



A guide to research activities

Promoting and Supporting Quality Research in Suffolk



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Introduction

Every day County Council staff are helping customers and their families to make decisions about their lives. These decisions are based on knowledge of what works best, knowledge which comes from a number of sources – from personal experience of working with people, feedback from customers, service evaluations and research.

Research is essential in planning and delivering effective and high quality care services. The amount of research taking place across care services has never been as great.

But how do we know that the research *used* to inform practice is of a good enough standard? How can we ensure that the research we *undertake* meets these standards too? How can members of the public involved in research have *confidence* in the benefits of these projects?

While universities and other professional bodies often employ ethics committees to monitor and evaluate the quality of research, there has been no formal way of doing this within care services.... until now.

Children and Young People and Adult & Community Services

Within Suffolk County Council, social care services are organised into two

Directorates:

- Children and Young People, which comprises Education, Connexions, Early Years and Children's social care services;
- Adult and Community Services, which is made up of Adult Community Learning, Libraries & Heritage and Adult social care services.

While the government only requires us to scrutinize research carried out in Social Care Services, the principles of good practice are universal and can be applied across all research projects, and cover all types of participants and service areas.

All social care services within both Children & Young People's Directorate and all of Adult & Community Services will therefore adopt the ethical standards outlined by the Research Governance Framework.

Research Governance

Research Governance is aimed at the promotion of quality research and the removal of unacceptable variations in research practice across health and social care.

(Essex County Council RGF)

In 2001 the Department of Health introduced the 'Research Governance Framework for Health and Social Care', outlining the general principles of good research practice:

- **ethics**: ensuring the dignity, rights, safety and well-being of research participants;
- **science**: ensuring the design and methods of research are subject to independent review by relevant experts;
- **information**: ensuring full and free public access to information on research findings;
- **health and safety**: ensuring the safety of research participants, researchers and other staff at all times;
- **Finance**: ensuring financial probity and compliance with the law in the conduct of research.

The Research Governance Framework places a responsibility on Local Authority Social Care departments to ensure that any research taking place within their organisation has been assessed against these good practice standards.

But Research Governance is not just about setting standards.

It is about supporting and encouraging individuals to undertake research and to use the findings from research to inform practice decisions.

You can access a full text copy of the Research Governance Framework for Health & Social Care (Second edition, 2005) at

<http://www.dh.gov.uk/assetRoot/04/10/89/65/04108965.pdf>

What is Research?

'Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.'

(Department of Health)

The definition used for Research Governance is intentionally broad, and includes activities that are not traditionally labelled research such as:

- surveys
- evaluations
- focus groups
- best value reviews
- audits
- student projects and dissertations
- some forms of consultation

The only activity that is ruled out is the *routine collection of management information*.

Research Governance covers both internally and externally funded projects as well as projects carried out in-house or by people employed by other organisations.

Please see Appendix E for examples of research that are covered by Research Governance.

How does Research Governance affect me?

There are 4 main reasons why you may become involved in research:

- you may want to ***conduct*** some research yourself, either as part of a training programme, (BA Social Work, PQ, Leadership & management training etc), or as part of your job;
- you may be asked to ***participate*** in a research project that is conducted by someone else;
- you may be asked to ***assist*** researchers to contact key groups of people who use services, their family carers or staff groups;
- you may be involved in ***funding*** research activity.

In whatever capacity you become involved in research, if the project involves contacting or accessing data relating to any of the following groups it will be covered by the Research Governance Framework:

- children and young people who use services
- adults who use services
- family carers
- staff or volunteers of Adult & Community Services
- staff or volunteers of Children's social care services within the Children & Young People Directorate
- staff or volunteers of contracted agencies.

The Research Governance Group (RGG)

A Research Governance Group has been established to evaluate and give final approval for all research studies.

Current members of the group include:

- Head of Service Development Care
- Research & Analysis Manager
- Professional Advisors for both Adult & Children's social care services
- Representatives from Learning & Development
- Representatives from Performance

In addition to evaluating proposals the Research Governance Group also supports researchers in developing projects to ensure they meet quality standards.

A list of all projects approved by the Research Governance Group is maintained on the Suffolk County Council website:

www.suffolk.gov.uk/CareAndHealth/ResearchGovernance

A full text copy of all project findings will be placed in the corporate library (The Knowledge Centre) based at Endeavour House.

Information about all projects and their findings is placed on the Social Care Institute of Excellence (SCIE) National Research Database: www.scie.org.uk/research

Research Governance Group – Terms of Reference

The Research Governance Group's role is to consider any proposal to undertake research, including a study, survey or consultation that involves children or adults who use care services, their family carers or council staff.

