Warwickshire County Council

Social Care Research Governance Application Guidance

Version: 1.1

Date Issued: March 2018. Updated: Aug 2024 Team: Learning & Organisational Development

Protective Marking: Public



This guidance accompanies the Social Care Research Governance application forms

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1. What is research governance and why is it needed?

The <u>UK Policy Framework for Health and Social Care Research</u> (2017) states 'Research is a core function of health and social care. It is essential for our health and well-being and for the care we receive. Research should improve the evidence base, reduce uncertainties and lead to improvements in care'.

At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and wellbeing of the research participants.

Proper governance of research is essential to ensure that the public can have confidence in, and benefit from, quality research in health and social care. The public has a right to expect high scientific, ethical and financial standards, transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements.

We want to make sure that social care research within Warwickshire County Council is of good quality, ethical and useful.

Our research governance process helps us to do this and makes sure that people carrying out research, consultations and evaluations take all reasonable steps to protect the dignity, rights, safety and wellbeing of the customer, families, carers or staff involved in the study.

2. What projects need to go through the research governance approval process?

Warwickshire County Council social care research governance approval is required **before** you begin your project or research if you want to:

- find out something that will produce new knowledge, by using clearly defined questions and systematic and rigorous methods;
- collect information from adult or children's social care customers, carers, staff or volunteers for example, through a questionnaire, interview, or focus group; or
- have access to existing personal information about social care customers, carers, staff or volunteers, anonymised or identifiable, held on paper or electronic records, for research purposes and not for routine monitoring of services or management purposes.

Exceptions

You don't need to apply for research governance approval if:

- you will only be collecting routine management information as a normal part of your dayto-day work;
- you will not be involving any Warwickshire County Council adult or children's social care, or Public Health staff, customers, carers or volunteers, or information we hold about them; or
- you will be carrying out financial audits.

3. Warwickshire Social Care Research Governance approval process

We follow the Department of Health's Research Governance Framework (RGF) for Health and Social Care and the more recent Health Research Authority's UK Policy Framework for Health and Social Care Research. We have reviewers drawn from Warwickshire County Council staff who are responsible for deciding whether or not your research application should be approved.

They will consider:

- the feasibility of your proposed research;
- whether you've addressed all the issues in the application form; and
- whether the plan meets the standards set by the Policy Framework. (An important exception is **any** research involving people who lack capacity to consent under the Mental Capacity Act this can only be approved by an 'Appropriate Body'. See Section 6).

Please remember – getting approval is likely to be quicker if you send us clear, relevant and detailed information when you apply.

Timescales

We aim to:

- let you know we have received your application and supporting documents within 5 days of us receiving them; and
- let you know whether your application has been approved within 15 working days of us receiving all documents.

If we are unable to keep to these times we will explain why as soon as possible.

What happens next?

Your application will be considered by the research reviewers most knowledgeable about the topic or area you wish to investigate.

Through the research governance process, we will check:

- there is no potential risk of physical, emotional or psychological harm to anyone taking part, or that where there are potential risks, ways of managing these risks have been identified;
- the proposed project plan is not unnecessarily intrusive it collects only the information needed to achieve its aims, and nothing else; and
- there are no concerns about the research methods or ethics, including regarding informed consent.
- the proposed project and findings will be of some benefit to the host organisation & that there is a fit with the Social Care & Health or Children & Young People Directorates' aims and outcomes.

If we are concerned about any of these things, we will give you feedback about the areas of concern and may invite you to re-submit your project plan, or we may not give approval.

If your project has already had approval from elsewhere (for example, from a university or through the Social Care Research Ethics Committee) it will still need to be considered by us. All paperwork and any letters of approval should be submitted.

The reviewers will decide one of the following:

- to approve your application;
- to approve it, but with some conditions; or
- not to approve it.

Even if your plan is approved, either with or without conditions, you will still need permission from the relevant service area / Service Managers to begin your research.

If your plan is not approved, we will explain our reasons and may make some suggestions about how to improve the application.

Registering your research

Once your application is approved, we will register the details of your research on a local database. This will enable the study to be tracked; help to ensure that Warwickshire County Council gets full benefit of the findings and that the study gets promoted within the relevant areas.

4. Flowchart of Warwickshire Social Care Research Governance approval process

Applicant downloads a Research Governance Application Pack from WCC Website or requests by email from pe-researchgovernance@warwickshire.gov.uk

Applicant completes and returns application, supporting documentation and application checklist to pe-researchgovernance@warwickshire.gov.uk

Application and supporting documentation is checked and logged

Applicant is contacted within 5 working days to confirm receipt of application and to request additional documentation/clarification about project if required. Applicant is advised to approach relevant service area / managers to gain permission, in theory, to involve staff or customers if approved.

