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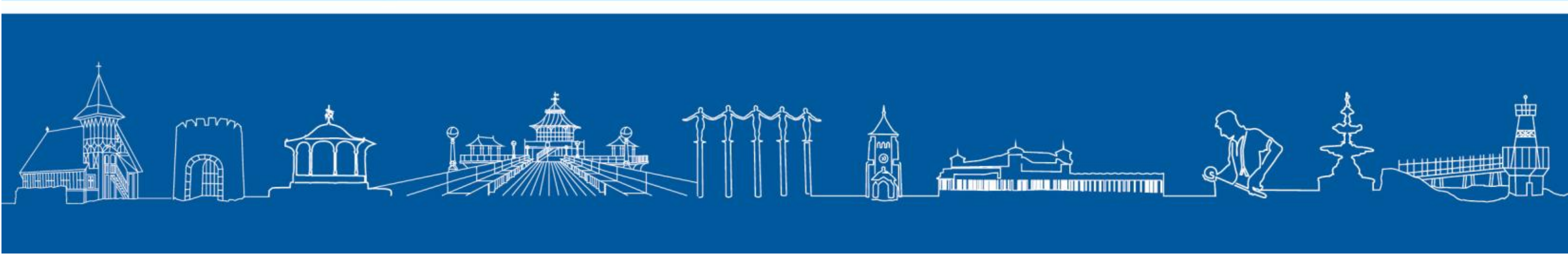
North Somerset Council

Research Governance Policy



Contents

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1. Introduction

At North Somerset Council we utilise research to support the development of our strategies, policies, programmes, and services. By setting clear standards and processes, the research governance policy outlines how we will support high-quality, innovative, and cost-effective research, ultimately leading to better outcomes for our residents. Effective research governance is essential to maintaining public trust in our use of research. We will maintain trust through ethical practice, the management of risk, transparent processes, high quality output, and the effective application of research findings and recommendations.

2. Aims

Our research governance policy aims to:

- Support the development of quality research and the robust management of any potential risks and rewards, including safeguarding the public, the interests of North Somerset Council, and our partners.
- Affirm academic collaborations by providing clarity on expectations, approvals and ethical standards
- Ensure that research is carried out in a planned, open, and rigorous way.
- Ensure that research is relevant to North Somerset Council as an organisation.
- Ensure that research is conducted to a high standard in accordance with ethical and data protection principles.
- Ensure that we are not duplicating other work unnecessarily.
- Ensure that the investment of resources in research represents value for money.

3. The UK Policy Framework for Health and Social Care Research

The United Kingdom's (UK) Policy Framework for Health and Social Care Research sets out the principles of good practice in the management and conduct of health and social care research in the UK. The UK Framework is statutory guidance to which local authorities, NHS trusts and NHS foundation trusts in England must have regard (in accordance with Section 111(6) and (7) of the Care Act 2014). The principles of the UK framework have wider application and provide the foundations for research governance across all North Somerset Council's directorates.

The UK framework identifies good research to be:

- Safe.
- Scientifically and ethically sound with the relevant approval.
- Legal and compliant with relevant insurance and indemnities.
- Conducted by competent people who can weigh up the benefits and risks.

The UK framework also states that research should:

- Be set out in a clear research proposal.
- Involve the public.
- Let people choose whether to take part and respect privacy.
- Ensure integrity, quality, and transparency with details of the planned research published and findings published too.
- Consider the needs of participants after the research has ended.

4. What is research?

This policy defines research as,

> a systematic and rigorous effort by colleagues from partner organisations, and/or postgraduate students, to answer clearly defined questions to generate new knowledge on behalf of, or in partnership with, North Somerset Council.

This definition differentiates research from routine activities conducted by council employees such as consultations and surveys. Consultations and surveys are typically designed to gather feedback from residents, staff, and stakeholders. These activities usually fall under the CLT-approved consultation and research strategy, guide and toolkit and are focused on seeking input for decision-making, service improvement, or policy development. They are not considered research unless they involve systematic methods aimed at generating new knowledge, include sensitive personal data, or contribute to academic publications. Examples include random sampling to achieve a representative sample, any methodology that aims to reduce response bias and focus groups.

If a survey or consultation is purely for feedback and does not include these research elements, it does not need to go through the formal research governance process. However, if it is intended for research purposes (e.g., publishing findings, contributing to postgraduate academic qualifications, or using advanced research methods), it would require approval through the research governance process.

In addition to this, the following activities are not considered research under this policy:

- Collecting routine management or monitoring data as a part of your normal, day-to-day work.
- Conducting 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.
- Carrying out financial, practice or service quality audits.
- Making a Freedom of Information (FOI) 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 Policies.