In doing so the group will: -

- Promote research and the research evidence database, both within and outside the council;
- Review all applications for research;
- Make decisions about research applications on the basis of set criteria (see Risk Matrix Tool at Appendix B);
- Ensure consistency and quality of research standards;
- Prevent multiple or repeated requests for access to children and/or adults who use services, their family carers and staff;
- Provide advice to researchers about the process, their research proposal and approval decisions;
- Protect the interests of children and/or adults who use services and family carers;
- Protect the interests of staff;
- Ensure the council is not exposed to undue risk arising from research;
- Establish mechanisms to ensure research is monitored by appropriate council officers following approval being given;
- Ensure the Council's legal requirements are met (e.g. Equal Opportunities, CRB, Data Protection, Caldicott, Freedom of Information, Mental Capacity);
- Oversee a register of approved research projects;
- Ensure information on research projects is submitted to the National Social Care Research Register;
- Register approved and completed research on the SCIE database;
- Periodically report on research activity involving children and/or adults who use services, family carers and council staff;
- Delegate such decisions (e.g. to the Research and Analysis Manager) as it considers fit;
- Monitor these delegated decisions;
- Monitor research outcomes;
- Maintain a collection of completed research projects in the Knowledge Centre, with researcher's agreement.

The Researcher

Does my project need formal approval?

Anyone wishing to undertake research that involves children and/or adults who use services, their family carers, staff or data about any of these groups will need to have their project plan registered and approved by the Research Governance Group.

This applies to all of the following:

- student projects and dissertations that involve research
- internally funded and externally funded research projects
- research that is carried out in-house as well as projects that are conducted by external researchers, i.e. people who are employed by another organisation (this includes provider agencies)

The following questions should help you to decide if your project is subject to formal approval:

1: Are you attempting to discover answers and new knowledge by addressing clearly defined questions with systematic and rigorous methods?

✓ **Yes** - This is research and must be submitted for approval

2: Will additional information to that routinely obtained from people who use services, their family carers, staff, volunteers and stakeholders be collected as part of the work (for example via survey, interview, focus group etc)?

✓ **Yes** – This work is subject to Research Governance approval

3: Will you require access to existing information, (anonymised or named,) held by Children and Young People or Adult & Community Services for reasons other than to monitor performance and plan services?

✓ **Yes** - this work is subject to Research Governance approval

What if my project has already been approved by another organisation?

Even if your project has already been approved by an external ethics/scrutiny committee, (i.e. from a University, Health or other professional body), it must still be approved by the Research Governance Group.

When making an application to the Research Governance Group, please include a copy of any external approval the project has received.

What is the Application Process?

If you wish to undertake a piece of research you must first complete a research application form. A copy of the application form can be found at Appendix A of this booklet or downloaded from the website:

www.suffolk.gov.uk/CareAndHealth/ResearchGovernance

The application form gives you an opportunity to present your ideas and proposed actions to the Research Governance Group. It has been designed to act as a checklist to assist you in providing all the relevant information the Research Governance Group will need in order to make a decision. It is important to give as much detail as possible, as missing information will cause delays in the approval process.

Once you have completed the application form, you can post it to:

Head of Service Development, Care
Adult & Community Services
Endeavour House
8 Russell Road
Ipswich, IP1 2BX

or email it to: research@socserv.suffolkcc.gov.uk

What supporting information will I need to send with my application form?

You will need to include:

- a timetable for your project;
- a copy of the information letter and copy of any consent forms you intend to send to participants;
- copies of any questionnaires;
- copies of the questions you are going to ask if you are using formal interviews;
- a summary of the discussion topics you are going to use if you are using informal interviews or focus groups;
- any letters of permission from participating organisations;
- confirmation that CRB checks have been completed, if appropriate;
- a copy of any external approval the project has received.

How long will it take to assess my application?

Once the Research & Analysis Manager has received your proposal, it will be passed to the Research Governance Group to consider at their next available monthly meeting.

Do I need to attend the Research Governance Group?

It is not necessary for applicants to attend the Research Governance Group. If, however, you wish to make your application in person, please inform the Research & Analysis Manager when submitting your proposal.

Gaining approval

The Research Governance Group may reach 4 different decisions:

- it may approve your proposal in full;
- it may approve your proposal subject to amendments being made;
- it may reject your proposal because the risks to participants are too high, the benefits of the research are felt to be insufficient or undeveloped, or because someone else has done a similar piece of research;
- If your research proposal involves research participants who lack mental capacity then we are required to forward it to a nationally accredited group, for approval (see appendix D).

How will my project be evaluated?

The Research Governance Group will assess your proposal against the five good practice standards of research (see p4). In addition, a Risk Matrix Tool has been designed to assist in the evaluation of research projects. A copy of the Risk Matrix Tool can be found at Appendix B.

If approval is not given the research must not be carried out.

How will the project be monitored?

It is the responsibility of the research sponsor to ensure that the project follows good practice and ethical standards throughout, (see Roles and Responsibilities on p14). In addition they must ensure that the project keeps to the approved work plan/proposal. The sponsor is also responsible for managing any complaints that arise from the project or inappropriate behaviour in the conduct of the research. The Research & Analysis Manager should be kept informed of the progress of the study.

What must I do once the project is completed?

Once you have completed your project you must first share the research findings with your line manager/sponsor. The final report should then be submitted to the Research Governance Group.

