IRISS
Institute for Research and
Innovation in Social Services

# Guidance on Research Governance & Ethical Research Practice

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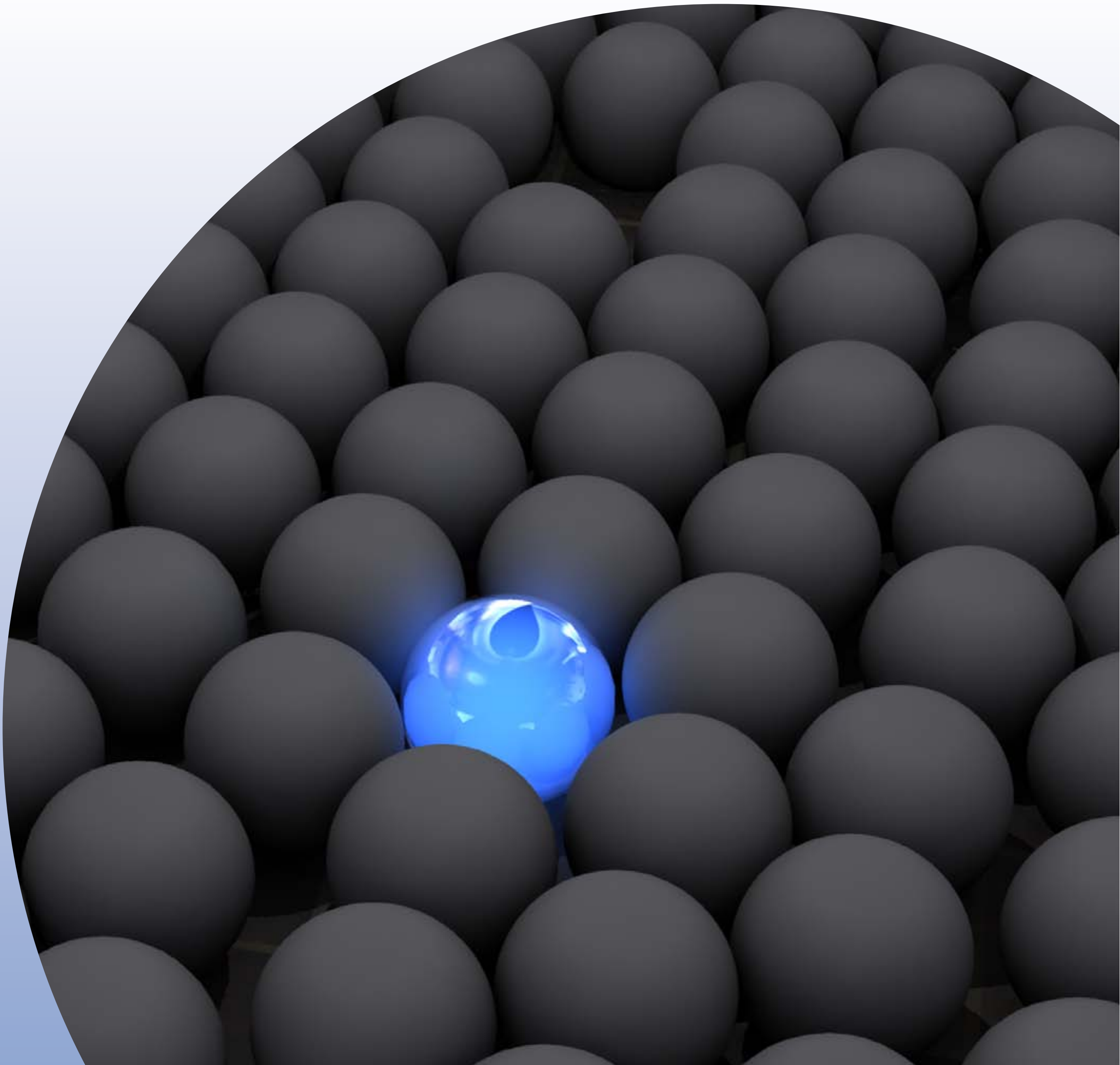

# Contents

# Summary

## Background

This document offers guidance to help social service organisations develop systems and processes to ensure good research governance and shared ethical principles for conducting social services research in Scotland.

The guidance has been produced by the Institute for Research and Innovation in Social Services (IRISS) in collaboration with a working group made up of key stakeholders (see appendix A). IRISS however, accepts sole responsibility for the final content of this report.

## Status & spirit

The status of this guidance is advisory. It is up to individual social service organisations whether and to what extent they adapt and adopt the guidance. The layout of the document reflects the priority areas for development. The spirit of the guidance is supportive: it is designed to promote the adoption of systems and processes that are proportionate to the nature and extent of research activity within each social service organisation.