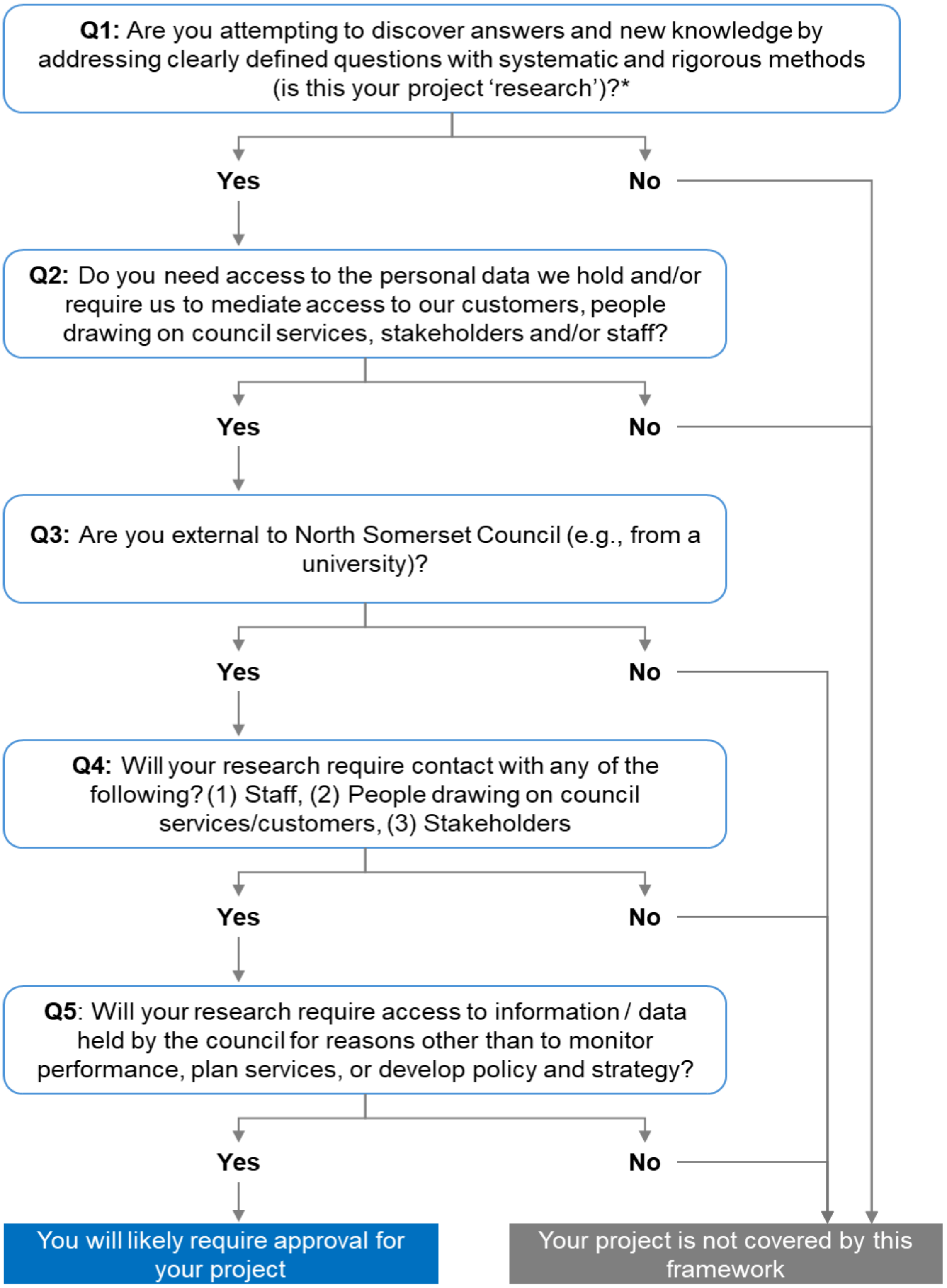
The Medical Research Council (MRC) and the NHS Health Research Authority have developed a useful decision tool to help you determine if your work is research: Is my study research? The decision tree introduced in the following section will also support you to understand whether your proposed project requires research scrutiny.

Appendix 6 presents a selection of questions to support you to determine if what you are working on must be subjected to the NSC research governance process.

5. Does my research require scrutiny?

Please use the decision tree to determine whether your research requires scrutiny from the research governance panel.

Does my research require scrutiny?



Q1: Are you attempting to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods (is this your project 'research')?*

Q2: Do you need access to the personal data we hold and/or require us to mediate access to our customers, people drawing on council services, stakeholders and/or staff?

