

Research Governance Framework

Handbook

revised Oct 2007



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1. Introduction

Thinking of doing social care or related research on the Isle of Wight?

The Council is an ethical and competent learning organisation. We further this by encouraging high quality and safe research across the public and third sector community.

Research benefits our knowledge about the community and how we act. If undertaken competently and responsibly, it improves lives and benefits our environment. We also have a responsibility to ensure that research is carried out in a proper, non-abusive and respectful way.

This is why we have a process for supporting and giving approval to research.

What does the Research Governance Framework cover?

We count 'research' as including any study, survey or consultation intended to gather information, which involves access to people in contact with public or community services, either directly or indirectly.

Our research governance framework covers all forms of research conducted by external researchers as well as the staff of the Council and our other public and third sector partners.

The Council will not sponsor or support research involving social care service users, their families and carers unless it has been approved by the research governance framework. Other research involving citizens using a wide range of public and third sector services may also be required to have full approval.

The Research Co-ordinator can discuss early ideas and proposals; some projects may not need to use the process.

If research ideas are realistic and achievable, researchers can apply online through this website to gain approval to proceed. Applicants will need to prepare and submit a full research proposal that will set out how the project is worthwhile and safe to proceed. Information on how to do this can be found in the section called 'Making an Application'.

Students undertaking research through a university can ask their supervisor to provide advice and support in preparing a research proposal. There is also plenty of information

on this website that clearly sets out what is needed in a full application, and there is a web link to our easy online application process.

Projects can benefit from our expertise and links.

Our research framework is not simply an approval process. Our reviewers will give helpful advice and support to competent applicants if it will improve the rigour of methodology, the ethical approach or the benefits of the project. Applications have access to a pool of expertise and knowledge.

We can also advise applicants on making applications to other governance processes and NHS bodies.

If I decide to submit a research application – what next?

Research applications pass through our research approval process. We will decide whether to approve research proposals by checking them against our standards and principles criteria.

Once we have your application form and proposal we will give you a decision as soon as we can. If your application is straightforward, you have addressed all the areas outlined in the Research Proposal Guide and it does not involve a level of risk to participants, your application should be processed quite quickly; often within two weeks. If your application is more complex, it will be referred to the Research Governance Board and this decision might take a bit longer.

What happens when I get approval to proceed?

Provided your application is given approval to proceed, you will be able to go ahead with your agreed project plan. Your research will be registered on the Council's research database and if appropriate on the Social Care Institute for Excellence online database. You will also be helped and monitored by a named contact within the sponsoring organisation.

We will expect you to keep to your project plan and to maintain the high standards that were agreed in the application. The Research Governance Board will take steps to intervene if there is evidence that this is not the case

If you do not receive approval, you will be given reasons and information about how to appeal the decision. Where possible, you will be given advice on how you might change your proposal to ensure it complies with the Council's requirements.

Contacts

Who should I contact to find out more?

Contact the Research Governance Co-ordinator to discuss your ideas and making an application.

Martin Johnson, Research Governance Co-ordinator,
Partnership Manager (RGF Lead)
County Hall
High Street
Newport
Isle of Wight
PO30 2EA

Telephone: 01983 823825
martin.johnson@iow.gov.uk

2. Getting Started

Please be sure that you are clear about the application process before planning research.

1. Check through the RGF website or Handbook before making any application.
2. Apply for approval in plenty of time. Don't leave it to the last minute. You will not be permitted to proceed without approval.
3. Be clear about the RGF principles and standards on the 'preparing a principled application' page in this handbook.
4. Check the sections on 'research with people who lack capacity' and 'arrangements for monitoring and supervision'. Check that you have covered these issues.
5. Contact the Research co-ordinator to discuss the application
6. Prepare your research proposal; gather the documents that you need.

Document Checklist	✓
A completed project proposal	
Research timetable	
Information for participants	
Participant consent forms	
References	
CRB Checks (yourself and other researchers)	
You may choose to add:	
A literature review	
Copies of approvals from University, NHS or other RGF panels	
Letters confirming sponsorship and academic support	
A communication and dissemination plan for the final report	

Other documents that will support your application.	
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7. Start to complete the online application form; you can stop at any time and save your form, returning to it later.
8. Check that your proposal and application will satisfy the checklist in the 'research proposal guide' section.
9. Prior to submitting an application, call the Research Governance Co-ordinator and give notice of its arrival.
10. Print off the completed application form and send it with all of the documents to the Research Governance Co-ordinator.

3. Research Standards

Please Check Through This Section Before Completing Our Online Application Form.

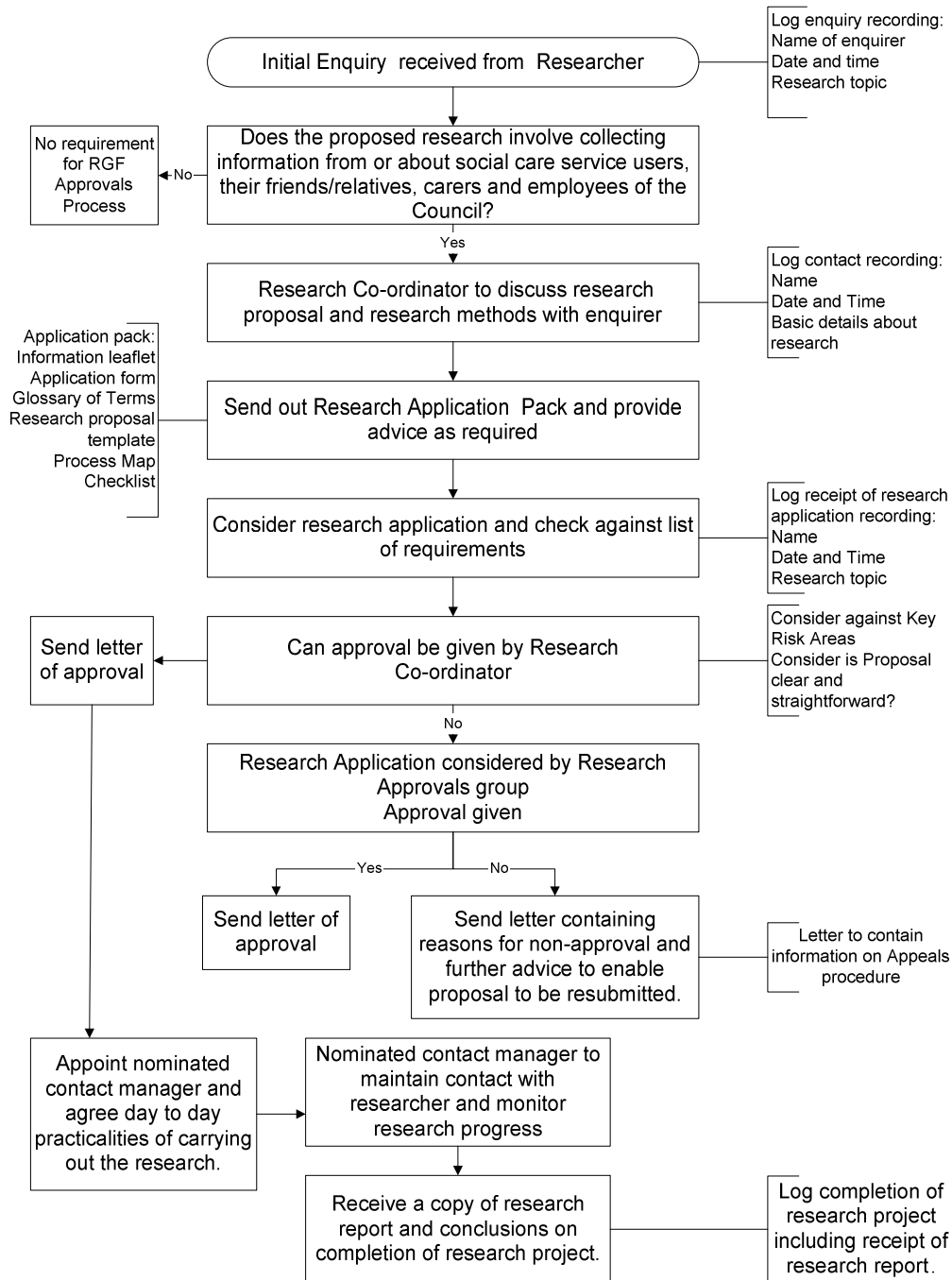
Our standards are common to all good research or evaluation, particularly where the project involves vulnerable people, their families, carers, communities and working people.