## Goals

The goals of research governance are to support:

- An increase in the quantity, quality and range of research
- Research being used to inform policy and practice
- Using research to improve the provision of social services and outcomes for service users
- Research that is methodologically and ethically sound
- Research that is properly managed and monitored

## Responsibilities

It is the responsibility of principal researcher(s) to demonstrate how they will meet and adhere to the principles of ethical research practice; and it is the responsibility of the organisation making decisions in relation to research governance to ensure any research activity demonstrates explicitly how it is adhering to and addressing the principles of ethical research practice.

## Definitions

*Research governance:* research governance is concerned with the development of shared standards and mechanisms that permit the proper management and monitoring of research. Research governance is more than, but includes research ethics. Governance includes other key areas such as good science, information, health and safety, research commissioning and priorities, utility, dissemination and use.

*Research:* for the purposes of research governance, and to ensure a proportionate use of governance procedures, it is important to define research in such a way that it distinguishes activities that require governance, ethical approval and risk management from the more routine collection of data for the purposes of monitoring, audit and review. The Social Services Research Group (SSRG, 2005) suggest that in the context of research governance "…research means the systematic collection of data, using explicit research methods and techniques." (p 15). The same document includes extracts from a Research Governance Framework developed by Essex Social Care RGF Alliance that offers three questions (adapted below) to help those responsible for research governance decide whether an activity should fall within the scope of a research governance framework:

1. Does the activity attempt to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods?
2. 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 (e.g. via survey, interview, focus group etc.)?

3. 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?

Ultimately, those with responsibility for research governance will have to use judgement to assess the potential risk of harm of any research related activity and consider whether it needs to be subject to the procedures of their research governance framework.

# Part One: Research Governance Guidance

## 1.1 Background

In order to protect service users and carers from harm, and improve outcomes for people using Scotland's social services, it is vital that research on Scottish social services is conducted ethically. To bring this about social service organisations that commission, fund, approve, support, monitor and invest in research require supportive guidance on research governance. Skinner (2008) proposed that the development of a research governance framework would contribute to a research infrastructure that supports good social science and increases research capacity and capability.

There are many codes of practice for conducting ethical research and a well-established literature on research ethics and governance. This document is based on a review of existing literature and consultation with a working group of stakeholders from Scotland's social service research community (see appendix A for working group members).

## 1.2 Introduction

This guidance is designed to provide a frame of reference on research governance and research ethics for those commissioning, managing, approving, supporting or funding research in, on or by social service organisations. Although these two dimensions are linked there is a distinction to be made between research governance and research ethics:

> *Research governance:* concerns the development of shared standards and mechanisms that permit the proper management and monitoring of research. Research governance is more than, but includes research ethics. Governance includes other key areas such as good science, information, health and safety, research commissioning and priorities, utility, dissemination and use. Governance is an in-house process to ensure that research meets all statutory requirements, has all the necessary resources, finishes properly and publishes appropriately.
>
> *Research ethics:* concerns the principles of ethical research practice. It is about protecting all those involved in research from harm by ensuring their rights, dignity and safety.

## 1.3 Implementing Research Governance and Principles of Ethical Research Practice

Successful implementation of research governance will rely in large part on the degree to which social service organisations are able to build appropriate structures and create cultures that recognise the central place good governance occupies in ethical research practice. Social service organisations should only commission, conduct, or permit research that can demonstrate compliance to the principles set out in part two of this document. This guidance does not seek to impose a particular model of practice but proposes some general principles and processes to support the development of good research governance.

## 1.4 Procedures to support research governance in social service organisations

Social service organisations that are commissioning, conducting or allowing researchers access to service users, carers or staff should have processes and procedures that:

1. Support timely review of research proposals
2. Are flexible and sensitive to the differing levels of risk involved in research, and the different needs of service users, carers, researchers and host organisations
3. Deal with cases of research misconduct, complaints or appeals
4. Source advice on statutory or legal considerations that might affect research
5. Support methodologically and ethically sound research, including practitioner research
6. Ensure research proposals make clear how the research adheres to ethical principles and abides by professional codes of research ethics