Q3: Are you external to North Somerset Council (e.g., from a university)?

Q4: Will your research require contact with any of the following? (1) Staff, (2) People drawing on council services/customers, (3) Stakeholders

Q5: Will your research require access to information / data held by the council for reasons other than to monitor performance, plan services, or develop policy and strategy?

You will likely require approval for your project

Your project is not covered by this framework

If you are unsure whether your project is research, consultation or performance management, please seek advice by emailing the relevant directorate's research governance lead(s)

6. Roles and responsibilities

Below are some of the roles of responsibility of people involved in the research governance and development process.

6.1. The chief investigator

The chief investigator is the overall lead researcher for a multi-site research project (i.e. a research project conducted in partnership with several other local authorities). Chief investigators are responsible for the overall conduct of the research project.

6.2. The principal investigator

The principal investigator is an individual responsible for the conduct of the research at a research site (i.e. North Somerset Council). There should be one principal investigator for each research site. In the case of a single-site study, the chief investigator and the principal investigator will normally be the same person.

6.3. The data controller

The data controller is the organisation responsible for the management and oversight of the data. This will usually be North Somerset Council.

6.4. The sponsor

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project. The sponsor is normally expected to be the employer of the chief investigator, or the university they are enrolled with.

6.5. Information governance officer

The information governance officer is the first line point of contact for individual information rights requests (such as subject access requests), freedom of information requests and other information governance and data protection-related matters.

6.6. The Caldicott Guardian

The Caldicott Guardian is a senior role for an organisation which processes health and social care personal data. They make sure that the personal information about those who use the organisation’s services is used legally, ethically and appropriately, and that confidentiality is maintained.

6.7. The research governance leads

Each directorate will have a nominated research governance lead[s]. Each nominee will hold a relevant qualification in research methods and/or have relevant research experience and hold a position in their directorates that oversees research activity. Our research governance leads are:

- Adult Social Services and Housing - The Principal Social Worker and Principal Occupational Therapist
- Children’s Services: - The Principal Social Worker
- Healthy and Sustainable Communities – Academic Public Health Lead
- Corporate Services – Consultation and Research Senior Analyst
- Environment, Assets and Transport Services – Nominated individual

The role of a research governance lead[s] is to work together with chief/principal investigators, the sponsor, information governance officers, the Caldicott Guardian, and relevant contracts teams to:

- Ensure that research is conducted by competent, well trained, and well supported people.
- Ensure that research activity is legal, compliant and has relevant insurance and indemnities.
- Ensure research proposals are scientifically and ethically sound with the relevant approval.
    - Establish whether the research design is of good quality, relevant, and is of sound methodology.
    - Acknowledges receipt of an application and resolves any missing or unclear information within the given timeframe before submitting it to the research governance panel meeting; also provides timely feedback to the applicant/s of the outcome of the meeting.

    - Consider the suitability of the data collection tools, with a particular focus on where primary data will be obtained and analysed as part of the research project. The research governance leads must determine whether data to be collected is not in excess of what is required to meet research objectives in line with data minimisation/protection principles.
- Assess whether proposed research will benefit North Somerset Council and its residents.
- Minimise undue intrusion and harm to all parties.
- Uphold the dignity, rights, and wellbeing of participants.
- Consider and advise on appropriate dissemination of research findings.
- Maintain and update a central and easily accessible electronic register of research that is being/has been conducted. This will ensure that when an audit on research proposals, outcomes, and output is requested either internally, or externally, the information can be shared quickly and accurately.
- Ensure that capacity and consent has been considered (where applicable) (see Capacity consent research - Home and Mental Capacity Act Code of Practice - GOV.UK).

7. The research governance panel

The research governance panel is a multi-disciplinary panel which sits bi-monthly to consider and robustly evaluate research applications, with the aim to:

- Build and maintain public trust in the research process by demonstrating that research is conducted responsibly and ethically.
    - Ensure that all proposed research considers the rights, dignity, and welfare of all involved.
    - Identify and mitigate against potential risks to participants, researchers, and institutions. This includes physical, psychological, and privacy risks.

- Ensure that the research design is methodologically robust, providing confidence that the results will likely be reliable and valid.
- Ensure that the research complies with legal, institutional, and research-based regulations.

The research governance panel includes:

- The research governance leads
- Information governance officer
- Additional directorate research leads
- The Caldicott Guardian (where applicable)
- Colleagues in commissioning (where applicable)

The chair of the panel will rotate between the research governance leads.