1. We regard research to be any form of disciplined inquiry that aims to contribute to a body of knowledge or practice. Projects must be well designed, of benefit and value to participants or subjects, avoid duplication of existing research, and be made fully available to anyone who will benefit from increased knowledge.
2. There must be a clear statement of research aims, which defines research objectives.
3. All research projects must subscribe to general research ethics informed by good practice, which provide guiding moral principles from inception through to completion... and beyond.
4. From the beginning, research should have appropriate and sustainable resources, in terms of people, time, transport, money.
5. Research participants and subjects should be treated with respect and regarded as partners in every project. All participants should have information that sets out clearly and accessibly what the research is about, what it will involve.
6. Informed consent must be obtained in writing on a written form of consent before research participation begins. Where a person cannot give informed consent, seek advice from the Research Co-ordinator about the issues involved.
7. Information collection and analysis methodology must be appropriate to research objectives. Clearly explained choices of methodology are required and we acknowledge that good research often uses a combination of approaches that complement one another.
8. Those involved in designing, conducting, analysing and supervising the research must demonstrate a full understanding of the area being researched.
9. Research must be carried out in an unbiased fashion. Researchers should not influence the results of the research in any way. The effect of bias and any controls to deal with it should be explained.

10. Researchers should be appropriately skilled and knowledgeable about research methods. They must have knowledge of the chosen methods, understanding of research issues, clear appreciation of the needs to safeguard vulnerable people and the possible need for support.
11. Non-abusive approaches to the participation of service users, staff and other people must clearly planned and implemented. Research activity must prevent any adverse effects of participant involvement through revealing information on their behaviour and preferences.
12. Risk and the potential for abuse in the research process must be identified and managed. People must be protected from potential physical or psychological harm, discomfort or stress, threats to a persons personal social standing, privacy, personal values and beliefs, links to family and the wider community, and their position within occupational settings.
13. Researchers must have an understanding of the actions needed should the possibility of risk or abuse be identified during the research process.
14. Applicants are expected to participate in the project approval process, engaging in a positive and constructive way with any advice, criticism or support that may be offered.

4. The Application Process

The agreed process that is followed for handling applications for approval is summarised here.



5. Research Proposal Guide

The following topic areas and questions need to be covered in any application to do research which involves direct or indirect access with social care service users, their families and carers and/or members of Council staff.

How you write your proposal is up to you, but if you can address the criteria in this guide it will help us to make a judgment about your research proposal so answering as many of the questions as possible will simplify the approval process.

Criteria	Questions to address in preparing your research proposal
Background	Why is this research important? What other studies have there been in this area? How will this research add to knowledge in this area? What do you want to find out? What is the main question you wish to answer? What are the specific questions you will ask to address the main question?
How you will do your research	Will you be doing this research on your own or with others? Have you provided full details of anyone else you intend to carry out this research with, including fieldworkers? Who are you targeting in this research? How many people or case files do you intend to interview or read through? Where will the research take place? Will participants be clearly and fully informed of the purpose of the research study? How will you do this? How will participants be clear about the expectations of the researcher? Do you have an information sheet and a consent form for participants? Supervisory arrangements -how do you plan your research will be supervised and monitored and by whom? Who will be funding your research?

- Timetable**
- When will your research start and finish?
 - Are there particular stages to the research e.g. piloting, then main research?
 - If so, what are they?
 - Is the timetable realistic?
 - Is it influenced by external constraints or deadlines?
 - How will you provide regular updates and progress reports and to whom will you provide them?
- Methodology**
- What sort of data will you be collecting? E.g. are you intending to count numbers, talk to people directly or a mixture of the two?
 - What is the main method you will use to carry out the research? E.g. Questionnaire, face-to-face interviews, focus groups, paper reviews etc.
 - How will you collect your data?
 - How will you select your sample?
 - How will you recruit your sample?
 - Will you be piloting your work?
 - Will you be paying participants?
- Ethical Issues**
- Is there any potential risk or harm to yourself or participants?
 - If so, what are the potential risks and what do you intend to do to reduce them?
 - How will you obtain informed consent?
 - Where informed consent is unable to be provided, what will you do? How will your research comply with equal opportunities?
 - How will participants be given the opportunity to complain?
 - Will you be insured against professional negligence claims?
 - How will you deal with complaints made against you by participants?
 - How will you deal with any sensitive matters that may be raised in the course of your research?
 - What follow-up support will be available to participants should they require it?
 - What will you do if the focus of your research project shifts or changes substantially from the proposal?

Data protection

Will you be using recording or video equipment?
How will you make sense of the data?
How will the data be stored?
For how long will the data be stored?
How will it be disposed of?
How will you ensure confidentiality and anonymity of data?
Who will have ultimate ownership of the data?
Are you or do you need to be registered under the Data Protection Act?

Dissemination

In what form will your findings be presented e.g. report, presentation, journal etc?
How will you be disseminating your findings?
To whom will you be disseminating your findings?
How will you ensure anonymity in any publications?
To whom does the research belong and have you thought about intellectual property rights?
Will you agree to have your proposal and results on the Council's research database?

6. Arrangements for Access, Monitoring and Supervision

Researchers cannot work in isolation; arrangements for access to information, monitoring of standards and supervision of work must be planned and implemented throughout the project.

The Sponsor

The researcher must have the agreement and support of a named Council or sponsoring organisation Manager, usually an experienced person, who will be the Council or sponsoring organisation's sponsor for the proposed research project. This person's role is to facilitate access to research participants and to oversee and monitor the progress of the research; however s/he is not responsible for providing support and advice about the research itself.

Applicants and sponsors must be aware of the sponsor role and responsibilities, as set out in the 'Role of the Sponsor' section of this guide.

The Supervisor

The researcher is responsible for identifying an appropriately qualified and experienced research supervisor who is able and willing to provide guidance, support and advice about the research. The researcher is also responsible for securing the supervisor's agreement to undertake this task. If the research is being done through or as part of a university course, the research supervisor will probably be a member of the university's academic staff.

Once a research supervisor has been identified and approved by the local authority, the named person must be fully aware of their role and in particular of the need to: -

- Ensure that the researcher is aware of the council or sponsoring organisation's research governance process.
- Offer regular support and advice throughout the conduct of the study and to monitor the research progress.
- Ensure the researcher maintains regular contact with the named internal manager/sponsor responsible for overseeing the research for the sponsor organisation.
- Promptly bring to the sponsoring organisation's attention any matter that affects the ability of the researcher to continue the research or of the supervisor to continue to provide supervision.
- Promptly bring to the sponsoring organisation's attention any matter that may adversely impact on the interests of the participants, their families or carers or of the council and its officers.
- Promptly bring to the sponsoring organisation's attention any other matter that the supervisor considers relevant.

7. The Role of the Sponsor

As the research sponsor the local authority or host partner organisation has responsibility for overseeing the research ensuring all necessary agreements and safeguards are in place before the research begins.