7. Ensure evidence is provided to support claims that ethical approval has been obtained from other external ethical or governance systems
8. Manage multi-site projects
9. Manage approving access to organisations contracted to deliver social services
10. Identify gaps in knowledge, where research has particular relevance for policy, service planning, delivery and practice
11. Approve access to service users, carers, staff or personal data for researchers external and internal to the organisation, and that appropriate consent has been received
12. Ensure training on research ethics, governance and commissioning for relevant staff in order to sustain structures and cultures that are supportive of good research governance and ethical research practice
13. Provide resources (staff handbook, access to web based resources and tools) to aid staff understand and comply with research governance and ethical research practice
14. Support active communication and dissemination routes to ensure research findings reach and are made meaningful to relevant audiences
15. Ensure adherence to data protection legislation, the Adults with Incapacity (Scotland) Act 2000 and any other legal requirements

At the very least organisations should ensure that:

1. Checks are made that all external research (regardless of whether the proposed study has received external ethical approval) has an identified sponsor and there are sound financial and management arrangements for the project in place
2. Internal research activity is subject to an assessment of the potential risks involved
3. A record of all applications is maintained, risk assessments completed, and outcomes of both internal and external research are recorded
4. The results of the research are published in the public domain

## 1.5 Role of lead on research governance

The working group felt that one of the most important steps an organisation could take to achieve good research governance was to identify and support someone with research expertise and experience to lead on research governance.

This person could lead on:

- Documentation design
- Initial screening to make a judgment about the level of risk of harm to potential research participants
- Checking whether the required documentation and approvals have been provided
- Assessing the appropriateness of the research proposal to local needs and circumstances
- Identifying and monitoring the volume of research activity that requires research governance
- Being the point of contact for other social service organisations and those wishing to undertake external and internal research
- Being the point of contact for other research governance systems (e.g. Higher Education Institutions; the Chief Scientist Office (CSO) who provide and assess the Research Governance Framework for Health and Community Care[1]; NHS R&D departments and Research Ethics Committees (RECs) for health research in Scotland)
- Helping the organisation identify knowledge gaps, research priorities and guard against the over burdening of particular service user populations
- Promoting the benefits of governance to senior managers
- Promoting research activity through providing support and communicating research training opportunities
- Promoting research use through active communication and dissemination systems

## 1.6 Research committee

Some social service organisations who have high levels of internal and external research activity may wish to

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[1] http://www.sehd.scot.nhs.uk/cso/

establish a group or committee to ethically review those proposals deemed complex, medium or high risk where no other option exists. Equally social service organisations who have lower volumes of internal and external research activity may wish to set up a joint ethics group or committee to establish a consortium approach[1] so they can share systems and resources across a number of organisations. The ESRC REF (2007) sets out some illustrative case studies that highlight some of the ethical and practical issues research commonly raises and the ways in which research committees can respond.

The NHS Research Ethics Committees (RECS) have a pool of lay and professional members to draw upon but must have the Chair or Vice-Chair, an expert member and a lay member at each meeting. The REC will generally consist of clinicians, pharmacists, GPs, social workers, clergy, teachers, police, psychologists, statisticians, lawyers and members of the general public that bring their skills, knowledge and experience to the debate. To be quorate at least seven members must attend the meeting to review research proposals. Sub-committees of between three and six members can meet with the consent of the main REC to consider matters listed in the Standard Operating Procedures (SOPs).[2] NHS RECs have a 60 day turnaround time, track their research and provide training and expenses to their committee members.[3] Governance arrangements for research conducted in NHS Scotland are overseen by the research and development departments of Health Boards. Representatives from operational, managerial and policy staff give approval for research once ethical approval has been granted. They are also responsible for ensuring compliance with the Scottish Executive Health Department Research Governance Framework for Health and Community Care (Scottish Executive Health Department, 2006).

Some social service organisations have developed their own ethics committees: they include staff responsible for data protection, freedom of information and external stakeholders from Universities, health and user & carer organisations. Some have up to 20-30 members with a mix of skills and expertise enabling them to select the most appropriate people to review proposals.

## 1.7 Corporate governance

Organisations may find that developing a corporate Research Governance Framework would be advantageous. A corporate approach would facilitate a shared system, pool resources and ensure uniform procedures. It is likely that many potential research participants will be using services provided by other agencies or other departments of the same local authority or organisation. For example, if the proposed research activity was to involve staff, service users or carers from more than one department or section this may raise potential difficulties for the organisation if some departments or sections are covered by research governance systems and others are not.

## 1.8 Defining research

Social service organisations are advised to make explicit their thresholds. What types of information gathering activity should be included or excluded from having to adhere to the ethical principles laid out in this document and be subject to research governance? A judgement about the risk of harm is likely to be the ultimate issue for deciding what research, evaluation or auditing activities would need to be subject to research governance. However it might be useful to consider the three questions we identified above:

1. Does the activity attempt to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods?
2. 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 (e.g. via survey, interview, focus group etc.)?
3. 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?

