NAVIGATING ETHICAL APPROVAL AND ACCESS IN SOCIAL CARE RESEARCH

January 2014

Preamble

This document has been produced by the Scottish Government, the Association of Directors of Social Work (ADSW) and the Institute for Research and Innovation in Social Services (IRISS) to assist in answering queries regarding the need for ethical approval from those wishing to undertake social care research activity. It is divided into two parts. Part One identifies a number of general principles which underpin ethical considerations and seeks to define what should be identified as research activity. Part Two outlines different routes for granting ethical approval and access for research activity.

Foreword

This is intended as a practical tool for those working in the front line of Scotland's Social Work Services, who wish to conduct their own research, whether driven by practice need or as part of their formal learning. It is important that employers support the development of the evidence base through enabling staff and students. Implemented appropriately, this tool will ensure this aim can be achieved in a way which safeguards all of those involved. I commend it to you.

Alan Baird
Chief Social Work Adviser

PART ONE

The focus of ethics

Consideration of ethical procedures in research is part of the wider debate on research governance. In their Research Governance Framework Resource Pack for Social Care (2nd edition 2010), the Social Services Research Group (SSRG) outlines five key domains for research governance:

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

The focus of this document is primarily on procedures relating to ethics, although reference will be made as appropriate to the wider context. For a much fuller discussion of all aspects of research governance refer to the SSRG Resource Pack.

The key driver for ethical procedures is to ensure the dignity, rights, safety and well-being of research participants and to avoid the risk of harm. The ESRC Framework for Research Ethics (2010)[1] outlines the key principles of social research ethics:

- integrity, quality and transparency
- overt research
- confidentiality and anonymity
- voluntary participation
- avoidance of harm
- Independence.

The potential for harm may be increased where:

- there are concerns about informed consent and incapacity not being addressed

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[1] www.esrc.ac.uk

- there are high levels of contact between researcher and participant(s) and the potential impact of this is not being addressed
- there is a lack of competence or experience by the researcher and this is not being adequately addressed
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- the need to collect sensitive data is not being fully justified
- conflicts of interest are not being fully described and minimised
- Sensitivities are not being adequately addressed.

Certain research situations require particular sensitivity to ensure that an ethical approach is maintained. These include:

- research involving vulnerable groups, for example children and young people, individuals with a learning disability or cognitive impairment, or individuals in a dependent or unequal relationship
- research involving sensitive topics, for example participants' sexual behaviour, their experience of violence, abuse or exploitation, or their mental health
- research involving groups where permission of a gatekeeper is normally required for initial access to members, for example ethnic or cultural groups
- research involving access to records of personal or confidential information
- Research which could induce psychological stress or anxiety.

Defining research activity

An understanding of what should be defined as 'research' is essential in order to know when it is appropriate to seek ethics approval. In the interests of proportionality, it is important to define research in a way that distinguishes it from the more routine collection of data for the purposes of monitoring, audit, service evaluation or review.

Guidance is provided by the Essex Social Care RGF Alliance who pose three questions:

- Does the activity attempt to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods?

- Does the activity involve the collection of data from service users, carers, staff, volunteers or stakeholders that is additional to that routinely collected by the agency to plan individual services?
- Does the activity require access to existing information (anonymised or named) held by the agency for reasons other than to monitor performance and plan services?

It is important to note that social care tends to adopt a wider definition of research than health. This may become increasingly evident in the context of integration. For health in England guidance has been provided for the NHS from NRES (the National Research Ethics Committee) on the defining characteristics of research[2].

> The primary aim of research is to derive generalizable new knowledge, whereas the aim of audit and service evaluation projects is to measure standards of care. Research is to find out what you should be doing; audit is to find out if you are doing planned activity and assesses whether it is working.

The Social Care REC in England however operates to wider interpretation of research. As noted in the Appendix:

> Most service evaluations would be accepted as suitable for review by the Social Care REC. Investigators and sponsors may have a number of reasons for seeking REC review (such as vulnerable participants; wanting advice on consent procedures; ability to reassure publications editors).

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[2] National Patient Safety Agency (2010) *Defining Research,* National Research Ethics Committee

PART TWO

Procedures for approving research access

There are a number of potential routes for approval of research activity; there needs to be clarity as to where ethical consideration fits in to this process. Unlike England, where a Social Care Research Ethics Committee [3] has been established under the auspices of the Social Care Institute for Excellence (SCIE) (see Appendix), in Scotland there is no standardised procedure for the approval of research focusing on social care.

Drawing on the 12 local authority responses to an ADSW request for information, a number have a written procedure with guidance in place; others identify an individual or team to consider proposals. The number of proposals received in any year is generally modest: Scottish Borders and Angus indicate four or five a year; Dundee and South Lanarkshire around 20 (the majority in the latter from undergraduate and Masters students); and Glasgow 35, including some that already have NHS ethical approval.