In particular the person named as the sponsor in the application should ensure that the following areas are addressed: -

- That written agreements are in place prior to final agreement is given for the research to commence.
- That the project has proper and sustainable supervision from an appropriate person.
- Ensure that every person working on the project is fit to do so as agreed at the approval stage ; that a structured approach to staff and public involvement is also being followed as agreed at project approval.
- Make sustainable arrangements to facilitate access to research participants and to oversee and monitor the progress of the research on behalf of the council.
- That throughout the project the agreed management and monitoring arrangements are clearly understood.
- That responsibilities between organisations and individuals are clearly set out and understood before and during the project.
- Sponsors and applicants should be aware of the complaints process set out in the 'Appeals and Complaints' section of this handbook. Participants and others must be able to make a complaint at any stage of the project; support may need to be given where appropriate.
- For complaints arising from matters for which there is no legal liability, a non-negligent harm policy, which for the Isle of Wight Council is part of the normal Council complaints procedure, must be followed.

8. Research That Involves Adults Who Lack Capacity To Give Their Consent

The implementation of the mental Capacity Act 2006 brings changes to research co-ordination and governance.

The Act provides new safeguards for people who cannot give or renew their consent to be involved in research projects.

Recent guidance has begun developing a framework for the handling of applications for research that fall into this category. The Isle of Wight Council will be working closely with NHS colleagues to ensure that applications are dealt with as effectively as possible, particularly during the early implementation period.

It would be wise to consider ensuring a longer planning and preparation period to your project if you think that it will trigger the terms of the new Act.

National Patient Safety Agency guidance sets out the proposed framework for applications received before and after 1st October 2007.

The Department of Health has also set out guidance on the role of consultees who are required to represent the views of people who lack capacity to consent who are invited to participate in research projects.

Both of these documents are available via the Research Governance Co-ordinator.

This section of the Guide will be updated as Mental Capacity Act compliance arrangements are clarified.

If you think your project may involve participants on the Isle of Wight who are unable to give informed consent, please read the guidance above and contact the Research Governance Co-ordinator as soon as possible.

9. Key Risk Areas

As well as considering the research proposal and the answers to the questions on the application form, the approval process will also consider the following issues.

The vulnerability of the research participants.

Some prospective participants including children, people with learning difficulties or service users with mental health issues cannot give informed consent. Before commencing any research it is essential that consent is obtained from a responsible person with the legal ability to give such consent on the subject's behalf. If you think your project will involve adults who cannot give informed consent, see the handbook page '*Research That Involves Adults Who Lack Capacity To Give Their Consent*'.

The researcher's experience.

The level of experience of the researcher is likely to have a bearing on the way in which research is carried out and the impact on the participants. This may range from general inexperience, being a student, lacking knowledge of the subject, lack of experience of working with the client group or lack of knowledge of the best methods to use in the research. It is essential to ascertain the level to which the researcher's qualifications and experience are relevant and appropriate to the research area and methodology.

Research method and any additional issues this may raise.

For example research requiring participants to be interviewed in their own homes means increased levels of disclosure of personal information and potential risk.

Collection of sensitive information.

Before approval is given for research involving the collection of sensitive information such as criminal records, psychiatric history or health status, consideration must be given to whether the collection of this information justified. And if it is justifiable, to what extent is the research in the interests of the research subject?

Privacy and confidentiality.

Are the proposed methods of ensuring anonymity and confidentiality of participants adequate? Does the information collection process conform to the Data Protection Act and local Caldecott Guardian standards?

Requirement for consent.

All research requires an information sheet to be provided to participants and a consent form to be completed before any interviews can be carried out. The research proposal must define the potential benefits of the research, along with how consent will be obtained. Participants may be willing to take part if they feel the study has a wider benefit, however if informed consent cannot be obtained, the participant cannot be interviewed as part of the research.

10. Research Governance Board - Terms of Reference

The Research Governance Board is a partnership body set up to manage the Research Governance Framework. The Board is also the approvals panel; In some circumstances, it can delegate this role to the Research Governance Co-ordinator.

The Board will ensure that the Research Governance Framework competently processes and monitors research, including a studies, surveys, evaluations or consultations. Such research will be subject to the Framework if it involves services users, their families or carers and council staff either directly or indirectly.

In doing so the Panel will oversee arrangements to :-

- Promote research and research outcomes both within and outside the council.
- Review all applications for research.
- Make decisions about research applications on the basis of set criteria.
- Ensure consistency and quality of research standards.
- Prevent multiple or repeated requests for access to service users and staff.
- Provide advice to researchers about the process, their research proposal and approval decisions.
- Protect the interests of service users, their families, carers staff and public.
- Ensure the Council and partners are not exposed to undue risk.
- Ensure that research is monitored by appropriate council or partner officers.
- Ensure the Council and partner's legal requirements and obligations are met (e.g. Equal Opportunities, CRB, Data Protection, Caldecott).
- Oversee a register of approved research projects.
- Periodically report on research activity involving services users, their families or carers and council staff.
- Delegate such decisions (e.g. to a Research Co-ordinator) as it considers fit. This will normally apply to non-complex or non-contentious applications.

- Monitor these delegated decisions.
- Monitor research outcomes.
- Establish a library of completed research that has been undertaken with council staff and with service users, their carers and their families.

11. Can You Help Us Guarantee High Standards of Research on the Isle of Wight

All social care research and evaluation projects have to be passed through the Council's Research Governance Framework. The process relies on the help and assistance of people with research expertise.

The Council's Research Governance Framework ensures that projects are well planned and executed, ethical and of benefit. A small group of volunteers with varied experience of research support the process by undertaking peer reviews of research and evaluation applications. New peer reviewers are always welcome.

Why do it?

The peer review process helps people to share knowledge and skills, as well as refreshing their involvement in the world of research and evaluation. Reviewers enhance their CV and can influence the quality of sometimes high profile knowledge building.

Very little time is required to undertake each review and peer support is available. Approved training on research methodologies and ethical decision making is available.

Can you help?

Masters level research or previous involvement on the business end of research programmes would qualify anyone to join the peer review group. Experience of social care or educational research is desirable but not essential. If you are interested, please contact the Research Governance Co-ordinator.

12. Appeals and Complaints

The Research Governance Framework (RGF) Board has a working draft Appeals and Complaints process which will be approved by the RGF Board during 2007.

If an applicant disagrees with the decision of the Board in respect of an application, they have access to appeal.

The applicant also has options for making formal complaints about the process and decisions.

Taking Action

The Board will welcome appeals, concerns, comments or complaints about the process, conduct or standards of the RGF. The Board is a multi agency partnership committed to dealing with appeals and complaints promptly and at the most practical level. However, partners on the Board have arrangements to escalate the response to appeals and complaints should this be necessary

Applicants can challenge the decision or the process they have been involved in with a view to seeking a changed decision, improvement to the Research Governance Process or some form of redress.

Complaints received by those involved with the RGF that reflect on the conduct of the Council, will for example also be referred to the relevant Council team to be dealt with as part of the Council's procedure for handling complaints.

Complaints may be referred to other partner organisations with responsibility for the management of complaints about aspects of their service.

Complaints that are not concerned with the Council's responsibilities will be dealt with by the Board within the review and decision framework of the appeals process. The Council's standards for dealing with complaints will be followed.

Complaints About Research Projects

The Board will take continuing responsibility for the standards, behaviour and ethics of projects that have received approval to proceed. Complaints about the conduct of researchers or the impact of research or evaluation projects can be addressed to the Board as set out below. The Council's complaints management standards will be applied.

If the Board chooses to withdraw 'consent to proceed', participating organisations will cease to co-operate with the research project. The Board will also take steps to ensure that stakeholders in the research are aware of the steps it has taken.