The Social Care Institute for Excellence (SCIE) are currently working with the National Research Ethics Service (NRES) to agree definitions of audit, service evaluation and research that will apply to social care research in England.

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[1] Please refer to the Research Governance Framework: A resource pack for Social Care (2005) for further details on organisations who have adopted this approach

[2] http://www.nres.npsa.nhs.uk/news-and-publications/publications/

[3] http://www.nres.npsa.nhs.uk/rec-community/

## 1.9 Assessing risk of harm

The SSRG (2005) resource pack sets out a risk assessment tool for assessing the risk of harm. Although it does not define harm, it points to areas where the potential for harm is increased if not addressed. These areas include:

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

Tiered approaches to assessing risk of harm often consider that a low or minimal risk of harm is associated with data gathering and analysis that uses: anonymised records and data sets; information systems for internal management purposes; and data sets that exist in the public domain. Whilst this is usually a reasonable assumption it is not always the case and careful assessment should still be made.

Other research activity – such as the following – is normally considered to require special and careful monitoring and support from governance systems:

- Research involving vulnerable groups – for example, children and young people, those 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 illegal or political behaviour, their experience of violence, their abuse or exploitation, their mental health, or their gender or ethnic status
- Research involving groups where permission of a gatekeeper is normally required for initial access to members – for example, ethnic or cultural groups, native peoples or indigenous communities
- Research involving deception or which is conducted without participants' full and informed consent at the time the study is carried out
- Research involving access to records of personal or confidential information, including genetic or other biological information, concerning identifiable individuals
- Research which could induce psychological stress, anxiety or humiliation or cause more than minimal pain
- Research involving intrusive interventions – for example, the administration of drugs or other substances, vigorous physical exercise, or techniques such as hypnotherapy

## 1.10 Criteria for considering research proposals

The SSRG (2005) resource pack outlines five key domains for a research governance lead or committee to consider:

1. *Ethics:* ensuring the dignity, rights, safety and well-being of research participants
2. *Science:* ensuring the design and methods of research are subject to independent review by relevant experts
3. *Information:* ensuring full and free access to information on the research and its findings
4. *Health and safety:* ensuring at all times the safety of research participants
5. *Finance and value for money:* ensuring financial probity and compliance with the law in the conduct of research

These five areas are reflected in the principles of ethical research practice outlined in part two. It will be up to individual social service organisations to develop processes and documentation that facilitates the researcher(s) to detail and explain how they meet and adhere to the ethical principles.

## 1.11 Documentation

Research proposals should include most or all of the following information:

- Aims of the research
- Scientific background of the research

- Study design
- Participants – who (inclusion and exclusion criteria), how many, how potential participants are identified and recruited, vulnerable groups
- Methods of data collection
- Methods of data analysis
- Response to any conditions of use set by secondary data providers
- Principal investigator's summary of potential ethical issues and how they will adhere to and meet the principles of ethical research practice
- Benefits to research participants or third parties
- Risks to participants or third parties
- Risks to researchers
- Procedures for informed consent – information provided and methods of documenting initial and continuing consent
- Expected outcomes, impacts and benefits of research
- Dissemination plans (and feedback to participants where appropriate)
- Measures taken to ensure confidentiality, privacy and data protection
- Reimbursement and payment [1]

## 1.12 Examples of local research governance processes

Examples of local research governance processes are set out in the SSRG (2005) resource pack. Key features of local frameworks include:

- A lead research governance manager/co-coordinator
- Electronic management of research governance
- A traffic light system for assessing risk
- Electronic documentation including an application pack with a proposal template
- Arrangements to process low risk proposals within a few days, others within one month
- A pool of internal staff and external members make up a research governance group to review applications
- A database of research activity

## 1.13 Monitoring, dissemination and use

A component of good governance is to illustrate the value and findings of research to inform practice and policy. This involves monitoring the type of research activity taking place within a social service organisation in order to identify knowledge gaps, research priorities and guard against the over burdening of particular service users. It also involves actively disseminating the findings of research to relevant audiences.

The Scottish Council for Voluntary Organsations (SCVO) have established an Evidence Library where research relating to the Third Sector is placed. More information on this facility can be accessed online[2]

## 1.14 Commissioners of research

Commissioners need to show a commitment to ethical research practice by asking researchers to demonstrate how they will adhere to the principles of ethical research practice. They need to be mindful of not overburdening particular groups of service users, addressing knowledge gaps and identifying research priorities. They also need to show a commitment to dissemination and research use. The Social Research Association (2003) has published a guide to commissioning research guide that discusses ways of commissioning social research projects, choosing researchers, and makes recommendations about good practice. Commissioning practices are important as they affect the quality and nature of social research. The SRA suggest that the object of commissioning procedures should be to produce high quality, useful and cost-effective research by fair and accountable means, and to optimise the balance between these five factors.