Members of the panel will consider whether research proposals:

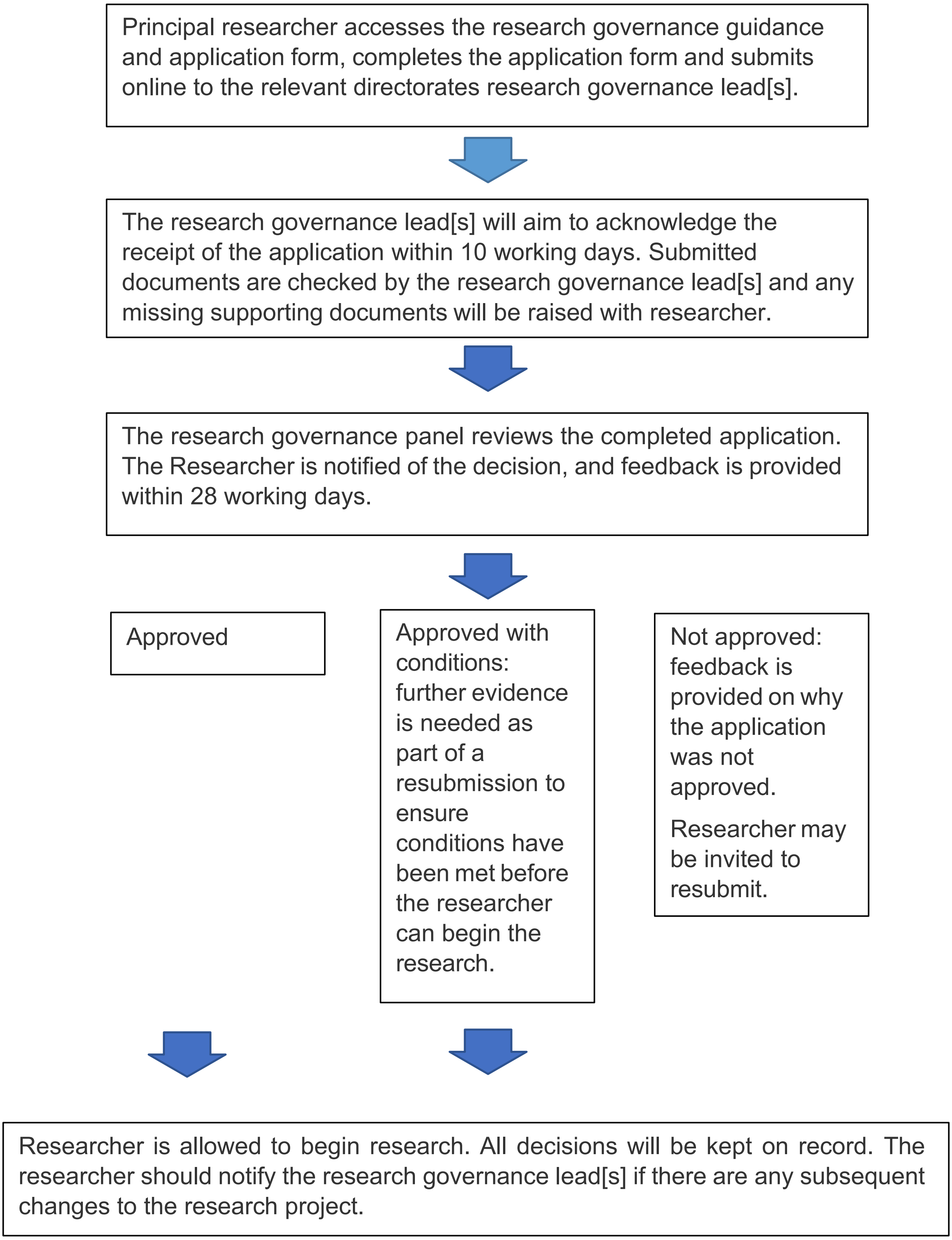
- Are safe.
- Are scientifically and ethically sound.
- Have received the relevant external approval (where applicable – this must be shared with the panel and a record kept locally).
- Are legal and compliant with relevant insurance and indemnities.
- Have been proposed by competent chief/principal investigators.
- Have satisfactorily weighted the benefits and risks.
- Are transparent.
- Consider the needs of participants after the research has ended.

The final approval for research activities will be the responsibility of the research governance panel. Members of the research governance panel must reach a consensus for the approval of proposed research to be agreed.

Where a decision cannot be made research governance leads will seek a decision from the relevant assistant director[s].

Research studies involving 4 or more local authorities will need approval from each of the relevant Directorate Directors.

8. The research governance process



Principal researcher accesses the research governance guidance and application form, completes the application form and submits online to the relevant directorates research governance lead[s].