Making A Complaint To The RGF Board

Comments, concerns or complaints should be addressed to the Chair of the Isle of Wight Research Governance Board and sent c/o the Research Governance Co-ordinator. Complaints may be forwarded to the formal complaints procedures of RGF partners.

Making a complaint to the Board does not remove or override the applicants right to make a direct complaint through the Isle of Wight Council's concerns, complaints and compliments process. Contact with this service can be made by calling Isle of Wight Council on Tel 01983 821000.

Scope of the Appeals Process

The Board will consider appeals with regard to:

1. Outright refusals to grant approval to proceed.
2. Withdrawal of approval following previous approval to proceed.
3. Requests by the Board for supplementary submissions or changes in a proposal that are linked to conditional approvals to proceed.
4. Conditions linked to approval to proceed.

The Appeals Procedure

Applicants are invited to appeal in writing, setting out the reasons for re-consideration of a decision. Appeals should be addressed to the Chair of the Isle of Wight Research Governance Board and sent c/o the Research Governance Co-ordinator.

A response to the applicant will be made within 5 working days, indicating how the appeal will proceed.

The Chair of the Board will arrange a review of the processing of the original application, decisions made or withdrawal of consent to proceed. The review will be conducted by a member of the Board and a Peer Reviewer (who may also be a Board member), and be concluded within 14 working days. The lead reviewer will make direct contact with the applicant and convey a conclusion reached through review.

The lead reviewer can make a number of decisions;

1. reverse or amend a previous decision,

2. establish new conditions for approval,
3. refer the final outcome of the review to the Board for decision.

The lead reviewer's decision will normally over-ride previous decisions. Any decision to refer the review to the Board for decision will be taken in association with the Research Governance Co-ordinator.

If the applicant is dissatisfied with the outcome of the review, they will be invited to request that the lead reviewer refers the outcome of the review to the Board for final consideration and decision. The Board will invite the applicant to make a representation to Board members.

The Board meets on a quarterly cycle and will normally consider appeals during this cycle, although applicants can make a case to the Chair for an extraordinary meeting.

The Chair of the Board will communicate the final decision of the Board to the applicant.

For further information, contact the Research Governance Co-ordinator.



Frequently Asked Questions

What is research?

Research is defined as any work which involves collecting information from or about service users, their relatives and carers and employees of the council. It includes surveys, focus groups, consultations, reviews, evaluations, Best Value Audits, and student projects.

What is meant by the principal/main researcher?

The person designated as taking overall responsibility for the design, conduct and reporting of the study.

What about anyone else involved in the research?

The other participants in the research are called the research team. These will be other researchers who, with the Main Researcher, comprise the people conducting the study and includes field workers.

Who will organize access to research participants if I am conducting a survey?

A "nominated link officer" or "sponsor" who will be a named council officer, usually an experienced manager, is appointed to provide a link between the council and the researcher. This person's role is to facilitate access to research participants and to oversee and monitor the progress of the research on behalf of the council. They are NOT responsible for providing support and advice about the research itself.

What is a research proposal?

A written document that defines the subject of the research, the methodology, timescales and plans that show how the research will be carried out. It accompanies the application form and should also address the criteria set out in the Research Proposal Guide. The proposal and the application must be approved before the research can begin.

What about Data Protection?

Confidentiality is essential in research and researchers should be aware of data protection legislation and local authority procedures and requirements for data protection.

What information should participants be given?

An information sheet including: What the research is about, the researcher's name and contact details, how and why the participant was selected, how to withdraw from the research, how to complain, what information will be gathered, what the information will be used for and what will happen to any information (eg: interview tapes; questionnaires etc) after the research has been completed. It should be in the participants own language and be accessible to people with disabilities.

What happens to research when it is completed?

The RGF panel is compiling a database of all research carried out to inform future research and improve service delivery. Managers in the sponsor organisation also receive copies.

How do I decide what to research?

If a researcher is not clear on what to research, for example to undertake a student project, the RGF Board will compile a list of research needs that could be used to improve knowledge and services.

What are Intellectual Property Rights?

Ownership of the research usually resides with the principal researcher or the research team. For research that has been commissioned (ie funded by an external organization or group), depending on the contract, it is possible that the Intellectual Property Rights may lie with that body. Sponsorship of a piece of research will not necessarily confer rights on the sponsor.

What is a research sponsor?

A sponsor is an organisation (likely to be the local authority) taking primary responsibility for: ensuring the design of the study meets applicable standards, ensuring that arrangements are in place to ensure appropriate conduct and reporting, and ensuring that all the necessary agreements are in place and are documented. The sponsor is usually, but does not have to be, the main funder. The sponsor might be the local authority, a university or a research foundation. Local Authorities are automatically a sponsor of research that involves service users, their families, and carers and the local authority's staff. In practice, the sponsor will be the manager who has agreed to support the research project and provide access.

Who decides if a proposal is acceptable?

A panel made up of the Council's Caldecott Guardian. Service Managers from Adult and Children's Services, practitioners and services users, meet regularly to consider applications. This process is also delegated to the Research Governance Co-ordinator for non-complex applications.

Who is the research supervisor?

The person who is responsible for the management of the researcher(s) and the research. For a student, it is usually a tutor at the University where they are studying.

What is informed consent?

Researchers have a responsibility to ensure the interests of the research participants are respected. The agreement of potential participants must be sought prior to commencement of that research. Consent should be obtained in writing and must be freely given based on a full understanding of the purpose of the research and what will be required of participants. A copy of the consent form should be provided with the application for approval. The researcher has a duty to ensure that sufficient information is given to enable participants to choose whether they wish to take part in the research. Participants should be made aware that they have a right to withdraw from the research

at any time and that exercising that right will in no way affect the level or quality of services they receive.

Children and vulnerable adults are unlikely to be able to give informed consent themselves and researchers will need to address this issue in the research proposal.

If it is intended to involve adults who cannot give informed consent, please contact the Research Governance Co-ordinator at the earliest possible stage in the project planning process.

Who do I contact if I am thinking about doing some research?

The Council's Research Governance Co-ordinator is the council officer who is the official point of referral for all prospective research applicants.

Sample Online Application Form

Isle of Wight Council



Research Application Form

Please note: Provided you are logged into My Profile you can save the contents of this form at any time. This will enable you to return to the form at any stage, complete and submit it later.

It is a requirement that you send in some additional forms of documentation in order to complement the information provided in this application form. Please ensure you read the Getting Started page before proceeding, paying particular attention to the 'Document Checklist.'

Once the form is complete, please ensure that you print the page containing your unique reference number. This will appear once you hit the 'submit' button to send the form to the service.

You will need to send the print-out of your unique reference number, along with the additional required documents to the following address:

Research Governance Co-ordinator
 Community Services
 The Guildhall, High Street
 Newport, Isle of Wight
 PO30 1TY

About You

Forename	martin
Middle name/Initials	
Surname	johnson
Building/house name/number	Guildhall
Street address	High Street
Town name	Newport
County	Isle of Wight
Postcode	PO331PS
Tel number (include area code)	01983 823825

Isle of Wight Council Research Governance Handbook Materials

Email address	martin.johnson@iow.gov.uk
Fax	
Current employment	Service Manager, Partnerships. Isle of Wight Council
Your qualifications	MBA, Diploma in Social Work, Diploma in Management Studies.
Your previous research experience	Masters degree level dissertation. Study and practice teacher 1984-1998, Research reviewer for IWC 2005-, Lead manager on a number of service evaluations and consultation studies 1996-. member of the IWC research Governance Board.