The procedure in Glasgow provides one example of a local scheme for processing applications. There are two application procedures, one a full application, the other a fast-track application for those that have been pre-approved by health ethics. Ethical approval from the host organisation is anticipated; the proposal and supporting material, for example questionnaires, information leaflets and participant consent forms, are reviewed by the internal social researcher and the decision to approve (or otherwise) is taken by the Head of Service. In Falkirk applicants for research access are asked to complete a questionnaire which is considered by the Performance and Information Manager and the relevant Social Work Manager(s). Factors to be considered include 'the potential benefits of the research, the workload demands the research would generate on the service, as well as issues of client confidentiality and consent'. A period of two months to reach a decision is indicated.

The outline below sets out a suggested procedure for the types of projects which occur most frequently. An underlying principle is that there should not be duplication of formal ethical approval for any one project.

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[3] www.screc.org.uk

It is important to distinguish between <u>ethics approval</u> and <u>access approval</u>, and to recognise that even when ethical approval has been obtained research access may still need to be negotiated in the agencies where it is hoped to conduct the work.

It is also important that the timetable of the decision making process does not act as an obstacle. It is <u>suggested</u> that local authorities put in place a procedure which, while addressing the ethical issues in a proposal, should aim to be conducted in a period of 3 weeks.

Ethical approval for research originating in universities

Student projects

All universities are required to have ethics committees to consider student research proposals. These will vary in terms of structures (for example departmental and university level), in the scope of projects which they consider, and in the procedures which must be followed. Some will set out specific requirements for a participant information sheet and consent form.

It is suggested that when agencies are approached by students it should be confirmed that a) their proposed project comes within the definition of research and, if so, b) their project has received ethical approval from the relevant University ethics committee and c) there is a formal system for supervision by their academic sponsor. Assuming this is confirmed, access can then be granted (subject to availability and resource). Agencies may wish applicants to provide specific details on selected aspects of the proposal, for example the anticipated time involvement or the potential benefits.

Case Example

A part-time postgraduate student (employed in a statutory organisation) approaches a local authority asking if it will identify eight members of its Child Protection Committee willing to participate in a multi-disciplinary focus group. For the dissertation element of the course he is exploring the impact of the child protection inspection programme in Scotland on improving child protection. The student asks the authority to forward the contact details for those willing to participate and indicates he will then arrange for each of them to be sent an information sheet and consent form. The letter indicates the researcher is not aware of any risks associated with the study and addresses issues of anonymity and data storage.

Research proposals led by University researchers

Internal university procedures for staff projects will have similar requirements for approval by a University ethics committee. They may however be larger in scale and may involve research across a number of agencies and/or sectors. If the project includes activity within the NHS, ethics approval will be required from the appropriate NHS ethics committee (NRES). Projects may be led by a mix of researchers from universities and other organisations; the university-based researchers should obtain ethical approval for the project from the University ethics committee.

When agencies are approached by university–based researchers it should be confirmed that a) their proposed project comes within the definition of research and, if so, b) their project has received ethical approval from the relevant University ethics committee. Assuming this is in place access can then be granted (subject to availability and resource).

When the application is from researchers without access to a university ethics committee, for example from a third sector organisation or an independent research institute, the agency will need to use its own process to scrutinise the ethical aspects of the research. The external research ethics application form used in Glasgow highlights key areas that need to be considered and asks for a brief explanation of how the ethical risks will be addressed.

- Obtaining informed consent – A copy of the proposed consent form along with a separate client information sheet, written in a simple, non-technical language, must be attached to this proposal form
- Special consent – If you intend to approach vulnerable participants (e.g. children, people with learning disabilities, ethnic minorities, people in care facilities) please document how you intend to approach the issue of informed consent.
- Right of withdrawal
- Confidentiality of personal data
- Anonymity of participants
- Please state any potential hazards to participants arising from the research, their estimated probability (if possible) and the precautions taken to overcome the hazards.

For projects which require access to more than one local authority, ADSW have a Research Approval Template to be completed by the Organisational Development Standing Committee. This asks what ethical approval process the research proposal has been subject to, and also asks for detail of the governance arrangements in place to oversee the research.

Ethical approval for research originating in local authorities

Internal projects are often those where there is most discussion as to whether the proposal constitutes research or whether, for example, it is internal audit.

Case Example

As part of its annual budget setting process, one local authority redesigned its fostering scheme to reduce reliance on independent fostering agencies and introduced changes to ensure the payment system supported the placement of the most vulnerable children and to incentivise additional placements with existing carers. A review was undertaken as part of the internal audit programme to determine the extent to which increased numbers had been accepted as foster carers and the reliance on independent agencies had been reduced. This work was deemed to be audit and did not therefore require formal ethical approval.

Where the proposed work is deemed to fall within the definition of research, a similar procedure to that outlined above for external applications should be followed. For employees who are conducting the research as an element of part-time university study, the proposal should be routed through the university ethics committee.

Local authorities may also commission research. It is essential that the proposal is subject to the same independent ethical scrutiny as other applications.