Once all requested documentation has been received and any initial concerns responded to, the application is forwarded to reviewers

Reviewers assess the application and respond to pe-researchgovernance@warwickshire.gov.uk within 10 working days

Applicant is notified of the outcome of the review via email within 15 working days of receipt of all relevant documents

The application is either:

Approved.

Permission from Service

Managers

must still be obtained.

Approved with conditions.

OR

Permission from Service **OR** provided on why the Managers must still be

obtained even if conditions are met. Not approved.

Feedback will be application has been

rejected.

All applications are logged on a local database

Where approval has been given, the applicant emails a copy or a summary of the final research report to pe-researchgovernance@warwickshire.gov.uk

Complaints regarding the Research Governance process should be sent to: pe-researchgovernance@warwickshire.gov.uk

5. Main roles and responsibilities within the Research Governance Framework

Research Supervisor's responsibilities

Research is an evolving process. Things can change on a day-to-day basis and the unexpected can occur. For this reason, your project will need to be reviewed regularly by a research supervisor.

For in-house research undertaken by an employee of Warwickshire County Council, a named individual from Warwickshire County Council should act as your research supervisor.

We expect that research by students will be supervised by an academic supervisor.

The research supervisor should offer you regular support and monitor your project's progress. They should make sure your research is worthwhile, of high quality and offers value for money.

A supervisor should make sure you:

- are aware of the appropriate application procedure and of the requirements of Warwickshire County Council's research governance process;
- have the necessary expertise to carry out the research;
- have access to the necessary resources;
- propose methods for the collection and analysis of data that are ethical and sound;
- obtain research ethics committee approval, if necessary;
- address any data protection and intellectual property rights issues; and
- comply with Warwickshire County Council research governance requirements.

Researcher's responsibilities

The researcher will be responsible for:

- carrying out high quality research in accordance with the Policy Framework and with all specific compliance conditions notified during project approval;
- consulting a supervisor before designing the research;
- applying for research governance approval before starting any project and complying with the research governance application guidance;
- reporting any problems arising from the study in the appropriate manner;
- disseminating findings appropriately;
- not engaging in misconduct or fraud;
- liaising with appropriate operational staff to seek their willingness to engage with the research proposals and

• telling an appropriate professional about anything that suggests that someone might be at risk (for example, an adult or a child at risk of abuse or injury) or likely to harm another person.

Research Sponsor's responsibilities

The sponsor must be a named individual. For students, their research supervisor will also be the research sponsor. For research undertaken by Council employees, the research sponsor will be a Service Manager, Head of Service or Strategic Director.

The Research Sponsor will ensure:

- researchers are supported in and held to account for the professional conduct of research;
- proposed research is worthwhile and offers value for money;
- responsibilities of the organisations and individuals involved are clearly defined and agreed, and that contracts are signed where required; and
- progress of the research is monitored.

Further details about roles and responsibilities within the RGF are in the Department of Health's Research Governance Framework for Health and Social Care and the Health Research Authority <u>UK Policy Framework for Health and Social Care Research</u>.

6. Good practice in social care research: standards for researchers

We expect researchers to follow the Department of Health's <u>Research Governance Framework for Health and Social Care</u>, the Health Research Authority <u>UK Policy Framework for Health and Social Care Research</u> and any other relevant guidance for researchers in social care which is available now, or in the future.

Ethics

- The dignity, rights, safety and wellbeing of participants must be the primary consideration in any proposed research.
- All proposed research involving customers, carers, staff or volunteers, or access to their personal information, must go through the research governance process.
- Appropriate arrangements must be made for obtaining informed and written consent from participants. In cases where it's not possible, for reasons of mental capacity, to obtain a written signature directly from the participant, the researcher must follow Mental Capacity Act (2005) principles, regulations and the Code of Practice. If the research proposes to include people who lack capacity, researchers are legally required by the Mental Capacity Act to obtain approval for arrangements from an Appropriate Body before starting the research. All NHS RECs established under Governance Arrangements for Research Ethics Committees in England and Wales, and the Social Care REC, are appropriate bodies for the purposes of approving research under the Mental Capacity Act. See Health Research Authority Mental Capacity Act.
- Informed consent includes: giving participants as much information as is appropriate about
 the purpose of the project and its intended outcomes; explaining clearly their rights, and
 limits to their participation e.g. location, time involved, how data will be stored; raising
 awareness of any potential risk of harm involved in taking part; ensuring agreement to take

part is freely given; ensuring participants are made aware of their right to refuse to take part in, or to withdraw from a project, without suffering any effect on their services; giving specific consideration to obtaining informed consent from 'vulnerable' populations e.g. children, people with learning difficulties, people with dementia; ensuring that all reasonable steps will be taken to assure confidentiality or anonymity.