About the other people who will be involved with the research

1. Research Supervisor

Please provide the name and contact details of the Research Supervisor:

Job Title	Chief Executive.
Organisation	Isle of Wight Council
Forename	Jo
Middle name/Initials	
Surname	Duckworth
Address	Chief Executives Office, Isle of Wight Council, County Hall, High Street, Newport. PO30 1TY
Tel number (include area code)	01983 821000
Email address	jo.duckworth@iow.gov.uk
Fax	
Your supervisor's research qualifications and experience	Degree level research 1990, lead manager on high level strategic research and evaluation projects 1990-2005.

2. Lead Researcher

Please provide the name of the Lead Researcher:

Job Title	Service Manager

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Name of lead research organisation	Isle of Wight Council
Forename	Martin
Middle name/Initials	
Surname	Johnson

3. Research Team Members

Please provide the names and contact details of the research team members:

Use this space to provide details of the research team members (including fieldworkers)	Lesley Johnson, Public Sector Research Assistant, University of Portsmouth. contact c/o the Lead Researcher.
--	--

References

Please provide the names and contact details of two referees who will support the application, giving their opinion of the project and the researchers' competence to undertake the project. (This can include the Research Supervisor). References must be posted in separately to the submission of the electronic application.

NOTE: Referees are not needed where the research sponsor or nominated link manager is the line manager of the applicant.

1. 1st Referee

Job Title	Director of Community Services
Organisation	Isle of Wight Council
Forename	Sarah
Middle name/Initials	
Surname	Mitchell
Address	Isle of Wight Council, County Hall, High Street, Newport, Isle of Wight, PO301TY
Tel number (include area code)	01983 821000
Email address	sarah.mitchell@iow.gov.uk
Fax	

2. 2nd Referee

Job Title	Senior Lecturer
Organisation	University of Portsmouth
Forename	
Middle name/Initials	
Surname	

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Forename	Charles
Middle name/Initials	
Surname	Goddard
Address	University of Portsmouth, Richmond Building, Richmond St, Portsmouth, PO39YH
Tel number (include area code)	01983 823818
Email address	elaine.tracey@iow.gov.uk
Fax	

Research Sponsor

Who will be funding the Research?	Isle of Wight Council
--	-----------------------

Please provide the name and contact details of the Research Sponsor:

Job Title	Community Leisure Development Manager
Organisation	Sports Unit, Isle of Wight Council
Forename	Lee
Middle name/Initials	
Surname	Matthews
Address	Sports Unit, Guildhall, High St, Newport, Isle of Wight, PO301TY
Tel number (include area code)	01983 823818
Email address	lee.matthews@iow.gov.uk
Fax	

About the Research

Title of the research project	Evaluation of the satisfaction of people with a Learning Disability who have participated in community based sport as part of their activities funded by Individual Budgets.
A brief abstract of the project -	The Isle of Wight Council has piloted and facilitated a range of new daytime and evening activities for people

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<p>please provide a brief abstract describing your project objectives and methodology. This text will be uploaded into the Social Care Institute for Excellence (SCIE) national online research database (max 100 words)</p>	<p>with a learning disability who have individual personal care budgets. The Council has commissioned a study of the impact on user satisfaction with the new daytime activities. The study focusses on the piloting of community based sporting activities and the satisfaction of service users and carers who have engaged with these activities. The study will present a qualitative comparative assessment of satisfaction covering the activities and their impact on daily living.</p>
<p>Aims and Objectives of the project (max 100 words)</p>	<p>Provide commissioners and service users/carers who have Individual Budgets, with a comparative assessment of satisfaction with community sporting activities commissioned and facilitated by the Council.</p>
<p>When do you propose to start this research?</p>	<p>12th December 2007</p>
<p>Planned project completion date</p>	<p>12th March 2008</p>
<p>Brief description of the methods to be used</p>	<ol style="list-style-type: none"> 1. Quantitative assessment of take up and provision. 2. Piloting of questionnaires, survey methods and focus group formats with service users, carers and service providers. 3. Quantitatively identify a survey sample. 4. Survey period using sampled questionnaires and focus groups. 5. Feedback findings to participants, commissioners and service providers.
<p>Will your project involve participants over the age of 16 unable to give informed consent to their involvement or the use of their identifiable personal information?</p>	
<p>*If yes, please ensure that you have contacted the Research Governance Co-ordinator prior to the submission of this application.</p>	
<p>Have you included a copy of your research proposal with this application?</p>	<p> <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Draft </p>
<p>Does your Proposal address the issues raised in the online IWC RGF 'Research Proposal Guide?'</p>	<p> <input checked="" type="radio"/> Yes <input type="radio"/> No <input type="radio"/> Partly </p>
<p>Will your research involve you talking directly to council or sponsoring organisation staff, service users, their families or carers?</p>	
<p>If yes, do you and all members of your research team have up to date CRB certificates?</p>	<p> <input checked="" type="radio"/> Yes <input type="radio"/> No </p>
<p>Will the research involve you handling information that identifies individuals?</p>	<p> <input checked="" type="radio"/> Yes <input type="radio"/> No </p>
<h3 style="margin: 0;">Checklist</h3>	
<p>Please provide the following documents with your application</p>	
<p>*List of any other documents provided:</p>	
<p>1. Literature Review</p>	<p>4.</p>

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2. Letter of support from MENCAP 'In Control'	5.
3.	6.

Declaration

It is a condition of using the IWC Research Governance process that;

Once approval to proceed on social care based projects has been given, the Council will upload the title and abstract information on the Social Care Institute for Excellence (SCIE) online research database.

On completion of these projects, a final abstract indicating outcomes will be required for the SCIE online database. On completion of all projects, a copy of the research or evaluation report, together with an abstract of findings will be required of applicants for the sponsoring organisation and the RGF library.

If there any reasons why you are unable to agree fully to this (e.g. copyright issues) please set out these reasons here

To the best of my knowledge the information provided in this application and supporting documentation is accurate. If any significant changes are made to the research or the proposal I will inform the Council Research Co-Ordinator at the earliest opportunity.

Signed.....

Name.....

Date.....

Data Protection Act 1998

This application may be monitored by the Isle of Wight Council for regulatory, quality control or crime detection purposes. Information from this application will be processed in accordance with the Data Protection Act 1998 for the purpose of processing your particular enquiry/request. The Isle of Wight Council ("the Council") is the data controller. By completing this form you consent to the Council contacting you by email or nominated contact method in relation to your enquiry/request.

The information contained in this application may, in exceptional circumstances, be subject to disclosure to third parties under either the Data Protection Act 1998 or the Freedom of Information Act 2000 to the extent the law allows and in accordance with the Isle of Wight Council's Access to Information Policy. Disclosure will only be made where in all the circumstances it would be fair to do so and in the public interest.

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Please note that the Council may process your information in the absence of consent for the purpose of crime prevention or detection so far as is in accordance with the law.

Sometimes we may use your information to keep you informed about services, goods or relevant issues that we believe may be of interest to you. If you wish to receive this information for these purposes please tick this box

To improve the quality of other services that we provide to you the Council wishes to hold your non-sensitive personal information on a secure central database. This will enable all Council services to use this information when they are providing a service to/for you. If you wish your non-sensitive personal information to be held by the Council please tick this box

Please now ensure that you print the page containing your unique reference number.

To complete the application process, you will need to send the print-out of your unique reference number, along with the additional required documents to the following address:

Research Governance Co-ordinator
Community Services
The Guildhall
High Street
Newport
Isle of Wight
PO30 1TY

Appendix 3



Research Approval Checklist

This tool is reproduced with permission from the Social Services Research Group, Research Governance Framework Resource Pack, April 2005.