The research governance lead[s] will aim to acknowledge the receipt of the application within 10 working days. Submitted documents are checked by the research governance lead[s] and any missing supporting documents will be raised with researcher.

The research governance panel reviews the completed application. The 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. All decisions will be kept on record. The researcher should notify the research governance lead[s] if there are any subsequent changes to the research project.

9. What you need to do – Beginning to end.

Stage A: Application and the research governance panel

1. Establish whether you are doing research.

2. Discuss your research proposal and research design with the relevant people (such as your sponsor, the data controller, personal tutor/PhD supervisor or manager).

3. Develop your research proposal and research design with due consideration for research standards, ethical considerations, and the Caldicott Guardian principles.

4. Consider whether your research needs to be subjected to the research governance process (see appendix 6)

   a. The research governance leads will be the chief/principal investigators initial point of contact and can offer information and advice about the research governance process.

5. Ensure that you are clear on everybody's roles and responsibilities.

6. Where applicable, complete any external ethics processes.

7. Write your research governance application (see appendix 1).

8. Submit your research governance application, research proposal, external ethical approval (where applicable), and research timeline to the relevant research governance lead via email. You will also need to submit data collecting tools. You may be required to supply evidence of a current DBS certificate.

   a. When the research governance leads receive initial applications for research governance approval, they will offer preliminary feedback on whether an application has all the required information to be considered by the research governance panel. The research governance leads will aim to respond to initial research governance applications within 10 working days. During busy periods or increasing demands on time, meeting this deadline may not always be feasible.

b. If you have not submitted all the required information the research governance lead will sent the application back to you asking for more information.
c. If you have sent all the required information, you will be notified of the date and time your proposal will be considered by the research governance panel. The research governance lead who received your initial proposal will endeavour to inform you of the panel’s decision within 15 working days of the decision being made.
d. You must not start any research activities without the research governance panels agreement, nor without the informed consent of the people you are planning to invite to take part in your research. You must consider capacity and consent (see Capacity consent research - Home and Mental Capacity Act Code of Practice - GOV.UK).
e. In cases where approval cannot immediately be given, the research governance panel will provide written feedback to address areas of concern and encourage, where appropriate, revision of the research design and/or application for research governance approval.
f. Upon receiving a response from the research governance panel; amend and resubmit your application for research governance. Resubmission should be within 12 weeks of receiving the initial decision. If your proposal has been approved, you are ready to seek consent from potential participants (where relevant).
g. If your research cannot be approved, you should seek guidance and support from your sponsor, research supervisor and/or line manager. Any complaints about the process can be sent to
   Complaints Manager,
   Town Hall,
   Walliscote Grove Road,
   Weston super Mare,
   BS23 1UJ
   Telephone: 01275 882171

Email: complaints.manager@n-somerset.gov.uk

9. Do I need **Additional approval?**

  a. Some research may require NHS Health Research Authority approval including review by an NHS Research Ethics Committee. If this applies to you then you must share your ethical approval letter with the research governance panel before starting your research.
  b. Students who are undertaking research as part of a formal university programme to achieve a postgraduate qualification (i.e. MSc, PhD) must seek to obtain a university ethical review for their project, if this is required, before submitting a research governance application to the relevant research governance lead.

10. Details of your research project will then be placed in an electronic register and may be published on our website.

Stage B: Research in progress

11. Obtain informed consent from potential research participants before starting any research activities (See appendix 2).

12. The chief investigator and/or your sponsor/research supervisor will monitor your work to ensure compliance with your application details, research standards, and ethical principles.

13. The chief investigator and/or your sponsor/research supervisor will periodically update the relevant research governance lead on your progress. In cases where the design of the research changes as the research progresses, the research governance panel must be notified. The research governance panel will then consider whether the research should continue or be paused to request, and consider, an updated application for research governance approval.

Stage C: Completed research study

14. Discuss your research findings with the chief investigator and/or your sponsor/research supervisor and identify any valuable outcomes. Discuss and consider wider dissemination.

15. Submit report /dissertation and any data gathered to the research governance panel, via the relevant research governance lead, together with a plan for dissemination/publication. The research governance panel may recommend changes to the research report or sign it off as complete. The panel with consider the plan for dissemination and offer advice on the next steps.

16. Send an accessible summary of the findings to the research participants where appropriate.

17. Publish and disseminate findings in accordance with the research governance panel's recommendations. This may include publishing your findings on our website and/or in our newsletters.

