Guidelines: Social Care Research

1. Does your project involve Social Care Research?
   If you propose to carry out research in England which involves adult social care practitioners, adult social care clients and/or social care resources, then your project falls under the Secretary of State for Health’s remit and is governed by The Research Governance Framework of the Department of Health. The framework includes any person involved in health and social care research: participants, principal investigators and researchers, host organisations, funders, and managers. It includes research undertaken by industry, charities, research councils, universities, and NHS staff. Recognising that implementation of the Framework in social care requires separate consideration, the DoH has also published an Implementation Plan for Social Care.

   The framework requires research proposals to be reviewed across the five ‘domains’ of research governance:
   - ethics
   - science
   - information
   - health and safety
   - finance (and value for money).

   Currently, only adult social care is formally covered by the DH RGF, although some Councils have chosen to implement the framework corporately and the Department for Children, Schools and Families, and the Association of Directors of Children’s Services recommend the RGF as good practice.

   **Notes on Designing Social Care research**
   RDInfo provides a flowchart and comprehensive step-by-step guidelines for designing a research project in Social Care, aimed at students and early career academics. These guidelines include very useful links to relevant resources relating to Social Care research. Additional useful information about research governance in social care can be found in the Social Services Research Group (SSRG) RGF Resource Pack for Social Care (http://www.researchregister.org.uk/files/RGFGuidancepack2010.pdf) and at the Social Care Institute for Excellence (SCIE; www.scie.org.uk) which is developing a national research register for social care.

2. Does your project involve NHS patients, staff and/or facilities?
   If your study of adult social care in England involves NHS patients or their data (i.e. recruited by virtue of being NHS patients) or NHS staff or NHS facilities, you must gain approval from the DoH National Research Ethics Service (NRES) before it may proceed. This also can apply to research involving children where services for children are provided on a multi-agency basis, such as by a children’s trust. 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.

   You are also advised to consult Differentiating between research, service evaluation and audit to determine whether or not your ‘research’ requires NRES ethical scrutiny. This can be particularly complex for those carrying out social care rather than health care research, those carrying out what the NHS might categorise as an audit or a service evaluation and
when research involves respondents who lack mental capacity (see below for further information).

If you are intending to apply for NRES approval you should consult their guidance for the most up-to-date information. You will need to apply for NRES approval using the Integrated Research Application System (IRAS). IRAS is a web-based integrated research application system that captures the information a researcher needs to submit for the relevant permissions and approvals to enable the conduct of health and social care research. It streamlines the application process by allowing study information to be entered in one place without duplication in separate application forms for each review body.

3. Is Your Research Funded by the Department of Health and / or does it involve people lacking Capacity to Consent Under the Mental Capacity Act 2005?

Every research proposal involving research within social care must have an independent favourable ethics opinion from an appropriate research ethics committee, confirming that it complies with recognised ethical standards. Under the overall auspices of the National Research Ethics Service (NRES), a specialised Social Care Research Ethics Committee (SCREC: www.screc.org.uk) has been set up to review adult social care research proposals from researchers based in England. This has a particular remit:

- All adult social care research that is funded by the Department of Health must gain ethical approval from SCREC. Application for approval is done via the IRAS system of the National Research Ethics Service. Information about applying is provided on the SCREC webpage.

- All social care research that involves people lacking capacity to consent, must be reviewed by SCREC which is recognised as an Appropriate Body under the Mental Capacity Act 2005. (University RECs are not recognised Appropriate Bodies for these purposes).

However:

- SCREC is not available for routinely reviewing all social care research. Rather it seeks to complement, not replace, other Research Ethics Committees (RECs) by addressing gaps in provision, and it will take on specialist roles. In the main, university RECs (rather than SCREC) are expected to conduct ethical review of social care research undertaken within universities, unless the conditions listed above apply.

- All Councils with Social Services Responsibilities (CSSR) are required to review all research activities using the DH RGF and must have procedures and review panels in place to do this. The types of activity needing review are wider than within the NHS and include activities such non-financial audit and internal evaluations of services. CSSR staff members undertaking research projects as part of further academic training / qualifications will need to register their research project with their local authority.

4. How do you Apply for Ethical Approval through a University C-REC?

If your research does not need to go to SCREC or through NRES for ethical review, then you need to apply for ethical approval through your School’s Cluster-based Research Ethics Committee (C-REC). It is also likely you will need to apply for a CRB check.
Full information about applying through the University’s ethical review procedures, is available on the Research Governance website, with information specific to your School on your School website.

At the same time that you apply for ethical review at the University, you should also notify the organisations providing social care (see below) and this may include going through further ethical review. Please note: If any changes to your protocol are required by a Local Authority or another organisation providing social care, you will need to notify this to the C-REC where you applied for approval.