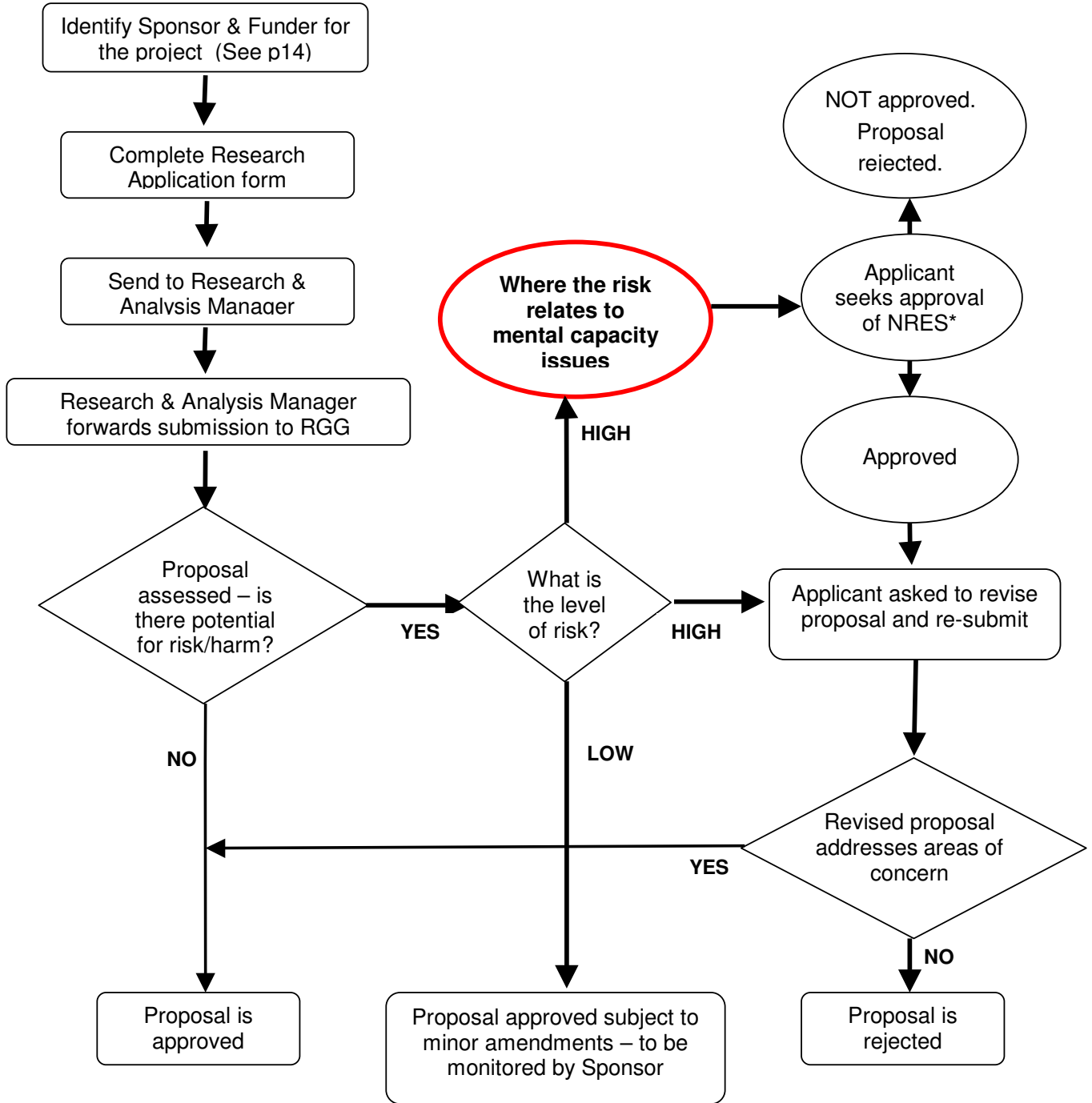
Once the report has received a final sign off by the Research Governance Group, the findings can be disseminated further.

All research participants must receive a copy of the research findings in an appropriate/user friendly format.

A copy of the final report will be placed in the corporate library or published on the website, for staff to access. The research will be registered in the SCIE database.



Summary Process Chart



• Any research for which participants are unable to give voluntary consent require the approval by an approved body.

NRES (National Research Ethics Service) to be contacted for social care research until SCREC (Social Care Research Ethics Committee) is operational.

Roles and Responsibilities in Research

In any research project there will be a number of different people involved. The grid below describes the main roles and responsibilities that may be associated with any research project.

It is essential that every research project has a named sponsor and funder.

In the case of in-house research there may be no difference between the Funder, Sponsor, Employing Organisation and Care Organisation. In the case of in-house research the Sponsor will be the project commissioner or your line manager.

