South Gloucestershire Council

Delivering for you

Research Governance in South Gloucestershire Council

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1. Introduction

Research governance aims to ensure quality research and better management of the risks to all those involved in research projects, including safeguarding the public and the interests of the council. For research to add value it must be carried out in a planned, open and rigorous way and be capable of repetition.

Research is defined as an attempt to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods.

For the purpose of this research governance framework, the research governance approval process must be used for studies that involve any of the following:

- Users of services provided or commissioned by South Gloucestershire Council, and/or their carers;
- Access to personal information held about individual users of services provided or commissioned by South Gloucestershire Council and/or their carers (for reasons other than monitoring performance and planning of services);
- Staff who work directly for South Gloucestershire Council or indirectly for a contracted provider of services, in their professional capacity.

You do not need to apply for research governance approval if:

- You will not require access to service users, carers or staff, or to personal information that the Council holds on any of these individuals;
- You will only be collecting routine management or monitoring data as a part of your normal, day-to-day work;
- You will be carrying out public consultations. A consultation is when we invite people to have a say on a question, proposal or options with the aim of influencing our decisions. Examples include service improvements, strategy / policy changes, the budget and council priorities. It should have a defined start and end date, not be an ongoing dialogue;
- You will be carrying out service evaluations. A service evaluation is the systematic collection and analysis of data, used to judge the quality or worth of a service or intervention and to provide evidence that can be used to improve it;
- You will be carrying out financial, practice or service quality audits;
- If you are making a Freedom of Information request. External requests for data that do not contain personal or sensitive fields, even where these requests require work to provide bespoke analysis of existing data sets, would usually be dealt with under the council's Freedom of Information and Environmental Information Requests Policy.

The Medical Research Council (MRC) and the NHS Health Research Authority have a useful decision tool to help you determine if your study is research: Is my study research? (hra-decisiontools.org.uk)

All studies and projects which meet the above definition of research are subject to research governance.

2. Research governance

Proper governance is essential to ensure that there is public confidence in the policies, strategies, programmes and services that are developed and delivered.

We also have a duty of care towards research participants and those carrying out research are required to take steps to minimise undue intrusion and harm to them.

The Council's research governance framework sets out the standards and defines mechanisms to deliver them. It provides the conditions to encourage high quality creative and innovative work to assist services in identifying best practice and improve services. The research governance approval process for the Council is currently overseen by the Public Health and Wellbeing Division which convenes the research governance panel. The role of the panel is to work together with researchers to ensure that research activities in and associated with the Council are good quality, relevant, of sound methodology, have secured the necessary ethical and research approvals so that the risk to all parties (including researchers and participants) is minimised and the dignity, rights and wellbeing of participants are respected with appropriate dissemination of research findings. This aligns with the principles for the management and conduct of research as outlined within the UK Policy Framework for Health and Social Care Research.

This research governance framework applies to:

- South Gloucestershire Council staff;
- Contracted providers;
- Independent organisations / agents acting on behalf of the Council and/or requiring access to the Council's information or clients.

3. Research standards

It is essential that existing sources of evidence / research are considered carefully before planning a research project. Research should never duplicate other work unnecessarily.

Research projects should:

- have a coherent aim;
- demonstrate a clear link to strategy, policy or practice;
- contribute something useful to existing knowledge;
- have been approved by an appropriate manager.

Researchers must ensure that all groups in society are respected and appropriately represented.

4. Ethical research

Informed consent is at the heart of ethical research. Those involved in research must be aware of their legal and ethical duties and all studies should have appropriate arrangements for obtaining informed consent. Informed consent involves providing an explanation of the nature and purpose of the research, the role of the participant, any possible harm they might experience and the degree of anonymity / confidentiality.

Particular care is needed in obtaining consent from children and vulnerable adults, such as those with mental health problems or learning difficulties. Arrangements must be made to ensure that relevant information is provided in appropriate written or pictorial form. In these cases, consent should be sought from those who have a legal authority to give it such as parents and guardians or other legal representatives. The role / responsibilities of parents, carers or supporters during the research should be clearly explained.

Risk of harm must always be kept to a minimum and explained clearly to the participants.

Example templates for participant information and consent forms are available in Appendix 1.

The appropriate use and protection of data is also critical. All those involved in research must be aware of their legal and ethical duties in this respect. Particular attention must be given to systems for ensuring confidentiality of personal information and to the security of these systems.

Data collected during research must be kept confidential and secure. It must be retained for an appropriate period to allow further analysis by the original or other research teams subject to consent and to support monitoring of good research practice by regulatory and other authorities. In most cases this stored data should be anonymised and kept for five years from the end of the research period (20 years if the research is child-related). Record retention schedules for each Council service are available here: Record retention schedules | South Gloucestershire Council (southglos.gov.uk).