10. Key things to remember about the research governance process

1. The research governance panel will examine each research proposal and final report to see if it meets required standards, is ethical, rigorous in method and of value to people drawing on council services.
2. If approval is not given, or withdrawn, the research must not be carried out. If research is undertaken without approval:
    a. The results from the research would not be formally recognised as valid by North Somerset Council.
    b. If harm is caused to any person or organisation during the research activities the chief and/or principal investigator might be held personally responsible for this.
    c. It may result in disciplinary action.
    d. A referral to the persons professional registration body may be required.

11. Feedback

We value your feedback and welcome both compliments and areas for development. You can send us feedback through our website. If you have any concerns about any action or decision taken by Adult Social Services and Housing, you should initially talk to the person you normally talk to. You can also contact our complaints manager at:

Complaints Manager,
Town Hall,
Walliscote Grove Road,
Weston super Mare,
BS23 1UJ
Telephone: 01275 882171
Email: complaints.manager@n-somerset.gov.uk

12. Accessible information

Council documents can be made available in large print, audio, easy read, and other formats. Documents on our website can also be emailed to you as plain text files. Help is also available for people who require Council information in languages other than English. Please ring 01934 888 888 for advice and support.

Appendix 1: Application for research governance approval

Reason for application:

Please check relevant boxes ☒

☐ **I am attempting to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods.**

☐ **I will be collecting additional information to that routinely obtained from people drawing on council services carers, staff, volunteers and stakeholders to plan individual services**

☐ **I require access to existing information (anonymised or named – delete as appropriate) held by North Somerset Council and/or it's partner organisations for other reasons than to monitor performance and plan services.**

Please provide the following details:

Research title:

Date of application:

Funder's Name:

Organisation

Address:

Phone: E Mail:

Sponsor's Name:

Organisation

Address:

Phone: E Mail:

The organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation. The main funder has a key role in quality assurance.

Chief Investigator Name:

Address:

Phone: E Mail:

Brief details of relevant previous research/relevant qualifications or training

Additional Investigators (i.e. Principal investigators)

Name:

Address:

Phone: E Mail:

Brief details of relevant previous research/relevant qualifications or training

✳Please add in details of any other researchers involved in the project here.

Organisation employing researchers:

Address:

Phone:

Organisation E Mail:

Safeguards

The work is with children under the age of 16	☐ Yes	☐ No	
The work is with vulnerable/seldom heard groups	☐ Yes	☐ No	
I confirm that a **satisfactory** safeguard check with the Disclosure and Barring Service on all researchers working on this project has been carried out	☐ Yes	☐ No	☐ N/A

Please give written details of any convictions the researcher(s) may have and give details of the safeguard check with the Disclosure and Barring Service. It is incumbent on you to ensure you have this clearance before commencing work with members of these groups.

Monitoring
Please say how the organisation will monitor the work to ensure that it is properly managed, and that researchers and others involved in the work understand and discharge their responsibilities *(i.e. supervision frequency, review meetings, frequency of sponsors updates to the Research Governance Lead.).*

Research details
Reason for the study
Aim and purpose
What existing sources of evidence have been considered?

Design, methodology and reasons for approach
Sample (inc. barriers and limitations)
People/stakeholder involvement in the design (coproduction?)
Arrangements to access participants and their details.
Name of link person to facilitate access to respondents and or their data (gatekeepers) *(if appropriate)*:
Estimated resource & costs

Expected outcomes	
Ethics	
As the chief/principal investigator I confirm I have read and agree to follow the standards and ethical principles as set out in the research governance guidance (Appendix 3 and 4)	☐ Yes ☐ No
Have you obtained ethical approval from an external ethics committee? If yes, which one?	
What are the risks and ethical issues involved in this study?	
What arrangements will be made to deal with the risks and ethical issues involved in the study?	
What arrangements will be made to obtain informed consent for participation in the study? Evidence how you will consider capacity and consent (see Capacity consent research - Home and Mental Capacity Act Code of Practice - GOV.UK).	

Information Management and Data Protection
What types of data will be collected? Have you ensured that all data collected is necessary for the research purpose?
How will the data be stored?
What is the legal basis for processing the data?
How long will the data be held for? How will this data be destroyed or anonymised?
Will the data be shared? If so, with whom, why is it being shared, and how?