If the study is part of academic work the University or College will be the Organisation and a named tutor the Sponsor

<i>Role</i>	<i>Responsibility</i>
<i>Care Organisation</i> Organisation providing health or social care to service users/carers participating in a study	<ul style="list-style-type: none">• ensuring that research involving their service users, carers or staff meets the standards set out in the Research Governance Framework• ensuring there is ethical approval for all research for which they have a duty of care• retaining responsibility for research participants' care
<i>Employing Organisation</i> Organisation employing the Principal Researcher. Employers remain liable for the work of their employees	<ul style="list-style-type: none">• ensuring researchers understand and discharge their responsibilities• ensuring the research is properly designed, and that it is well managed, monitored and reported, as agreed with the sponsor• taking action if misconduct or fraud is suspected
<i>Funder</i> Organisation providing funding for the study	<ul style="list-style-type: none">• assessing the quality of the research proposal• ensuring that the research commissioned represents a proper use of the funds it controls and is good value for money• assessing the quality of the research environment and the experience and expertise of the researchers• ensuring that a sponsor has been identified before research begins

<p>Principal/ Main Researcher</p> <p>The person designated as taking overall responsibility for the design, conduct and reporting of the study</p>	<ul style="list-style-type: none"> • developing proposals that are sound and ethical • seeking independent ethical review in social care • conducting research to the agreed proposal, in accordance with legal requirements and guidance • ensuring participants' welfare while in the study • feeding back results of research to participants
<p>Research Governance Group</p> <p>Committee established to provide an independent opinion on the extent to which proposals for a study comply with recognised ethical & good practice standards</p>	<ul style="list-style-type: none"> • providing independent expert opinion on whether the proposed research is ethical, methodologically sound and respects the dignity, rights, safety and well being of participants
<p>Sponsor</p> <p>Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage & finance a study</p>	<ul style="list-style-type: none"> • taking overall responsibility for confirming that everything is ready for the research to begin, including: <ul style="list-style-type: none"> - putting and keeping in place arrangements for initiation, management and funding of the study - satisfying itself the research protocol, research team and research environment have passed appropriate quality assurance - satisfying itself that the study has ethical approval before it begins - satisfying itself that access arrangements to respondents and/or their data are in place - satisfying itself that arrangements will be kept in place for monitoring and reporting on the research, including prompt reporting of suspected serious adverse incidents • ensuring the research complies with the law

Everyone involved in carrying out or monitoring research needs to be aware of their legal and ethical responsibilities in relation to:

- the Data Protection Act 1998, (amended 2000)
- Freedom of Information Act 2000,
- Role of Caldicott Guardian.
- Mental Capacity Act 2005

Please see Appendices C and D for further details.

The Participant

What does Research Governance mean for me?

If you are asked to take part in a survey or some kind of research or consultation, you will know that:

- the research carried out is likely to be of a good standard, is of value and will have been fully approved;
- the reasons for the research and your role in it will be fully explained to you in a way that is clear and easy to understand;
- you have certain rights – for example the right not to take part or to withdraw from the study at any time without it affecting any services you receive;
- you will be told about the results;
- you will know who you can make a complaint to if necessary.

If you are in any way concerned about a piece of research you are involved in please contact the Head of Service Development, Care on 01473 264661.

*Remember: you have the right to withdraw from a research project
at any time, without it affecting the care services you or
your relative receive from Adult & Community or
Children & Young People's Services*

Assisting a Researcher

How does Research Governance affect me?

You or your organisation may be approached to help researchers contact individuals to take part in a project. These individuals may be:

- children or young people who use services
- adults who use services
- family carers
- staff of Adult & Community Services
- staff of Children's social care services within the Children and Young People Directorate
- staff or volunteers of contracted agencies

Before you assist a researcher in this way, you must make sure that the project has received approval from the Research Governance Group. If approval has been given, the researcher will be able to provide a copy of the approval letter.

If you are unsure about whether a project has been evaluated by the Research Governance Group, or wish to find out more information about a particular project please contact:

Head of Service Development, Care
Adult & Community Services
Endeavour House
8 Russell Road
Ipswich IP1 2BX

01473 264661

research@socserv.suffolkcc.gov.uk

When putting researchers in touch with participants you must be clear about your responsibilities under the Data Protection Act 1998. Please refer to Appendix C. If you have any questions or concerns about what information is covered by Data Protection, please contact the Research & Analysis Manager.

You must only supply information that is relevant to the needs of the research project and has been agreed by the Research Governance Group

The Research Funder

If you or your organisation are considering funding a research project you must:

- assess the experience and expertise of the research team to undertake the work proposed;
- evaluate the quality of the research design to ensure that it is appropriate to the needs of the project;
- establish that the project represents proper use of funds and offers value for money;
- ensure that the project is adequately financed;
- ensure that a research application is submitted to the Research Governance Group.

The funder must also ensure that the project has a named sponsor. If a sponsor cannot be identified it is expected that the Funding Organisation will assume this role as well. (Please see p14 for Sponsor's responsibilities.)

The Care Provider

The Research Governance Framework covers all individuals receiving care services funded by Suffolk County Council. Providers wishing to undertake research involving these customers will therefore need to submit their proposal for Research Governance approval.