Further guidance around ethical research from the UK Policy Framework for Health and Social Care Research is included in Appendix 2.

5. Equality

The Council is strongly committed to meeting its duties under section 149 of the Equality Act 2010. As such, all research applications should consider protected characteristics (age, sex, race, disability, sexual orientation, marriage and civil partnerships, religion or belief, pregnancy and maternity and gender reassignment), ensuring these are actively included wherever possible and that reasonable efforts are made to involve hard to reach groups or communities.

6. Gaining approval for research projects

All council staff must ensure that this framework is met before conducting, commissioning or responding to a request for research. No research can take place without gaining the necessary approvals.

Researchers are required to submit a proposal to the supervised mailbox researchgovernance@southglos.gov.uk explaining the purpose and scope of the study/project using the form provided in Section 8.

On receipt of the application, an administrator will conduct an initial check of the submission to ensure that the application is fully completed, all required associated documents have been submitted with the application and that there is a minimum of four weeks between submission and the start date of the research. Incomplete applications will be returned to the researcher with a request for the additional information to be included in the resubmission. On receipt of a complete application, the administrator will send the application to two members of the research governance panel who will independently review the application and make their recommendations and advise on next steps. Panel members may seek the views of relevant operational managers / data owners and legal services as required.

Feedback on applications will be provided within 28 days. You will be informed via email whether your application has been approved, approved with conditions or not approved. If your research governance application is approved you may continue with research provided that other necessary requirements (such as ethics) have been met.

Where approval is not given immediately recommendations for changes will usually be made and / or conditions placed on the project. You will be expected to resubmit evidence to the panel to show that these conditions have been met before the research can proceed. Occasionally a research governance panel member may offer to work with the researcher and advise on revisions to the proposal or reject the proposal on the basis that it is not in the interest of the service/council for the research to take place. They will also look at the suitability of the researcher and where appropriate ensure that any corporate commissioning/procurement guidelines are followed. In situations where there is disagreement between the two reviewing panel members, the panel will convene with a quorum of at least three panel members, who will agree a decision about the application.

In cases where changes are made as the research progresses, applications must be re-submitted.

If you would like to appeal the decision / recommendation, and there are good grounds to do so, please resubmit your application to the mailbox with a detailed response to the panel's feedback. The full research governance panel will convene in this instance (quoracy- at least three panel members) and the researcher may be invited to attend a meeting to discuss further. Please note that the panel will not support research that is unethical and that has not received the necessary research proposals.

Please note that you will still need to go through NHS governance procedures if research is in a health care setting. For social care research involving four or more local authorities, approval must be sought from the Association of Directors of Adults Social Services (ADASS) for projects involving adults, and the Association of Directors of Children's Services (ADCS) for projects involving children.

A flowchart of the process is included in Appendix 3.

7. Research proposals

When applying for research governance approval you will need to give information about the aim, links to strategy, policy or practice and the value of the research to the council,

service and/or customer. It will need to explain your approach and consider any ethical issues which need to be managed. You will also need to provide details as to how you intend to comply with data protection regulations. It is recommended therefore that the research proposal and associated methodologies are well developed before you complete the form.

If you are not an experienced researcher, you may find the form a useful checklist when thinking through the research design.

Questions 1a and b will help you decide if your proposed work is subject to research governance approval.

Question 1a: Are you attempting to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods (is your project 'research')?

Question 1b: Do you need access to the personal data we hold and/or require us to mediate access to our customers, service users, stakeholders and/or staff?

If '**yes'** to both of these then you will need to complete an application for research governance approval.

If '**no**' your project is not covered by the research governance framework so you do not need to continue with the proposal. However, it might fall under other processes, e.g., freedom of information or data protection so further investigation is recommended.

If you are unsure whether your project is research, consultation or performance management please seek advice by emailing researchgovernance@southglos.gov.uk.

The following questions (Questions 2a-c) will help you decide how much of the form you need to fill in.

Question 2a: Are you external to South Gloucestershire Council (e.g., a university)?

Question 2b: Will your research require contact with any of the following?

- **Staff**
- **Service users / customers**
- **Stakeholders**

Question 2c: Will your research require access to information / data held by the council for reasons other than to monitor performance or plan services?

- **Service users / customers are named**
- **Service users / customers are anonymised**

If you have answered '**yes**' to **any** of these questions you will need to complete all parts of the form to seek approval of your project.

If you have answered '**no**' to **all** these questions you can complete the shortened version of the form.

8. Application for research governance approval

You can complete a research governance application by completing our application form.

Please attach any other relevant information and email to researchgovernance@southglos.gov.uk

Appendix 1: Informed consent checklists – example templates

There are two elements: the participant information sheet and the consent form.

The participant must be given a copy of their signed consent form and the information sheet.