Will the data be anonymised? If so, how?
Communication
What arrangements are you making to keep participants and others informed during the study and to inform them of the results when the study is completed?
Please say how you will report and disseminate the findings after the research governance panel has signed the research report and findings off.
Collaborative arrangements
Agreed boundaries (e.g. hours per week dedicated to the research, where research activities will take place, what is your work pattern?)
Agreed tasks and responsibilities:

I confirm that all involved have agreed ethical principles	☐ Yes	☐ No	☐ N/A
I confirm that all involved have agreed the amount of time each can spend on the work?	☐ Yes	☐ No	☐ N/A

Timescales
Expected commencement date:
Expected completion date:
State any milestones and targets:

Application to other Research Governance Processes	
I confirm that all necessary applications will be made to other research governance processes (i.e. university ethics committees etc)	☐ Yes ☐ No ☐ N/A
Please give details and attach copies of relevant documentation and approval	

Publishing Project details	
I confirm that details of the research and my name and contact details may be placed on any research publications that are share with local and national organisations	☐ Yes ☐ No
If you think this research should not be publicly available, please explain why.	

Principal/Chief Investigators Signature

I confirm that all roles mentioned in the guidance have been identified and all the individuals involved including myself agree their responsibilities and to adhere to the standards and ethical principles set out in the Research Governance Guidance.

Signature .... Date ..../...............

Signature…………………………………………………Date ……………/……………

Sponsor Signature

I confirm that I agree to the responsibilities of sponsor and to adhere to the standards and ethical principles set out in the Research Governance Guidance.

Signature .... Date ..../...............

Manager signature *(where appropriate)*

Name:

Position:

Please give reasons for supporting the work:

I agree to the researcher having access to appropriate research participants and their details in accordance with the standards and ethical principles set out in the Research Governance Guidance and confirm that I have made appropriate arrangements to facilitate this access.

Signature .... Date ..../.............../

Supporting documents included

Advertisements for research participant recruitment	☐ Yes	☐ No

Questionnaires / interview schedule	☐ Yes ☐ No
Participant information sheet	☐ Yes ☐ No
Informed consent sheet	☐ Yes ☐ No
Privacy notices	☐ Yes ☐ No
Other research governance scrutiny processes documentation	☐ Yes ☐ No
Details of the safeguard check with the Disclosure and Barring Service	☐ Yes ☐ No
Letter confirming external ethical approval (i.e. from a university)	☐ Yes ☐ No
Other documents please list:	

Please email all documents to the relevant research governance lead.

Thank you.

Appendix 2: Informed consent templates

Participant information sheet for adults

This is a suggested template, and you may wish to include additional details or try a different design. Keep to the point and use clear and accessible language. Use only the most necessary technical terms, providing definitions where appropriate. For examples of alternative formats please visit: Examples - Consent and Participant information sheet preparation guidance. These examples will support you to think through whether you might need to provide information in plain English or different formats that aid understanding.

If you are including children aged 16 and under as research participants you may need two versions of the information sheet, one for the parent and/or the carer and one using language that the child will understand.

Section A: The research project

1. Title of project.
2. Purpose and value of study.
3. Invitation to participate.
4. Who is organising the research.
5. What will happen to the results of the study?
6. Source of funding for the research.
7. Contact for further information.

Section B: Your participation in the research project

1. Why you have been invited to take part.
2. Whether you can refuse to take part.
3. Whether you can withdraw at any time, and how.
4. What will happen if you agree to take part (brief description of procedures and tests).

5. Whether there are any risks involved (e.g. side effects from taking part) and if so what will be done to ensure your wellbeing/safety.
6. Agreement to participate in this research should not compromise your legal rights should something go wrong.
7. Whether there are any special precautions you must take before, during or after taking part in the study.
8. What will happen to any information/data/samples that are collected from you.
9. Whether there are any benefits from taking part.
10. How your participation in the project will be kept confidential.

You will be given a copy of this to keep, together with a copy of your consent form.

Participant consent form for Adults

If you are including children aged 16 and under as research participants you may need two versions of the participant consent form sheet, one for the adults involved and something simpler that the child will understand.

Name of participant:

Title of the project:

Main investigator and contact details:

Members of the research team:

1. I agree to take part in the above research. I have read the participant information sheet, which is attached to this form. I understand what my part will be in this research, and all my questions have so far been answered to my satisfaction.

2. I understand that I am free to withdraw from the research at any time, for any reason and without prejudice.

3. I have been informed that the confidentiality of the information I provide will be safeguarded.

4. If I raise issues about my being hurt or abused or about the abuse of some other vulnerable person I understand that someone will contact me to talk about it before taking further action.

5. I have been provided with a copy of this form and the participant information sheet.

Data Protection Act 2018: I agree to the chief and/or principal investigator processing personal data that I have supplied. I agree the processing of such data for any purposes connected with the research project as outlined to me. I further agree to the chief and/or principal investigator processing personal data about me described as sensitive data within the meaning of the Data Protection Act 2018.