The principles of good practice outlined in Research Governance are universal i.e. they can be applied across all research projects, (not just social care), and cover all types of participant.

We would encourage providers to consider the benefits Research Governance offers in protecting all individuals.

We would therefore strongly recommend that providers wishing to undertake research with privately funded customer should also consider submitting a proposal for Research Governance approval.

Appendix A - Research Application Form

Research Title

Date of Application

Details of Main Researcher

Name

Job title

Address

Telephone no. (Inc. STD)

E-mail address

What experience do you have in undertaking research? Please give details of any relevant previous research

Details of person completing form *if different from Main Researcher*

Name

Job title

Address

Telephone no. (Inc. STD)

E-mail address

Details of Organisation Employing Researcher:

Name

Address

Telephone no. (Inc. STD)

E-mail address

Details of Sponsor

The sponsor takes responsibility for the initiation, management and financing of the project

Name

Address

Telephone no. (Inc. STD)

E-mail address

Details of Funder

The main organisation providing funding for the study through contracts, grants or donations. The funder has a key role in quality assurance

Name

Address

Telephone no. (Inc. STD)

E-mail address

Estimated costs of the project

What is the reason for the study?

Points to cover

1. Why are you undertaking this research?
2. Is it part of an academic course/study? If yes, please describe the course and give the name of the academic institution and your tutor

Background

Points to cover

1. Why is this topic important?
2. What is your particular area of interest?
3. What other projects/studies have been carried out in this area?
4. What existing sources of evidence have been considered?

Aim & Purpose**Points to cover**

1. What is the main question you are trying to answer?
2. What specific questions will you ask to address the main question?
3. How will your research add to any previous work?
4. What are the anticipated benefits to the service user and/or the authority?

Sample Details**Points to cover**

1. Who are you targeting?
2. How are you going to select your sample?
3. How many people will be involved?
4. Where will your study take place?
5. What sort of data will you be collecting?

Ethics

Points to cover

1. How are you going to recruit participants?
2. How will this comply with equal opportunities policy?
3. How will you obtain informed consent?
4. Are you going to involve your participants in planning the way in which it will be carried out?
5. Will you be paying your participants?

Risks

Points to cover

1. What potential risk or harm is there to your participants and yourself?
2. What arrangements will be made to deal with the risks involved in this study?
3. Have you checked your organisation is insured should they need to pay compensation or insurance?

Data Handling & Storage

Points to cover

1. How are you going to collect your data? e.g. questionnaire, interview, consultation, case file audit etc
2. Will recording or video equipment be used?
3. How are you going to make sense of your data?
4. How do you propose to store your data?
5. How long will you keep data?
6. How will you ensure confidentiality and anonymity of data?
7. Who will have ultimate ownership of the data?

Communication

Points to cover

1. What arrangements are you making to keep participants and others informed during the study?
2. How will you present the findings of your research? e.g. presentation, report, publication in journal
3. Will the way in which you present the findings of your research be appropriate to your audience?

In which parts of the research, if any, have people who use services and their family carers been actively* involved?

(*by actively involved we mean research that is carried out **with** or **by** people who use services, rather than research that simply gathers information from participants)

- As user researchers
- As members of a research group
- In commenting on documents
- As members of a departmental or wider research strategy group
- None of the above

Does the project involve:

- Work with children under the age of 16 Yes No
- Work with vulnerable groups Yes No
- I confirm that a safeguard check with the Criminal Records Bureau has been carried out on all researchers working on this project 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 Criminal Records Bureau. It is your responsibility to ensure that you have this clearance before commencing work with members of any of these groups.

Planned start date of research

Estimated completion date

State any key milestones

Is this your first application for registration for this project? Yes No

Date of previous application _____

Declaration

I have read the Guide to Research in Suffolk. I agree to carry out my study in accordance with Suffolk County Council Adult & Community Services and Children and Young People’s Services Research Governance Guidance and I understand that failure to do so could result in serious consequences.

Main Researcher Signature

Date:

Appendix B - Risk Matrix Tool

		Likelihood of harm				
		HIGH.....	LOW	Level of risk	
Subject/ participant characteristics	Informed consent & ability to withdraw from study not possible or unlikely due to age of child or incapacity of adult. Communication issues arising from language or literacy issues, sensory or speech impairments	Informed consent & ability to withdraw from study possible with a support to overcome communication barriers e.g. advocates, translators/interpreters, signers, or technology.	Informed consent and ability to withdraw from study fully possible.	⇒	Concerns about informed consent & communication barriers are fully identified & addressed	
					Concerns are not fully identified or addressed	
Researcher competence	Researcher(s) not well qualified with little or no experience or knowledge of either the topic of investigation, the participants or the methods to be used e.g. undergraduate researcher /student project.	Researcher(s) reasonably well qualified with experience and knowledge of two out of the three following factors – topic of investigation, the participants/ subjects or the methods to be used, e.g. non-researcher who has had formal research training who may work in a professional domain offering relevant experience and knowledge.	Researcher(s) well qualified with experience and knowledge of all three of the following factors – topic of investigation, the participants/subjects and the methods to be used. E.g. formal research training and/or qualification and/or experience and knowledge gained from working in an appropriate environment.	⇒	Any lack of competence by the researcher(s) fully addressed	
					Any lack of competence is not addressed	
Nature of information being sought	The topic and kinds of information being sought are likely to be regarded as highly personal or sensitive by those from whom it is being collected or about whom it is to be obtained. e.g. criminal records, psychiatric history etc.	The topic or the kinds of information being sought include items likely to be considered slightly personal or sensitive by some people e.g. age, ethnicity, income.	The topic and kinds of information being sought do not focus on personal information at all e.g. opinions about services received.	⇒	The need to collect any personal information is fully justified	
					The need to collect this information is not fully justified	
Appropriateness of method to subject & quality of research design	The methods are neither appropriate to the subject of the proposed study or the research questions being asked, the need for the study is not established and the project does not have the resources to properly address the research question(s)	The methods may not be appropriate either to the subject of the proposed study or to the main research questions, or the need for research is not established, or the project does not have the resources to properly address the research question(s)	The methods are fully appropriate to the subject of the proposed study and to the research questions being asked. There is a demonstrable need for the study and the resources to carry out the study are sufficient.	⇒	The case for & resources to do the study exist & methods are fully appropriate to the subject or main research questions	
					The case for & resources to do study are absent & methods are not appropriate to subject or main research questions	
Methods/ nature of data collection	High levels of face to face contact and/or interaction between investigator and participant e.g. participant observation or observation study	Some face to face contact and interaction for limited amounts of time.	No face to face interaction between investigator and participant	⇒	Possible risks arising from high level of contact are identified and fully addressed	
					Possible risks are not identified or addressed	
Level of privacy to participant	Not confidential	Confidential.	Anonymous.	⇒	If the study is not anonymous or confidential reasons for this are fully justified & conform to Data Protection Act principles.	
					Study is not anonymous or confidential and reasons for this are not fully justified	
Relationship between investigator & subjects/ Participants	Subjects/participants are personally known to investigator & investigator may have other duties or responsibilities towards all or some of the research participants which may create potential conflicts of interest	Limited information about subjects/participants is provided to the investigator to make the study possible or more reliable.	Subjects/participants are unknown to the investigator and cannot be identified.	⇒	Conflicts of interest are fully described & consideration given to how to minimise possible effects on study	
					Conflicts of interest are not fully described. Proposal does not adequately consider how to minimise effects on study	
External considerations	Study is likely to be extremely sensitive.	Parts of study may be sensitive.	No known sensitivities	⇒	Sensitivities have been identified and adequately addressed	
					Sensitivities have not been adequately addressed.	

Equalities – reasonable steps should be made to ensure that the research sample is representative i.e. particular groups of people are not excluded from the study due to language, ethnicity, gender, age, disability, sexual orientation or religious reasons

Benefits of the Research – It is essential that the researcher outlines the potential benefits of the research to enable the RGG to weigh up the potential risks against the possible benefits of the project.

Appendix C - Research Governance Framework: The Legislative Context

Data Protection Act 1998 (as amended 2000)

The purpose of the Data Protection Act (DPA) is to protect the rights of individuals by ensuring the ways in which data is obtained, stored, processed and shared by others is strictly governed. The DPA relates to personal data or information held by organisations about individuals.

What is personal data?

Personal data includes anything that can help identify an individual e.g. name, address, car registration, national insurance number etc.

Sensitive personal data includes information concerning racial/ethnic origin, political or religious beliefs, trade union membership, physical or mental health, details of sexual orientation, criminal record etc. In the case of sensitive personal data, subjects must give their explicit consent before data can be processed.

What are the Key Principles of the DPA?

1. Personal data must be processed fairly and lawfully. Data can only be processed if ONE of the following conditions apply:
 - the individual about whom the data has been collected has given informed consent i.e. they clearly understand the purpose for which the data is being collected and how it will be stored;
 - it is necessary for:
 - i. performance or contract
 - ii. compliance with legal obligations
 - iii. protection of a person's vital interests, i.e. their life
 - iv. administration of justice
 - v. crown/public functions
 - vi. legitimate interests of a data controller/third party
2. Personal data must only be used for the stated purpose and should not be used in any other way without explicit consent from the data subject;
3. Personal data shall be adequate, relevant and not excessive;
4. Personal data shall be accurate and where necessary, kept up to date;
5. Personal data processed for any purpose or purposes shall not be kept for longer than is necessary;
6. Personal data shall be processed in accordance with the rights of data subjects;
7. Security measure shall be taken to prevent unauthorised or unlawful processing of personal data, and to protect against accidental loss or destruction or damage to personal data;
8. Personal data shall not be transferred to a country or territory outside the European economic area, unless that country or territory ensures an adequate

level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

Role of Caldicott Guardians

Caldicott Guardians are senior staff in the NHS and Social Services appointed to protect the personal information of service users.

