

Gateshead Council Research Governance Framework

1. Introduction

- 1.1 Gateshead Council wishes to contribute to a quality research culture that will help to improve social care services. But its primary responsibility is towards its service users, their carers, and Council employees. The participation of these in externally generated research, audit, evaluation and consultancy will depend not only on the requirements of its Research Governance Framework being met but also on the likelihood of the outcomes justifying the time staff may have to spend on the collaboration.
- 1.2 Gateshead Council understands the importance of research and it is committed to ensuring that research is carried out to high ethical and methodological standards. This Framework is intended to protect the psychological well being of vulnerable service users who participate in research, by ensuring that the appropriate steps are taken to recognise, minimise and deal with any distress that it might cause to them.

2. Scope and Purpose

- 2.1 This Framework covers all research, audit, evaluation and consultancy that involves access to service user, carer or staff populations, including volunteers, to whom Gateshead Council has a duty of care, by staff who are not employees of the Council or its contracted agencies. It will apply where access to service user, carer or staff groups is to be gained through Gateshead Council or its contracted agencies. It also covers the data held about service users, their carers, and staff.
- 2.2 The purpose is to protect the participants in research or similar work by ensuring that there are clear arrangements to identify and manage any risks associated with that work. It will do this through requiring explicit agreements about the roles and responsibilities of those involved.
- 2.3 Where a research application includes Gateshead Council in a multi-site study of social care services the proposal will be referred to the Research Committee of the Association of Directors of Social Services for approval. This is in line with recent ADSS policy. Approval by the ADSS Research Committee will not guarantee participation by Gateshead Council, which would ultimately be a decision by senior managers. This stipulation about the ADSS may need to be amended to take account of the establishment of Directors of Children's Services.

3. Framework Principles

Ethics

- 3.1 Gateshead Council requires all external research proposals to have obtained ethical approval from a competent independent body. This should normally be done by the sponsor (see 4.1 below). Social care service users are likely to be vulnerable on grounds of age or disability and so this is especially important.
- 3.2 Gateshead Council requires that an ethical review includes:
- A full description of the process of obtaining informed consent from participants, identification of those responsible for obtaining it, the timescale for obtaining it and the process for ensuring consent has not been withdrawn.
 - Assurance about the completeness, adequacy and clarity of the written and oral information to be given to participants or their advocates. This will include inclusive approaches to service users and carers with communication needs or who are from minority ethnic communities.
 - Clear justification for including individuals who cannot consent in the work and a full account of the process for obtaining authorisation for their inclusion, for example the witnessing of verbal consent. Where service users cannot consent due to permanent mental or other incapacity the advice of the relevant physician or formal representative must be sought. **See 2009 Amendment at 8.1**
 - Where the work will involve sensitive topics and some distress may be caused despite precautions, arrangements for providing social or psychological support are in place both during and after the conduct of the work;
 - Arrangements for maintaining the confidentiality of data, e.g. the control of access to interview tapes and transcripts;
 - Arrangements for the appropriate archiving and protection of data both during and at the end of the research;
 - Guarantees to meet obligations under Data Protection legislation or protocols, where appropriate through a data controller/processor agreement with Gateshead Council;
 - Arrangements where appropriate to reimburse service users participating in research for their out-of-pocket expenses, which may include travel, child minding, carer support, and also those of any personal assistants who may be needed to facilitate participation;
 - Guarantees that agreements are in place for dealing with any disclosures or the emergence of information relevant to the care of an individual during the

work. This may include explaining in advance the limits to a promise of confidentiality;

- Arrangements for communicating the findings of the work to the participants, and then to the wider professional community. This will be done in formats appropriate for the service user or carer groups involved.

3.3 Where a proposal will involve NHS patients as well as social care service users (for example when an inter-agency or multi-professional service is being provided) the proposal should be submitted to the relevant local NHS Ethical Committee for approval.

4. Responsibilities

4.1 Externally generated research proposals are required to identify a sponsor. The sponsor will be responsible for ensuring that:

- The proposal is worthwhile, methodologically sound and value for money;
- It has been ethically approved by a competent independent body;
- The researchers have the necessary skill, experience and resources to complete the work, and that the relevant disclosures have been obtained through the Criminal Records Bureau;
- Intellectual property rights and their management have been properly addressed;
- There is a written agreement on the organisation responsible for managing and monitoring the study, and that they will be alerted if significant developments occur;
- An agreement is in place for providing compensation in the event of non-negligent harm, and that the sponsor has made the necessary financial arrangements.

5. Audit, Evaluation and Consultancy

5.1 Where a proposal is classed as audit, evaluation or consultancy rather than research, but which nevertheless involves contact with social care service users or carers and the access to them would be through Gateshead Council, then the proposal will need to satisfy the ethical review criteria above. In addition the organisation proposing the work will be required to obtain enhanced CRB disclosures for staff who will be in contact with service users or carers.

6. The Application Process

6.1 Any Council officer who receives an externally generated research, audit or consultancy proposal that may involve access to social care service users or their carers will forward it to the Research and Development Manager in Community

Based Services. The manager will ensure that the applicants are aware of the Research Governance Framework requirements and will discuss the proposal with the Research Governance Framework Forum. This Forum will include representatives from the relevant Council functions and Chief Executive's Department, and where appropriate user or carer views will also be sought.

- 6.2 When the Forum is satisfied that the RGF criteria have been met, the ability of operational staff to participate will be confirmed before the manager sends a written acceptance to the researchers. Proposals will receive a response within 20 working days.

7. Research by Council Staff

The RGF will apply to Council staff undertaking research as part of social work training, or as career development by social care professionals, where the research comes under **2.1** above. It will also apply to staff conducting research, coming under **2.1** above, on behalf of the Council.

Research proposals will be submitted on an application form that will contain a checklist of questions for the researcher. This will be designed to help them to think through their ideas before submitting them to the Research Governance Forum. Dissertation proposals from students must demonstrate ethical approval by the relevant University Ethics Committee.

- 7.3 Managers will forward research proposals to the Research and Development Manager in Community Based Services, who will use the same procedure as for external research. The Research Governance Forum will advise on ethical issues and potential risk elements, and help the researcher to support good practice. The Forum will include specialists in data protection, public consultation, user involvement, and research methods.
- 7.4 Where a proposal will involve NHS patients as well as social care service users (for example when an inter-agency or multi-professional service is being provided) the proposal should be submitted to the relevant local NHS Ethical Committee for approval. This will be in addition to the Council RGF procedure.

8. 2009 Amendment – Mental Capacity Act

- 8.1 The Social Care Research Ethics Committee (SCREC) is the national body empowered to grant ethical approval for research under the Mental Capacity Act 2005. This will be research involving people unable to give consent due to mental incapacity. Applications to the Council for such research must demonstrate that ethical approval has been given by the SCREC. According to the Mental Capacity Act, University Ethics Committees are not empowered to give ethical approval for research of this nature.