5. Notifying the Organisations that Provide Social Care
Where the research involves a service user, their relatives, carer or a member of staff under the auspices of the local authority (LA), then you must ensure that you:

- contact the relevant authority’s RGF lead and discuss local RGF arrangements. There may be other activities, such as internal service review, occurring which means that your research may not be given permission to take place. A list of contacts can be found at www.researchregister.org.uk/files/rgfcontactlists.pdf

- follow local RGF arrangements to seek formal RGF approval to undertake your research. This may take a few weeks depending on the complexity of your work. The authority will want to see your proposal; copies of all the materials you intend to use; copies of any ethical approvals obtained; arrangements for ensuring participants are able to withdraw at any time; arrangements for dealing with any disclosures; copies of CRB checks for any one likely to be alone with vulnerable people and will want to see your final research report.

- Any subsequent amendments to your research – for example changes to the questionnaire – will need to be approved.

- Your research will be registered locally and may be included on the SCIE register of research.

- If your research involves more than one authority (but less than four – see ADASS below 5a) reciprocal arrangements are in place which means you need only apply to one authority for approval. However each authority will need to give you permission to access people and / or data, usually through the RGF lead.

- Research in other organisations such as voluntary organisations, independent care homes and home care companies may also require CSSR RGF approval if they are providing services under contract to the CSSR.

As well as applying for research ethics approval, you must also notify the relevant Social Care providers of any proposed study. The following steps need to be carried out:

- notify the Social Care provider that you propose to conduct research in, or through, their organisation;

- seek formal permission;

- confirm that the providers of social care agree to retain overall responsibility for client care.
As an example, for further information about doing research with the East Sussex Adult Social Care service, please see their website.

Note: Some social care organisations have their own research governance procedures and will require that you not only notify but apply to them for ethical approval.

5a. Does your research involve four or more Local Authorities?
You should also note that if your study involves recruitment of participants through four or more Local Authorities with Responsibility for Providing Social Services, you will need to seek ethical approval from the Association of Directors of Adult Social Services (ADASS: www.adass.org.uk). 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.

6. Notes regarding Sponsorship:
Please note that no study may start until a Sponsor is identified, ethical approval is confirmed and formal permission is given by the relevant care organisation. The Sponsor (as distinct from the funder) is the organisation that is responsible for the research study. The Sponsor plays the major role in assuring the quality of the research project. According to the Research Governance Framework it is the Sponsor’s responsibility to be satisfied that:

- The research proposal respects the dignity, rights, safety and well being of participants and the relationship with care professionals.

- An appropriate process of independent expert review has demonstrated the research proposal to be worthwhile, of high scientific quality and good value for money.

- An appropriate research ethics committee or independent ethics reviewer has given a favourable opinion.

- The chief investigator, and other key researchers, including those at collaborating sites, have the necessary expertise and experience and have access to the resources needed to conduct the proposed research successfully.

- The resources are adequate to allow the collection, analysis and protection of high quality research data.

- The arrangements and resources proposed will allow the collection of high quality, accurate data, and the systems and resources proposed are those required to allow appropriate data analysis and data protection.

- Arrangements proposed for the work are consistent with this research governance framework.

- Organisations and individuals involved in the research agree the division of responsibilities between them.

- Proper arrangements are in place for the initiation, management and monitoring and financing of the research.
• Arrangements are in place for the sponsor and other stakeholder organisations to be alerted to significant developments during the study, whether in relation to the safety of individuals or to scientific direction.

• Appropriate indemnity or insurance arrangements are in place for compensation in the event of harm to the participants of the related research, and that these are known to the participants and subjects.

• There are suitable arrangements in place for the dissemination of the research findings.

• Intellectual property rights are addressed in any contract or terms of grants.

• Assistance is provided to any enquiry, audit or investigation related to the funded work.

In practice most or some of these responsibilities are carried out by the Principal Investigator, by the School or by the Research Team.

The University acceptance of the Sponsor role will depend upon the specific circumstances of each project, including the nature of funding, where the research is to be carried out and the suitability of the candidate, availability of an Academic Supervisor (in case of student projects) and the facilities available to carry out the research.

Where funding is through a Research Council scheme, Government Department, charity or other non-commercial body, the funder may be willing to act as Sponsor and the Principal Investigator is encouraged to ask the funder to Sponsor the research in the first instance. Where such funder is unable or unwilling to act as Sponsor, the University may act as Sponsor, subject to a case by case review.

If there is no external funder the University may be asked to act as Sponsor for the research. Where the research is to be carried out in an NHS site where the participants are owed a duty of care by the host site, the NHS site may act as sponsor or as co-sponsor.

If the University, and the host site where the research is to be conducted, share a significant interest in the study, there may be the possibility of the two organisations acting as co-Sponsors.

Applications for the University to undertake the role of Sponsor should be made:

• After funding has been confirmed; and

• After the protocol has been subjected to scientific critique commensurate with the nature of the research.

Currently applications for undertaking the role of Sponsor are signed off by the relevant Head of School or the Chair of your School’s Cluster-based Research Ethics Committee (C-REC).

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