(Complete with reference to the App Form and the Research Proposal Guide)

Name of research project

Name of research applicant

Application date

Date considered

Section A The Application Form

Has the applicant provided: -

- | | |
|--|--|
| <input type="checkbox"/> Contact details | <input type="checkbox"/> Supervisor details |
| <input type="checkbox"/> Researcher qualifications | <input type="checkbox"/> Researcher experience |
| <input type="checkbox"/> Research timetable | <input type="checkbox"/> Funder details/funding issues |
| <input type="checkbox"/> Consent forms | <input type="checkbox"/> Participant info letter/leaflet/sheet |
| <input type="checkbox"/> References | <input type="checkbox"/> CRB certificate |
| <input type="checkbox"/> Insurance details | <input type="checkbox"/> Other |

Notes

Section B *The Research Proposal*

1. Background

Has the applicant demonstrated the value of the research proposal? In particular, does the proposal: -

- | | |
|--|--|
| <input type="checkbox"/> Explain why the research is important? | <input type="checkbox"/> Show how it will be of benefit and to whom? |
| <input type="checkbox"/> Shown that it is new work and that the researcher is aware of other similar research in the area? | <input type="checkbox"/> Provide clear aims and objectives? |

Notes

2. How the research will be done

Has the applicant discussed how the research will be carried out? In particular, does the proposal: -

- | | |
|---|--|
| <input type="checkbox"/> State how many others will be involved in the research, who they are and how the research will be funded | <input type="checkbox"/> Identify clearly who is being targeted as research subjects |
| <input type="checkbox"/> Show that participants will be clearly and fully informed of purpose of the research study | <input type="checkbox"/> Discuss when and where the research will take place |
| <input type="checkbox"/> Outline appropriate supervision arrangements | <input type="checkbox"/> Show that the participants will be clear about the expectations of the researcher |

Notes

3. Timetable

Has the applicant considered how long the research will take? In particular, does the proposal: -

- Provide a realistic timescale, including start and completion date
- Acknowledge any external constraints on carrying out the research
- Indicate particular stages to the study
- Plan to provide regular progress reports

Notes

4. Methodology

Has the applicant demonstrated that the design of the research study is appropriate? In particular, does the proposal: -

- Show that the methodology is appropriate to the research question
- Explain what sort of data will be collected and why
- Consider how the data will be collected
- Explain how the data will be analysed
- Describe how the sample will be selected
- Explain how research participants will be recruited
- Outline any piloting arrangements
- State whether participants will be paid

Notes

5. Ethical issues

Has the applicant thought about the affect of their research and anticipated possible problems. In particular, does the proposal consider: -

- | | |
|--|--|
| <input type="checkbox"/> The health and safety of research participants and/or researchers | <input type="checkbox"/> How informed consent will be obtained and how participants can opt out at any stage should they wish to |
| <input type="checkbox"/> What provisions are required to enable participants to complain should they wish to | <input type="checkbox"/> What risks may exist and how arrangements will be made for insurance if this is necessary |
| <input type="checkbox"/> How follow up support will be offered should participants require this as a consequence of the research | <input type="checkbox"/> How the research will include hard to reach people |

Notes

6. Data Protection

Has the applicant considered what will happen with the data they collect both during and after the research project has finished? In particular, does the proposal address:

- | | |
|---|---|
| <input type="checkbox"/> The use of recording or video equipment | <input type="checkbox"/> How data will be analysed |
| <input type="checkbox"/> Where data will be stored and for how long | <input type="checkbox"/> How data will be stored |
| <input type="checkbox"/> How confidentiality and anonymity of data and participants will be ensured | <input type="checkbox"/> Who will have ultimate ownership of the data |

Notes

7. Dissemination

Has the applicant considered how the findings will be used by the researcher, the

Council or others. In particular, does the research proposal consider:-

- | | |
|---|---|
| <input type="checkbox"/> In what form the findings will be presented | <input type="checkbox"/> How the findings will be disseminated |
| <input type="checkbox"/> To whom the research will be disseminated [including participants] | <input type="checkbox"/> Whether there is agreement for the research and results to be included on the Council's research database |
| <input type="checkbox"/> Whether the research, its subject or findings could be misused by any person or group and how this might be addressed. | <input type="checkbox"/> How the the final report will address the limitations and the extent to which the research findings can be generalised |

Notes

Section C *Approval Decision and Reasons*

Approved

Not approved

Send to Research Approvals Panel

Reasons

Signed
(& print name)

Date

RGF Risk Assessment Tool

This paper and the tool it describes has been extracted with permission from the [Social Services Research Group, Research Governance Framework Resource Pack, April 2005.](#)

Introduction

This document describes a simple tool that can be used by CSSRs and others to help them implement research governance arrangements.

Research governance offers safeguards to anyone participating in research and will help to ensure that any study that may be planned is of high quality.

It is important that all research activity is included within the scope of local governance arrangements. This is to ensure that the safeguards and quality standards offered by the framework are offered to all those involved in research. This might include service users, relatives and carers, care professionals or researchers themselves.

However, it is also important that time and resources within the governance process are focussed on research proposals that deserve greatest scrutiny. Whilst some research proposals will offer relatively little or no risk to participants, in other studies there may be a higher risk – for a variety of reasons.

What is the Research Governance Risk Assessment Tool?

The Tool offers a way of establishing the likelihood of harm to research participants and the degree to which the potential for harm has been identified and addressed within a given research proposal. It can help to ensure that the level of scrutiny given to a research proposal is proportional to the likely degree of risk to participants. It relies to a large extent on the professional judgements of those using it. It has been designed with simplicity and ease of use in mind and no claims are therefore made for it being comprehensive in scope.

How does it work?

The Tool helps those appraising a research proposal to consider both the likelihood of harm to participants that may arise due to the nature of the proposed research and the overall level of risk.

Likelihood of harm. The main part of the tool offers a series of statements, presented in rows and columns, against which a given piece of research can

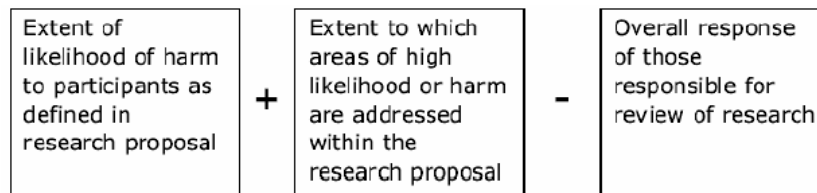
be assessed. The *left hand column statements* are those representing the highest likelihood of harm to participants. Statements found in the *right hand column* are those representing the lowest chances of harm occurring. Research proposals can be appraised against each of the statements contained in the rows to form an overall impression of the likelihood of harm to subjects/participants. For example, research proposals in which a large number of the cells in the left hand column appear to best describe the proposal indicate that the study is one in which the chances of harm to participants is likely to be high.

Risk. Likelihood of harm predisposes research participants to greater levels of risk. However, a predisposition does not mean that this greater risk is inevitable. It is important also to consider the extent to which the research proposal identifies and addresses areas likely to give rise to higher chances of harm. If a research proposal identifies and addresses these, then the overall level of risk will be reduced.

To take account of this, *if the review of a research proposal indicates that, for a given row, there is a high chance of harm*, then it is important to consider if there is also a *high level of risk*.

At the end of each row there are two cells that describe two logical possibilities if a high chance of harm is identified. For each row, either:

the concerns or issues relating to the area giving rise to the higher chance of harm have been fully addressed in the research proposal, or the issues concerned have not been fully addressed.



The final page of the Tool is intended to record the outcome of the review process and offer recommendations to investigator, sponsors or funders where appropriate, to address any concerns that may be identified.

Who is it for?