Caldicott Standards

1. *Justify the purpose.* Every proposed use or transfer of personally identifiable information within or from an organisation should be clearly defined and scrutinised, with continuing uses regularly reviewed by an appropriate Guardian.
2. *Do not use personally identifiable information unless it is absolutely necessary.* Personally identifiable information items should not be used unless there is no alternative.
3. *Use the minimum necessary personally identifiable information.* Where use of identifiable information is considered to be essential, each individual item of information should be justified with the aim of minimising the need to identify individuals.
4. *Access to personally identifiable information should be on a strict need-to-know basis.* Only those individuals who need access to personally identifiable information should have access to it, and they should only have access to the information they need to see.
5. *Everyone should be aware of their responsibilities.* Actions should be taken to ensure that those handling personally identifiable information are aware of their responsibilities and obligations to respect an individual's confidentiality.
6. *Understand and comply with the law.* Every use of personally identifiable information must be lawful. Someone in each organisation should be responsible for ensuring that the organisation complies with legal requirements.

Freedom of Information Act 2000

The Freedom of Information Act 2000 (FOI) gives a general right of access to all types of recorded information held by public authorities, including the NHS and local authorities. Exemptions from that right are specified in the Act (for example, information relating to personal data, law enforcement, national security, etc). More details on Freedom of Information can be found at <http://www.dca.gov.uk/foi/index.htm>

Appendix D – The Mental Capacity Act 2005

Introduction

The Mental Capacity Act 2005 (MCA) provides a statutory framework to empower and protect vulnerable people who are not able to make their own decisions at the time that the decision is required to be made. It makes it clear who can take decisions, in which situations, and how they should go about this. It enables people to plan ahead for a time when they may lose capacity. The MCA received royal assent on 07 April 2005 and applies to England and Wales.

The legal framework provided by the MCA is supported by the Mental Capacity Act Code of Practice which provides guidance and information about how the Act works in practice. A link to the Code is attached here: <http://www.dca.gov.uk/legal-policy/mental-capacity/mca-cp.pdf>

The Code has statutory force. People who are placed under a duty to have regard to the Code include those working in a professional capacity e.g. doctors, social workers and those conducting research that falls under the Act's research provisions.

Under Section 42 of the Act any person carrying out research in reliance on any provision made by or under the Act (Section 30 – Section 34) has a duty to have regard to the Code.

When finalising a protocol and applying for ethical review (see Implications for Research Governance) the following chapters of the Code may be particularly useful:

Chapter 2: Setting out the underlying principles of the Act

Chapter 3: Helping people to make decisions for themselves

Chapter 4: Dealing with assessment of capacity to consent

Chapter 11: Describing the criteria for approval of research

A copy of the Mental Capacity Act Code of Practice plus additional guidance, policy documents and further information can also be accessed by following the attached link: www.suffolkas.org

In particular, Chapter 11: 'How does the Act affect research projects involving a person who lacks capacity?' provides relevant information.

Application of the Act to Research

- The Mental Capacity Act applies to England and Wales only;
- Medicinal Trials conducted under the Medicines for Human Use (Clinical Trials) Regulations 2004 are specifically except from its provisions;
- The research provisions of the Act (Sections 30 – 34) apply to the conduct of intrusive research. **Intrusive research** is defined in Section 30 (2) of the Act as:

Research of a kind that would be unlawful if it was carried out:

(a) on or in relation to a person who had capacity to consent to it

(b) but without his / her consent

The Mental Capacity Act (2005) has a number of implications for the practice and governance of research, most of which represents existing good practice. The specific implications of the Act for social care research governance procedures provided in outline here and readers are strongly advised to read the Code of Practice, a link to which is provided above.

In addition the Department of Health has produced guidance regarding Research Governance relating specifically to the MCA. A copy of this guidance which has been adapted by Suffolk County Council.

The Act is underpinned by a set of **5 key principles** to which staff have a duty to consider when undertaking research. These are explained in full within Chapter 2 of the Code of Practice.

Implications for Research Governance

Section 30 of the Act makes it clear that these provisions directly apply to any research for which participants are unable to give voluntary consent. All such research will need approval by an approved body and only ethics committees operating under the National Research Ethics Service (NRES) are recognised to approve research proposals under the MCA.

It is intended that the new Social Care Research Ethics Committee (SCREC) will be able to undertake this role for social care research although unfortunately at this time (October 2008) the SCREC is not yet fully operational.

In the interim, applications under the MCA relating to research outside the NHS will be accepted for review by the NHS Research Ethics Committees (NHS RECs) and NRES has designated around 30 RECs to receive new applications under the MCA, who are aware of the scope of the Act and that they may receive non-NHS applications. Any research that is undertaken and is not approved by a recognised committee will be unlawful under the MCA.