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[1] See invo.org.uk for guidance on reimbursement and payment of expenses

[2] http://www.scvo.org.uk/EvidenceLibrary/

## 1.15 Ethical approval systems in Scotland

The NHS has a nationally Integrated Research Application System (IRAS)[1] for applying for ethical and R&D approval for research. Applications to the newly formed social care REC for England can also be made on IRAS. There are 14 NHS and one independent Research Ethics Committees (RECs) in Scotland who consider all research proposals involving NHS staff, resources and service users and can consider applications from the private sector. These RECs occasionally receive studies that include large elements of social services research and many committees have social service representation on them. The CSO would like to see social services included in the Governance Arrangements for Research Ethics Committees (GAfREC) and is currently rationalising and reviewing the number of RECs to ensure there is not over-capacity. CSO has offered to facilitate the creation of a social services REC for Scotland in line with the one recently created in England. NRES are working with SCIE to create guidance and provide training for the English social care REC. Version 2 of GAfREC is currently out for consultation and can be found on the Chief Scientist Office (CSO) website[2]. Other ethical approval systems are operated in Higher Education Institutions where staff and students are subject to their institutional frameworks (often adopted and adapted from the ESRCs REF).

The vast majority of funding bodies who commission social science research such as the Joseph Rowntree Foundation, the Economic and Social Research Council (ESRC) and the Nuffield Foundation have their own ethical and governance frameworks with which those awarded grants are required to comply.

## 1.16 Professional bodies

The Association of Directors of Social Work (ADSW) role in social services research governance is currently being considered and clarified. ADSW are often asked to give their support to research projects. Although ADSW are in a position to consider projects and state whether or not they are broadly supportive of the activity, they feel that it is social service organisations themselves that are accountable for research carried out in, on or by their service users, carers or staff.

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[1] https://www.myresearchproject.org.uk

[2] http://www.sehd.scot.nhs.uk/cso/

# Part Two: Principles of Ethical Research Practice

The principles set out here are adapted from the ESRC's Research Ethics Framework (ESRC, 2007) and pay attention to the Government Social Research Ethical Guidance (GSR, 2005) and Barnardos' Statement of Ethical Research Practice. Both the GSR and the ESRC ethical principles and guidance were developed through widespread and thorough consultations with key stakeholders in social and government research.

1. Harm to research participants must be avoided. The interests of those involved in or affected by the research must be safeguarded.
2. Research participants must be informed in a full, accessible and meaningful way about the purpose, methods, funding and intended possible uses of the research. This includes what their participation in the research entails and what the potential benefits, costs or risks of their participation may be and how this will be managed. Any conflicts of interest or partiality must be made explicit.
3. Participation must be entirely voluntary and free from any coercion at all stages in the research process.
4. There must be sound application of social research methods and the research proposed must be deemed worthwhile. Disparities in power and status between the researcher and the researched must be addressed in relation to research design, methods and dissemination.
5. The confidentiality of information supplied by research subjects and the anonymity of respondents must be respected.
6. Findings must be reported accurately and truthfully.
7. Any legal requirements regarding age and capacity must be met.
8. Financial arrangements for ongoing provision of an improved situation for the service user or carer must be agreed prior to the research commencing.

It is the responsibility of the researcher(s) that these principles underpin their research practice. Researchers should be able to demonstrate clearly in their research proposal (to those who are funding, commissioning, supporting and or approving access to conduct research) how they will meet and adhere to these principles regardless of whether or not they have ethical approval from a research ethics committee, have the support of a professional body, or are a member of a professional research association and subscribe to an ethical code of practice.

It is the responsibility of the organisation making decisions in relation to research governance that research activity demonstrates how it is adhering to the principles of ethical research practice outlined above. [1] [2]

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[1] The Joint University Council Social Work Education Committee (JUCSWEC) (2002) has developed a specific code of ethics for social work and social research that expands on many of the principles laid out in this section.

[2] The Social Research Association (2003) have also produced detailed ethical guidelines.

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[1] Please note that this resource pack is currently under review and will be updated during 2009.

# Appendix A: Working Group Members

IRISS wishes to thank the following individuals who were members of a working group and agreed to act as a sounding board for the development of this guidance. IRISS accepts sole responsibility for the final content of this report. The report was prepared and drafted by Dr. Rhoda MacRae.

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