The tool can be used in a variety of contexts and settings and by a range of different people. It is primarily designed for use by CSSRs. The way it is used will depend on the local arrangements within which CSSRs respond to the RGF. For example:

Title of Proposal		Date	
Name of Researcher/Principal Investigator		Ref No	
Area	Likelihood of harm (tick boxes to indicate judgement)		
	High ←	→ Low	
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 <input type="checkbox"/>	Informed consent & ability to withdraw from study possible with support to overcome communication barriers e.g. advocates, translators/interpreters, signers, or technology <input type="checkbox"/>	Informed consent and ability to withdraw from study fully possible <input type="checkbox"/>
	Researcher competence	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 <input type="checkbox"/>	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 <input type="checkbox"/>
			Areas of high likelihood of harm addressed?
			Concerns about informed consent and communication barriers are fully identified & addressed
			Concerns are not fully identified or addressed
			Any lack of competence by the researcher(s) fully addressed
			Any lack of competence is not addressed

Area	Likelihood of harm (tick boxes to indicate judgement)		Areas of high likelihood of harm addressed?
	High	Low	
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. <input type="checkbox"/>	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 <input type="checkbox"/>	The need to collect any personal information is fully justified The need to collect this information is not fully justified
	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) <input type="checkbox"/>	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) <input type="checkbox"/>	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
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) <input type="checkbox"/>	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 <input type="checkbox"/>	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

Area	Likelihood of harm (tick boxes to indicate judgement)		Areas of high likelihood of harm addressed?
	High	Low	
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 <input type="checkbox"/>	No face to face interaction between investigator and participant <input type="checkbox"/>	Possible risks arising from high level of contact are identified and fully addressed
	Some face-to-face contact and interaction for limited amounts of time <input type="checkbox"/>	Anonymous <input type="checkbox"/>	
	Level of privacy to participant	Not confidential <input type="checkbox"/>	Confidential <input type="checkbox"/>
			<p>If the study is not anonymous or confidential reasons for this are fully justified & conform to Data Protection Act principles</p> <p>Study is not anonymous or confidential and reasons for this are not fully justified</p>

Area	Likelihood of harm (tick boxes to indicate judgement)		Areas of high likelihood of harm addressed?
	High	Low	
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 <input type="checkbox"/>	Limited information about subjects/participants is provided to the investigator to make the study possible or more reliable <input type="checkbox"/>	<p>Conflicts of interest are fully described & consideration given to how to minimise possible effects on study</p> <p>Conflicts of interest are not fully described. Proposal does not adequately consider how to minimise effects on study</p>
		Subjects/participants are unknown to the investigator and cannot be identified <input type="checkbox"/>	
External considerations	Study is likely to be extremely sensitive <input type="checkbox"/>	Parts of study may be sensitive <input type="checkbox"/>	<p>Sensitivities have been fully identified and adequately addressed</p> <p>Sensitivities have not been adequately addressed.</p>
		No known sensitivities <input type="checkbox"/>	

Comments from review

Subject/participant characteristics	
Researcher competence	
Nature of information being sought	
Appropriateness of method to subject	
Methods/nature of data collection	
Level of privacy to participant	
Relationship between investigator & subjects/participants	
External considerations	
Other comments arising from review e.g. balance of risks & benefits	

Overall adjudication Approval given Resubmit with minor changes Resubmit with major changes Proposal rejected

Signed.....

Date.....

Role/title.....

Guidance & examples

Further information about the categories used in the Tool and some examples are presented below. The information is intended to be indicative and not exhaustive.

Subject/participant characteristics

Some service users may experience particular difficulties in giving informed consent, or in withholding consent. This may be for many reasons, including:

- the age of a child (where the child is very young);
- the incapacity of an adult due to significant learning difficulties, or mental health issues including dementia;
- because of barriers to communication arising from language (for people whose first language is not English) or literacy (if people cannot read or write);
- because of sensory impairments (for example visual impairment, blindness, hearing impairment or deafness);
- because of speech impairments (for example, such as those arising from degenerative illness, or stroke).

The information given to participants to enable them to decide whether to take part should, for example:

- be clearly written so the participant has a full and accurate;
- understanding of exactly what they are consenting to;
- state that they can withdraw from the study at any time without this;
- affecting the services they receive in any way;
- provide information about to whom they may complain, should they need to.

If informed consent is difficult because communication barriers exist the likelihood of harm to research subjects/participants will be greater unless ways can be identified in the research proposal by which these barriers can be overcome. A research proposal has both to acknowledge the issue as well as offer an account of how any identified barriers will be surmounted.

For example, research in which people from ethnic minority groups will form part of the sample should be able to establish the preferred language of those within the sample and ensure that appropriate steps are taken to enable non-English speakers to take part. This might include the use of translated versions of letters, consent forms and postal questionnaires or ensuring that an interpreter is available for interviews. If the study involves children or young people, the provision of information about the project (necessary to ensure informed consent) might need to be made available to the parent/guardian as well as the child, and the information provided to the child or young person written in an accessible style.

Researcher competence

There are several dimensions to the issue of competence. A researcher may:

- be generally inexperienced – for example, if they are a student or someone who is not a professional researcher;
- they may lack any real knowledge of the subject under investigation;
- they may possess little or no experience of working with those people from whom information may be collected;
- they may not know about the best methods to use to achieve the objectives of the proposed study.

Each of these factors increases the likelihood of harm to participants. For example, those who may be asked to take part may be caused distress or inconvenience because a lack of knowledge of their needs might lead the researcher to use inappropriate methods to obtain the information required. The investigator's reputation may also be affected. In addition, a lack of knowledge may also mean that the research funder would be left out of pocket having committed resources to a study that may already have been completed already elsewhere without the researcher knowing about it, or have sufficient methodological flaws as to be relatively worthless.

If the researcher or researchers to be involved in the study are inexperienced the research proposal should clearly outline where lack of experience or competence may be an issue and what remedies will be applied. For example, if the researchers concerned do not have training in and experience of using the kinds of research methods appropriate to the topic, it may be that they will not be the right people to do the study. If a researcher lacks knowledge of the subject area or topic, they will at the very least, need access to those who do have this knowledge and can share this by offering support and guidance. If the investigator lacks knowledge of a service user group that will be the focus of the proposed study, they may need either to obtain this, or the proposal will need to demonstrate that they have access to sufficient appropriate support to compensate for this gap.

Finally, it is very important that any researcher working directly with service users or with case identifiable data has Criminal Records Bureau (CRB) clearance.

Nature of information being sought

Some research is likely to require the collection of information that might be highly sensitive or personal – for example:

- data relating to criminal records;
- psychiatric history;

- health status etc.

Alternatively, the data may be collected as a result of an invasive procedure of some kind such as a new, perhaps untested, therapeutic intervention.

The need to collect sensitive information of this kind should be fully justifiable and explained in the research proposal.

If the collection of sensitive data is not explained, not justified, or is considered unnecessary by those appraising the proposal, this data should not be collected.

If the collection of this information is justifiable, then a range of other issues relating to the level of privacy to the person about whom the data is collected will apply. This will be considered separately below.

Appropriateness of method to subject, or research questions and the quality of the research design

It's important that the methods used are the most appropriate for the subject of the study. If they're not, the results of the study may be compromised.

Firstly, the need for research should be established. If there is no need for the study there's little point in doing it.

Secondly, it's important that the proposed study has the resources needed to answer the research questions.

For example, a study requiring interviews with large numbers of service users will normally consume more resources than a postal survey of a group of comparable size. The methods should be appropriate to the subject. For example, using focus group interviews as a method of obtaining information about the use that hundreds of people make of a service won't be very useful if what's being sought is reliable information – that is, information that accurately reflects the views of all service users. A better approach would be a postal survey or survey interview using a sample selected in such a way that there can be confidence in the findings. On the other hand, if the purpose of using focus groups is to find out more about the kinds of issues that are important to these service users, a postal survey might be a waste of time as the questions asked might not capture the main issues for users unless the researcher has a detailed prior knowledge of these issues. In this scenario, the method of focus group or unstructured interview would be the more appropriate approach to take.

