether approval of the Association of Directors of Adult Social Services has been secured for multi-site (4+) studies.

*(xix)  Student Research*

The SCREC will not deal with student research; this will be the responsibility of the relevant UREC or UREC/CSSR collaboration, unless it is covered by the MCA. For practitioner-research, where there is no external funding, ethical review should normally be provided by the HEI (if appropriate) or by the CSSR's Local Governance Committee/Lead.

The figure below, '**Research ethics decision tree**', shows in diagrammatical form routes into social care research ethics approval.

**Figure A7.1 Research Ethics Decision Tree for Social Care Research**



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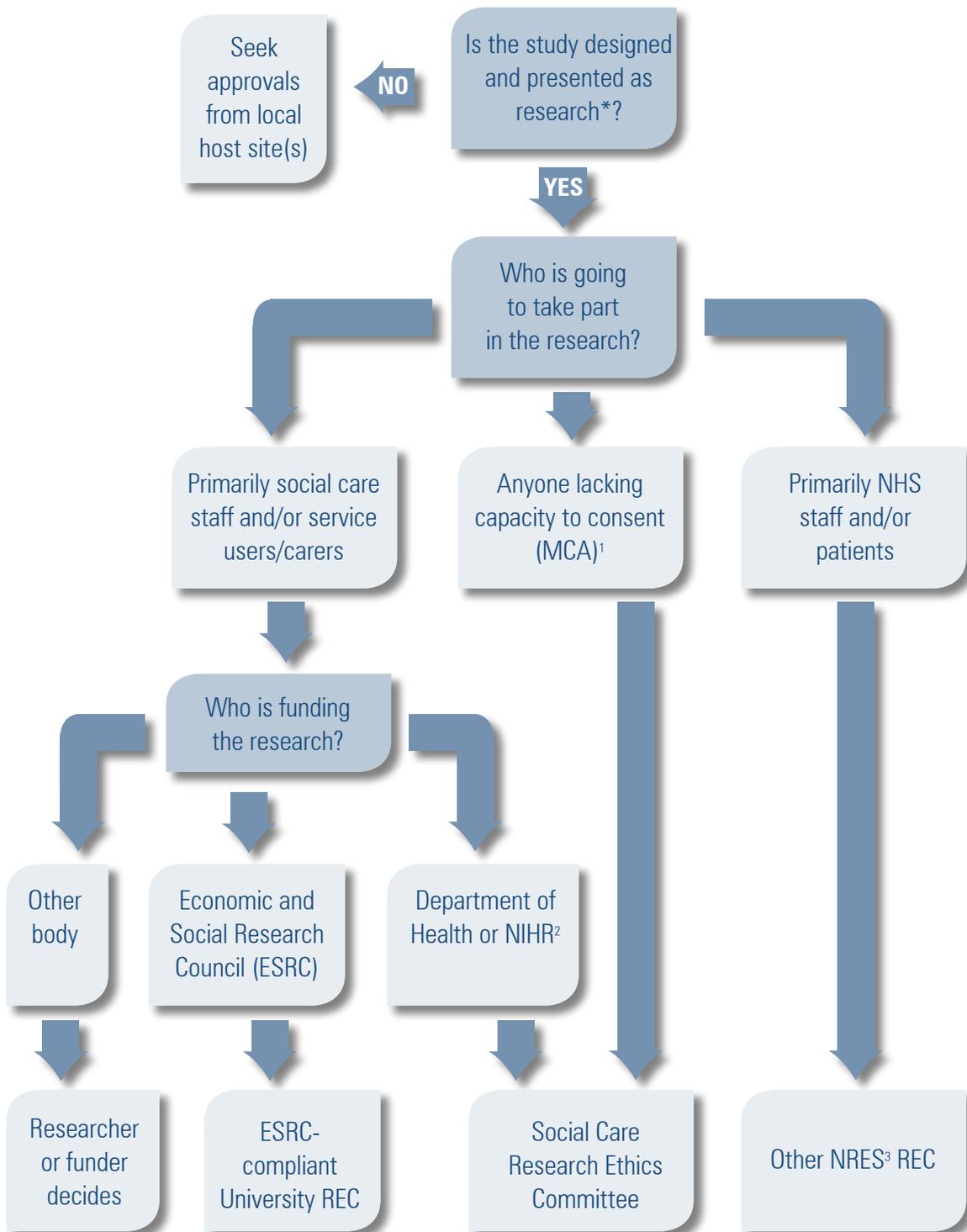
[1]  Mental Capacity Act, 2005     [2]  National Institute for Health Research     [3]  National Research Ethics Service

*The definition of research covered here includes that used in Chapter One:

*For the purposes of research governance, 'research' means the systematic application of established research methods and techniques to gather information on human participants in an explicitly planned way.*

This definition covers all research defined as intrusive by the Mental Capacity Act, as set out in Chapter 8:

*Research is intrusive if it is of a kind that would be unlawful if it was carried out:*

*(a) on or in relation to a person who had capacity to consent to it, but*

*(b) without his consent.*