Name of participant

………………………………………………………… ……………………………………………

(Print) Signed Date

Name of carer *(if appropriate)*

………………………………………………………… ……………………………………………

(Print) Signed Date

Name of parent *(if appropriate)*

………………………………………………………… ……………………………………………

(Print) Signed Date

Name of witness

………………………………………………………… ……………………………………………

(Print) Signed Date

YOU WILL BE GIVEN A COPY OF THIS FORM TO KEEP

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

Title of project:

I WISH TO WITHDRAW FROM THIS STUDY

Signed: ……………………………………………………………………… Date: ………………………………………………………………………………………

Appendix 3: Research standards

1. All research must have a coherent aim and demonstrate a clear link to strategy, policy or practice and have been approved by the research governance panel.

2. The quality of design, implementation and analysis of research must be reviewed independently by the research governance panel to ensure it meets ethical standards, achieves a high level of rigour and is potentially beneficial to people drawing on council services and/or the organisation.

3. All studies must have appropriate arrangements for obtaining informed consent and 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. You must consider capacity and consent (see Capacity consent research - Home and Mental Capacity Act Code of Practice - GOV.UK).

4. Participants or their representatives should be involved wherever possible in the design, conduct, analysis and reporting of research.

5. We are committed to meeting our 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. Some research might involve an element of risk to those participating in it. Risk must always be kept to a minimum and explained clearly to the research governance lead, research governance panel, sponsor, and to the participants.

7. It is essential that existing sources of evidence, especially systematic reviews, be considered carefully prior to undertaking research. Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is in itself unethical.

8. Data collected in the course of research 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.

9. There should be free access to information both on the research being conducted and on the findings of the research, once these have been subjected to appropriate review. This information must be presented in an accessible format. Reports need to be comprehensible and take language and other needs into account.

10. All those pursuing social care research must open their work to critical review through the accepted academic and professional channels.

Appendix 4: Principles of ethical research practice

According to the UK Policy Framework for Health and Social Care Research, the following statement of ethical principles serves as a benchmark for good practice.

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.

Principle 7: Legality

The chief and/or principal investigator 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 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 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. You must consider capacity and consent (see Capacity consent research - Home and Mental Capacity Act Code of Practice - GOV.UK).Where consent is refused or withdrawn, this is done without reprisal.

Principle 13: Insurance and Indemnity

Adequate 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 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.

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. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.

Appendix 5: Caldicott guardian principles

The Research Governance Framework in Health and Social Care incorporates stipulations of the Data Protection Act 2018 and requires that in the research setting, the appropriate use and protection of personal data is paramount. All those involved in research must be aware of their legal and ethical duties in this respect. These duties are summarised as follows:

Justify the purpose(s)

Every proposed use or transfer of personal identifiable information within or from North Somerset Council or services associated with it, should be clearly defined and scrutinised.

Don’t use personal identifiable information unless it is absolutely necessary

Personal identifiable information items should not be used unless there is no alternative. If there is a possibility of the person being easily recognised despite every effort to anonymise the data (e.g. small numbers and or localities) then the chief and/or principal investigator should avoid naming the source data (e.g. team, locality, school etc)

Use the minimum necessary personal identifiable information

Where use of personal identifiable information is considered to be essential, each individual item of information should be justified with the aim of reducing identifiability.

Access to personal identifiable information should be on a strict need to know basis

Only those who need access to personal identifiable information should have access to it, and only access to the information items they need to see.

Everyone should be made aware of their responsibilities

Chief and/or principal investigators are personally responsible for ensuring they handle personal identifiable information in accordance with the Caldicott Guardian principles. All researchers involved must be aware of their responsibilities and obligations to respect confidentiality.

Understand and comply with the law

Every use of personal identifiable information must be lawful. The Adult Community Care Caldicott Guardian can provide chief and/or principal investigator with further advice on how to comply with legal requirements.

Appendix 6: Does my research require review?

Ask yourself:

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

- Question 2: Do you need access to the personal data we hold and/or require us to mediate access to our customers, people drawing on council services, stakeholders and/or staff?
    - If 'yes' to questions 1 and 2, consider questions 3, 4 and 5.
    - If 'no': Your project is not covered by the research governance policy, so you do not need to submit a proposal.
    - If you are unsure whether your project is research, consultation or performance management please seek advice by emailing the relevant directorates research governance lead[s].
- Question 3: Are you external to North Somerset Council (e.g., from a university)?
- Question 4: Will your research require contact with any of the following?
    - Staff
    - People drawing on council services / customers
    - Stakeholders
- Question 5: Will your research require access to information / data held by the council for reasons other than to monitor performance, plan services, or develop policy and strategy?
    - If you have answered 'yes' to questions 3, 4 and 5 you will likely require approval for your project.