Research access protocol between Scottish Government and ADSW

A protocol has been agreed between the Scottish Government and the ADSW for research that is commissioned by Scottish Government (December 2010). This allows ADSW to provide advice to the Government on research it is planning from the national perspective of local authority social work services. Consent for access to social work staff and clients is then sought directly by Scottish Government or those contracted to undertake the research from Chief Social Work Officers at individual local authorities. Templates are provided for the letter to ADSW from Scottish Government and for the letter to local authorities.

Adults with Incapacity

There are particular requirements under the Adults with Incapacity (Scotland) Act for research involving adults with incapacity. Further guidance can be found at section 4 of the Adult with Incapacity (Scotland) Act 2000 Part 5 Code of Practice[4]. Where ethical approval is required, proposals must be submitted to the NHS Scotland a Research Ethics Committee through NRES, the National Research Ethics Service[5].

Under the Act the research must be about the cause, diagnosis, care or treatment of the person's illness, for example dementia, and applications should only be made where it is not possible to conduct the research with people with capacity. It must be likely to produce a 'real and substantial benefit' for the person, or to bring understanding that will help other people with the same condition. The research must involve no more than minimal foreseeable risk or discomfort and the adult should be withdrawn from the research immediately if at any time he or she objects in any way or appears to suffer discomfort. The researchers must get consent from the person's welfare attorney or guardian, if there is one, or else from the nearest relative.

Health and social care integration

The increasing focus on health and social care integration will require a good understanding of ethical principles and procedures in order to determine whether ethical approval is required and, where it is, to follow the appropriate route. For research which embraces the health sector, application needs to be made to one of the NHS Research Ethics Committees through the NRES system.

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[4] http://www.scotland.gov.uk/Publications/2008/06/13114117/5
[5] http://www.cso.scot.nhs.uk/aboutcso/Ethics/ResEthics.htm

There are currently eleven committees in Scotland although application can be made to any UK NHS REC.

Further reading

http://www.iriss.org.uk/sites/default/files/iriss-research-governance-ethical-practice-2009-09.pdf

http://www.ethicsguidebook.ac.uk

http://www.researchregister.org.uk/files/RGFGuidancepack2010.pdf

APPENDIX

Social Care Research Ethics Committee (England) [extract from website, www.screc.org.uk]

'The Social Care REC reviews applications involving the adult social care sector (e.g. in local authority, private and voluntary care settings), as well as studies which cross sector boundaries. The REC reviews:

1. Social care studies funded by Department of Health.
   - Research commissioned directly through the Policy Research Programme.
   - Health and Social Care Information Centre (HSCIC) studies (i.e. those to be designed by HSCIC for implementation by Councils with Adult Social Services Responsibilities, who do not then individually need to seek additional review).
   - Studies commissioned by or through National Institute for Health Research (NIHR) School for Social Care Research.
   - Social care studies funded (in rare cases) through NIHR.
2. Social care research that involves people lacking capacity in England and Wales and requires approval under the Mental Capacity Act 2005. The Social Care REC is recognised by the Secretary of State as an Appropriate Body for this purpose.
3. Social care research involving sites in England and another United Kingdom country.
4. 'Own account' research undertaken by Councils with social services responsibilities, where the Chief Investigator and/or sponsor feels there are substantial ethical issues.
5. Studies of integrated services (health and social care), provided that there is no clinical intervention involved.
6. Studies taking place in NHS settings with NHS patients where the approach uses social science or qualitative methods, provided that the research does not involve any change in treatment or clinical practice.
7. Intergenerational studies in social care, where both adults and children, or families, are research participants.
8. Other social care studies not suitable for review by other NRES RECs, subject to the capacity of the Social Care REC. This could include service user-led research.
9. Adult social care research involving changes in, or the withdrawal of, standard care.

Social care research does not require review by the Social Care REC if it is reviewed by another committee operating in accordance with the ESRC's Framework for Research Ethics, unless sections 1 or 9 above apply or the research involves NHS patients or service users as research participants. A review is required if there is a legal requirement for REC review e.g. under the Mental Capacity Act. Student research within the field of social care should ordinarily be reviewed by a University REC (UREC). If a UREC review is not available to a student, they can contact the Co-ordinator for advice.

The Social Care REC does not consider any research involving clinical interventions. Such research should be reviewed by another appropriate REC within the NRES.

NHS R&D officers will come across social science studies reviewed by the Social Care REC (under item 6 above) when investigators apply for research governance approval. The opinion given by Social Care REC has the same authority as that of any other NRES REC. Such applications do not require separate review by other NRES RECs.

All applications to the Social Care REC should be prepared using IRAS.

It should be noted that the Social Care REC operates to a wider interpretation of 'research' than may apply in the NHS. For example, most service evaluations would be accepted as suitable for review by the Social Care REC. Investigators and sponsors may have a number of reasons for seeking REC review (such as vulnerable participants; wanting advice on consent procedures; ability to reassure publications editors).'

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