- Participants should be informed that data giving postcodes or other geographic identifiers could lead to identification.
- The issue of informed consent still applies if data is collected through anonymous or confidential postal survey questionnaires. Those contacted will need to be given sufficient information about the project to be able to decide if they want to take part. If the method of data collection is by observation and relies on observing behaviour without the participant's knowledge, this should only take place in a location in which people would normally expect to be in public view. If possible, an attempt should be made to obtain consent after the research has taken place.
- Every effort should be made to ensure that the design of the research does not
 discriminate against participants on the basis of ethnic background, age, gender, sexual
 orientation or disability. This may mean that arrangements need to be made to ensure
 participation, e.g. through use of Braille, digital recordings, plain English, translations into
 minority languages, and payment of travelling expenses.
- Wherever appropriate, participants or representatives should be given the opportunity to help with the research, including planning, data collection and analysis.
- During contact with participants, care must be taken not to raise expectations or imply that resources will be made available as a result of their participation.
- Researchers have a duty to pass on requests for help or information to the appropriate
 agency, especially in any situation giving rise to serious concern: for example, all forms of
 adult or child abuse.
- An effective channel for registering any complaints must be identified to participants.
- All data is confidential and should not be put to any use that may conflict with the original purpose for which it is gathered, without the informed and written consent of the participants.
- All those carrying out research must ensure that secure systems are used for the storage of personal information.
- All those carrying out research must comply with legal and ethical duties regarding protection of data as laid out in the Data Protection Act 1998, General Data Protection Regulation (GDPR) and Caldicott principles. Researchers must also comply with The Mental Capacity Act 2005.

Further information is available from:

- Information Commissioner's website: information about data protection and Freedom of Information
- Guide to the General Data Protection Regulation (GDPR)
- Warwickshire County Council's Corporate <u>Data Protection</u> information

Science

- Research sources must be checked before undertaking new projects to avoid unnecessary repetition of previous research.
- All research governance application forms must be submitted for review through the Research Governance process. No work should begin on the research project until the appropriate level of approval has been granted.
- All data collected during the course of the research must be stored securely for an
 appropriate period to allow further analysis by the original researcher or others and for the
 purposes of monitoring and the development of good research practice. This may require
 the further consent of participants involved for example if there are any consequences
 for the participants from whom the data was originally collected.

Information

- Once appropriate approval has been granted, information about the research and its findings should be made freely available.
- There should be free access to the research and the results need to be presented in an
 accessible way for example in plain English, and in a format suitable for the participants.
- Findings must be made available to those participating in the research.
- All research should be open to critical review through accepted scientific and professional channels, as appropriate to the nature of the research project.

Health and safety

- The safety of participants and of researchers must be given priority at all times. Health and safety regulations must be strictly observed.
- Harm can arise to participants from stress through participation, loss of self-esteem, psychological injury or other unintended side effects of the research.
- Employing organisations are responsible for the safety of their staff. All researchers should carry identification and ensure that a system is in place so that their whereabouts are known. Contact should be made before any home visits, and a risk assessment carried out.

Finance and insurance

- If you don't work for Warwickshire County Council, you must consult your employer regarding details of arrangements for compensation to yourself or anyone harmed by the research, should the need arise, prior to submitting your application.
- Organisations that employ researchers must be in a position to compensate anyone harmed as a result of their negligence.
- Careful consideration must be given to the issues of intellectual property (ownership of the work that has been created through the research) where these are likely to apply.

- You must give details of any grants covering the project and any estimates of expenditure.
- You must state if you, or anyone else will profit financially from the research project.

For more information

- Research Governance Framework for Health and Social Care Research (2005)
- ➤ <u>UK Policy Framework for Health and Social Care Research</u> (2017)
- > Association of Directors of Adult Social Services (ADASS) Guidelines for researchers
- Association of Directors of Children's Services (ADCS) ADCS Research Group
- ➤ Health Research Authority: Research Ethics Service and Research Ethics Committees