Methods/nature of data collection

Methods of data collection that involve:

high levels of face to face contact or interaction between the investigator and the subject/participant, or where the methods are relatively intrusive.

may create situations in which one of those concerned may be placed in a vulnerable position of some kind, or one that may compromise the quality of the study. For example, research designs of this kind, in certain contexts may lead to:

- Risks to the researcher – for example if the research involves visits to the homes of people who are to be interviewed.
- The possibility of misconduct or abuse on the part of the researcher or the possibility that an accusation of misconduct may be made against them.
- A loss of perspective by the researcher arising from a failure to adequately manage fieldwork relationships – for example over involvement in the research environment.
- Stress to those from whom information is being sought – for example through the length of an interview, the timing or location of observations, the number of contacts between the researcher and the persons taking part in the research.

To address potential difficulties of this kind it may be necessary for the proposal to demonstrate how the safety of participants will be ensured. Where appropriate the proposal should also indicate how field researchers would be supported to manage fieldwork relations properly – a particular issue in any action research design.

Level of privacy to participant

If the data is not anonymised at the point of collection, the research proposal should explain why it isn't feasible or appropriate to collect the data in this way. The proposal will need to demonstrate that all stages of the data collection process conform to the standards laid down in the Data Protection Act and the local Caldicott Guardian. For example:

- the security of collected data;
- the method of analysis;
- the way that analysed data will be presented;
- the process by which collected data will be disposed of,

should all be described in any research proposal but are particularly important considerations if data isn't anonymous. Privacy is of the utmost importance if the collected data is of a sensitive or personal kind.

To address concerns about privacy a research proposal should clearly state what level of privacy can be achieved by the study and how this will be explained to subjects/participants. It may be desirable, for example, to state how attempts will be made to minimise the possibility that individuals might be

identified, for example by changing names, or selecting data that cannot be attributed to source. A clear account of:

- how collected data will be stored;
- who will see the collected data;
- how it will be analysed;
- how long collected data will be kept; and
- how it will be disposed of when no longer needed,

should all be included in a research proposal.

Relationship between investigator & subjects/participants

There are particular issues that should be carefully considered if the investigator and the subject/participants of a proposed study are known to one another (for example where a member of staff working in a day centre or residential care setting is asked or wishes to conduct a study of some kind on attendees/residents). Key issues might, for example, include:

- 'Audience effect', in which participant's opinions of, or attitudes toward, the researcher affect their behaviour towards the researcher or their response to questions the researcher may ask.
- An imbalance in power between the researcher and subject/participants may make it very difficult for consent to be withheld.
- There may be a conflict of interest on the part of the researcher arising from vested interests in securing a particular outcome to the study.
- A researcher's prior knowledge of the subjects/participants may affect
- What data is collected/not collected.

To address these concerns any pre-existing relationship between investigator and subjects/participants should be described. Where appropriate the proposal might offer remedies for any potential bias that may occur. For example this might be by ensuring that:

- consent is obtained by someone not known to participants,
- close supervision of the fieldwork process occurs, or
- a third party is used to conduct random 're-tests' to ensure consistency in data collected.

External considerations

Some research is likely to generate much more interest, and be of a much more sensitive nature than others because of heightened media interest, possible implications arising from findings, public concern, or, in local government settings, political agendas.

- There may be a risk that findings may be misinterpreted, by design or by accident.
- There may be pressure to complete the research and publish findings as soon as possible to satisfy demand for information or to support important decisions that may need to be made.
- It may be that the findings of a research study, or the area of investigation is one that key individuals or interest groups may find unpalatable, or alternatively, findings may be exaggerated to suit the agenda of such individuals or groups.

It may not be possible for the investigator or research team to anticipate how a completed study will be received, but an assessment of the policy environment within which the proposed study may be eventually received, and the outcome of research in the same field by others may provide clues. Other ways of addressing external considerations might include the provision of lay summaries of the findings – particularly of complex studies and large reports and being clear about any assumptions or values that may underpin the proposed study. Clarity about how research will be disseminated should be agreed before a study begins to help address these issues.

Other issues

Equalities

Equalities issues are a common thread running through the research assessment tool described here. Particular care is needed on the part of researchers to ensure that research methods do not unintentionally discriminate. After taking any explicit sampling criteria into account, all reasonable steps should be taken to ensure that particular groups of people targeted in a study are not excluded from participation. For example, interpreters or translation services may be required for service users whose first language is not English or who normally communicate using BSL. Questionnaire design should be 'disability friendly' in design. Buildings chosen as venues for focus group work should be fully accessible to people with physical or sensory impairments. Advocates may be needed for people with mental health issues or learning difficulties.

Effects on choice of research topic

An overriding purpose of the RGF is to protect service users from harm arising from unethical or poorly thought out research. It is not intended to prevent research into sensitive topics. Where the proposed topic is deemed to be a sensitive one, distress may be caused to research participants. Research participants able to give informed consent should be asked if they are prepared to accept the possibility that distress may be caused and reminded that they can choose not to take part in the proposed study at any stage. Whilst every effort should be made to ensure that distress does not occur, there may be occasions when the level of distress caused may be outweighed by the potential benefit of the findings. For example, a person with a terminal illness may find the process of taking part in a study of the quality of care provided to people who are dying distressing. However, they may also feel that lessons learned from the study will be of great benefit to others

finding themselves in the same situation at some future time. Where informed consent cannot be obtained, it will be much harder to justify distress because of potential benefit. In any event, it is essential that the researcher/investigator define the potential benefits of the research to enable those responsible for appraising the proposal to weigh up risks against possible benefits.

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Glossary of Terms

If you would like to see more terms appear in this glossary, please contact the Research Governance Co-ordinator at martin.johnson@iow.gov.uk or Tel. (01983 823825).

Main/Principal Researcher	The person designated as taking overall responsibility for the design, conduct and reporting of the study.
Nominated Link Officer	A named council officer, usually an experienced manager, appointed by the sponsor organisation to act on its sponsor responsibilities. The person provides a link between the council and the researcher. This person's role is to facilitate access to research participants and to oversee and monitor the progress of the research on behalf of the council. S/he is not responsible for providing support and advice about the research itself.
Research	Any work which involves collecting information from or about service users, their relatives and carers and employees of the Council. It includes surveys, focus groups, consultations, reviews, evaluations, Best Value audits, and student projects. It does not involve the routine collection of management information.
Research Governance Co-ordinator	The Council Officer who is the official point of referral for all prospective research applicants.
Research Governance Board	The partnership body responsible for considering any research proposals that involve direct or indirect access to service users, their families/friends or carers. Membership comprises the Research Co-ordinator, Council staff, representatives from other organisations and users of Council services.
Research Supervisor	The person responsible for the management of the researcher(s) and the research.

<p>Research Team</p>	<p>Other researchers who, with the Main Researcher, comprise the people conducting the study and includes field workers.</p>
<p>Sponsor</p>	<p>An organisation (likely to be the local authority) taking the primary responsibility for:</p> <ul style="list-style-type: none"> • ensuring the design of the study meets applicable standards. • that arrangements are in place to ensure appropriate conduct and reporting. • that all the necessary agreements are in place and are documented. <p>The sponsor is usually, but does not have to be, the main funder. The sponsor might be a local authority, a University or a research foundation.</p> <p>Local Authorities are automatically a sponsor of research that involves services users, their families and carers and the local authority's staff.</p> <p>The sponsor will be represented by a Manager who will fulfill the role of Nominated Link Officer (see below)</p>