Participant information sheet

The research project

(keep brief and in plain English)

- Title of the project
- Why we are doing it
- Who is doing it
- Who has funded it
- What will happen to the results
- Contact details for further information

Your participation

(Select the sections relevant to your project)

- Why you have been chosen to take part
- Whether you can refuse to take part
- Whether you can withdraw at any time and how
- What will happen if you agree to take part (brief description)
- Whether there are any disadvantages or risks involved and what will be done to ensure your well being / safety (e.g. side effects)
- Whether there are any special precautions you must take before, during or after taking part in the study
- What will happen to any information/data/samples
- How your participant in the project will be kept confidential
- Whether there are any benefits from taking part (e.g. payment)

Standard text

- Agreement to participate in this research should not compromise your legal rights should something go wrong
- You will be given a copy of this to keep, together with a copy of your consent form.

Participant content form checklist – example templates

- Title of project
- Researcher name and contact details

1. I have read the participant information sheet and I understand what my part will be in this research.
2. I am aware of how my data will be kept confidential and that I will not be identifiable in any of the study results. I agree to the researcher processing personal data about me described as sensitive data within the meaning of the UK General Data Protection Regulation (2021) and UK Data Protection Act (2018)
3. I understand that I am free to withdraw from the research at any time, for any reason and without prejudice. (Please include whether or not it will be possible for participants' data to be withdrawn from the study, including any cut-off date for this where applicable.)
4. I agree to take part in the above research.

Please add any further conditions specific to your study (e.g., consent to being recorded, consent for anonymised quotes to be used, etc.)

- Name of participant (signature, print, date)
- Name of parent / carer if appropriate (signature, print, date)
- Name of researcher (signature, print, date)

If you wish to withdraw from the research please complete the form below and return to the research named above.

- Title of project

I wish to withdraw from this study.

- Name of participant (signature, print, date)

Appendix 2: Principles of ethical research

According to the UK Policy Framework for Health and Social Care Research, the following statement of principles serves as a benchmark for good practice that the management and conduct of all health and social care research in the UK are expected to meet.

Principle 1: Safety

The safety and well-being of the individual prevail over the interests of science and society.

Principle 2: Competence

All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.

Principle 3: Scientific and Ethical Conduct

Research projects are scientifically sound and guided by ethical principles in all their aspects.

Principle 4: Patient, Service User and Public Involvement

Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.

Principle 5: Integrity, Quality and Transparency

Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.

Principle 6: Protocol

The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents - see HRA Planning and Improving Research page.

Principle 7: Legality
The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.

Principle 8: Benefits and Risks

Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated (A formal, structured risk assessment is only expected where identified as essential. The risk: benefit ratio will normally be sufficiently described and considered as part of review processes such as research ethics committee review.)

Principle 9: Approval

A research project is started only if a research ethics committee and any other relevant approval body (i.e. the HRA, the Administration of Radioactive Substances Advisory Committee (ARSAC), the Human Fertilisation and Embryology Authority (HFEA) or the Medicines and Healthcare products Regulatory Agency (MHRA)) have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.

Principle 10: Information about the Research

In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).

Principle 11: Accessible Findings

Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards (i.e. legal requirements or expectations of regulators). In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.

Principle 12: Choice

Research participants (Either directly, or indirectly through the involvement of data or tissue that could identify them) are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.

Principle 13: Insurance and Indemnity

Adequate (Special provision is not expected unless existing arrangements (e.g., professional insurance, membership of NHS Litigation Authority schemes) provide inadequate cover) provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.

Principle 14: Respect for Privacy

All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.

Principle 15: Compliance

Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

Principles that apply to interventional health and social care research

In addition to the principles above, the following principles apply to interventional research only, i.e., where a change in treatment, care or other services is made for the purpose of research.

Principle 16: Justified Intervention

The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).

Principle 17: Ongoing Provision of Treatment

The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g., continuing or changing the treatment, care or other services that were introduced for the purposes of the research).

Principle 18: Integrity of the Care Record

All information about treatment, care or other services provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected.

Principle 19: Duty of Care

The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional (Who may or (particularly where the research team is not local to the research site) may not be a member of the research team) retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

Appendix 3: Flow chart of the research governance approval process

Researcher accesses the research governance guidance and application form, completes the application form and submits online to the supervised mailbox researchgovernance@southglos.gov.uk

Receipt of application form is acknowledged by the research governance administrator within 3 working days. Submitted documents are checked and any missing supporting documents are raised with researcher.

Administrator sends completed applications to two members of the research governance panel for review. Researcher is notified of the decision and feedback is provided within 28 working days.

Approved

Approved with conditions: further evidence is needed as part of a resubmission to ensure conditions have been met before the researcher can begin the research.

Not approved: feedback is provided on why the application was not approved.

Researcher may be invited to resubmit.

Researcher is allowed to begin research. Panel decisions will be kept on record. The researcher should notify the research governance panel if there are any subsequent changes to the research project.