A link to the NRES website is attached which contains details of these committees and how to apply:

www.nres.npsa.nhs.uk/applicants/help/faq/mental-capacity-act-research-outside-the-nhs/

If a small evaluation or audit is being considered rather than a comprehensive research project then it is likely that this process does not need to be adhered to, although it is advisable to discuss this with an NRES adviser who will be able to provide practical help and advice to researchers.

References and acknowledgements

Department of Health (2007) 2nd Edition Research Governance Framework, Resource Pack

Department of Health (2008) Guidance on nominating a consultee for research involving adults who lack capacity to consent, London, The Stationary Office.

Mental Capacity Act (2005). www.opsi.gov.uk/acts/acts2005/ukpga_20050009_en_1

Ministry of Justice (2007) Mental Capacity Act 2005, Code of Practice, London, Stationery Office www.justice.gov.uk/guidance/mca-code-of-practice.htm

Appendix E - Examples of Research

Surveys are a very quick and easy way to gather the views of service users, their family carers, or staff involved in the provision of services. As a result, questionnaires are used frequently and in many different types of projects. Here are some different ways surveys have been used.

The **User Experience Survey**, commissioned by the Department for Education and Skills, gathered the views of children aged 10-17 known to Social Care Services. The results formed part of the overall performance evaluation of children's services by Government.

There is a lot of national data relating to the incidence of falls and the devastating impact falls can have on the lives of older people. There is, however very little regional data available. **Project Voice** aims to gather statistical data about falls within Suffolk, as well as gaining an understanding of older people's attitudes to falls, through self-completion questionnaires distributed via GP surgeries, mobile library units and Citizen's advice bureaus. The results will be used in the development of falls prevention services.

Longitudinal Surveys are generally conducted by professional or academic researchers. These involve monitoring individuals and collecting information about their changing circumstances over a number of years. Information may be gathered in a number of different ways.

The Centre for Child & Family Research has undertaken a **Prospective Babies Study**, building on the findings from their earlier Retrospective Babies Study. This project proposes following a cohort of children from the age of 0-3, tracing the decision-making processes that influence their life pathways. Information will be gathered from key individuals involved in the child's life – parents, carers, social workers, GP's etc, throughout the course of the project. Data will be gathered in a variety of ways including face-to-face interviews, case-file examination, and the use of observational tools e.g. HOME inventory.

Service Evaluations:

All organisations involved in providing care services will undertake service evaluations at some time. Residential homes may undertake internal reviews, voluntary organisations will assess the effectiveness of their service provision, social care departments will evaluate their current working practices. Data to inform service evaluations can be gathered in many different ways. A simple evaluation may only require statistical data e.g. how many customers have we served over what period of time, what services were provided etc, which can be extracted from databases or service records. More complex evaluations may involve seeking views of customers and staff through face-to-face interviews or self-completed questionnaires. Most service evaluations will be undertaken internally.

In 2006 the Adult Services Senior Management Group commissioned a **Review of the Community Teams** to assess current working practices and identify areas for future development. Information was gathered through a series of face-to-face structured interviews with a cross-section of staff from the community teams. The findings of the review contributed to the restructuring of the assessment and care management function.

Consultations:

There is a fine line between consultation and research.

Consultation differs from research in that it:

- is typically directive (from organisations) and conducted over short time scales
- usually addresses a narrow group of questions, often seeking expression of a preference for/endorsement of a change or modifications to a service
- may be more arbitrary and less systematic because generalisability is considered less important
- uses a smaller range of methods
- usually requires implicit consent rather than formal written consent

However consultation can involve the collection of personally sensitive information and may raise ethical issues. Furthermore any attempt to go beyond the answers to specific questions, and understand their underlying meaning moves the work into the field of research. As such, consultation should be subject to the same basic safeguards as more formal research projects.

Student Projects:

Many academic courses now require students to undertake a piece of research as part of their assessment. Tutors will offer advice on the type of research project required and will assist students in gaining ethical approval from the associated academic body. However if the research project involves people who use care services, family carers or staff of Children's social care services or Adult & Community Services, then it must also be submitted to the Research Governance Group for approval.

'Endings in Foster Care Placement' explored the process of loss for foster carers when placements end. In particular it looked at the psychological and emotional impact on carers when foster children leave. This project was conducted by a student as part of her Doctoral Degree in Clinical Psychology.

Audits:

Audit can be divided into structural, process or outcome. As an example of a structural audit you might check whether certain basic procedures and guidelines were in place at your practice. A process audit would then be to see if these guidelines were being followed and an outcome audit would try to assess if the quality of care was being improved. Auditing involves collecting together information from a range of sources and individuals using a variety of methods.

The Professional Advisors within Children's Social Care Service have undertaken a programme of themed audits. The themes of the audits were agreed by the Children's services management team – child protection, looked after children, family support and referral & assessment. Within each of these themes the Professional Advisors focus on a particular issue e.g. neglect/abuse. Each audit consists of 10-12 cases. A report is produced outlining the findings of the audit and an action plan is drawn up. Information for the audit is gathered through file sampling, questionnaires, and interviews.