

ISLE OF WIGHT COUNCIL

Research Governance Framework

Handbook

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1. Approving social care or related research on the Isle of Wight

As an ethical and competent learning organisation, the council insists on safe research of a suitable quality.

Research benefits our knowledge of our community and the impact of what we do. If undertaken responsibly, competent research can improve lives and benefit our environment. We also expect that research is carried out in a sound, non-abusive and respectful way. This is why we have a process for assessing and approving social care and related research.

What does the council's Research Governance Framework cover?

Our research governance framework (RGF) covers all forms of research conducted by external researchers, council staff and other research partners.

The council regards 'Research' as 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.

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 so it is worth checking the status of any proposed research. The council's manager responsible for the RGF can discuss early ideas and proposals, some of which won't require approval.

Researchers with realistic and achievable proposals can apply online for 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 what will be involved in making an application can be found on these web-pages.

Students undertaking research through a university can ask their supervisor to provide advice and support in preparing a research proposal. This website also provides the information needed to make a successful application.

If a proposal has already been approved through another research governance process, for example in another council, and NHS body or at a national level, there may be no need to make a full application. This can be discussed with the council's manager responsible for the RGF.

Projects can benefit from our expertise and links.

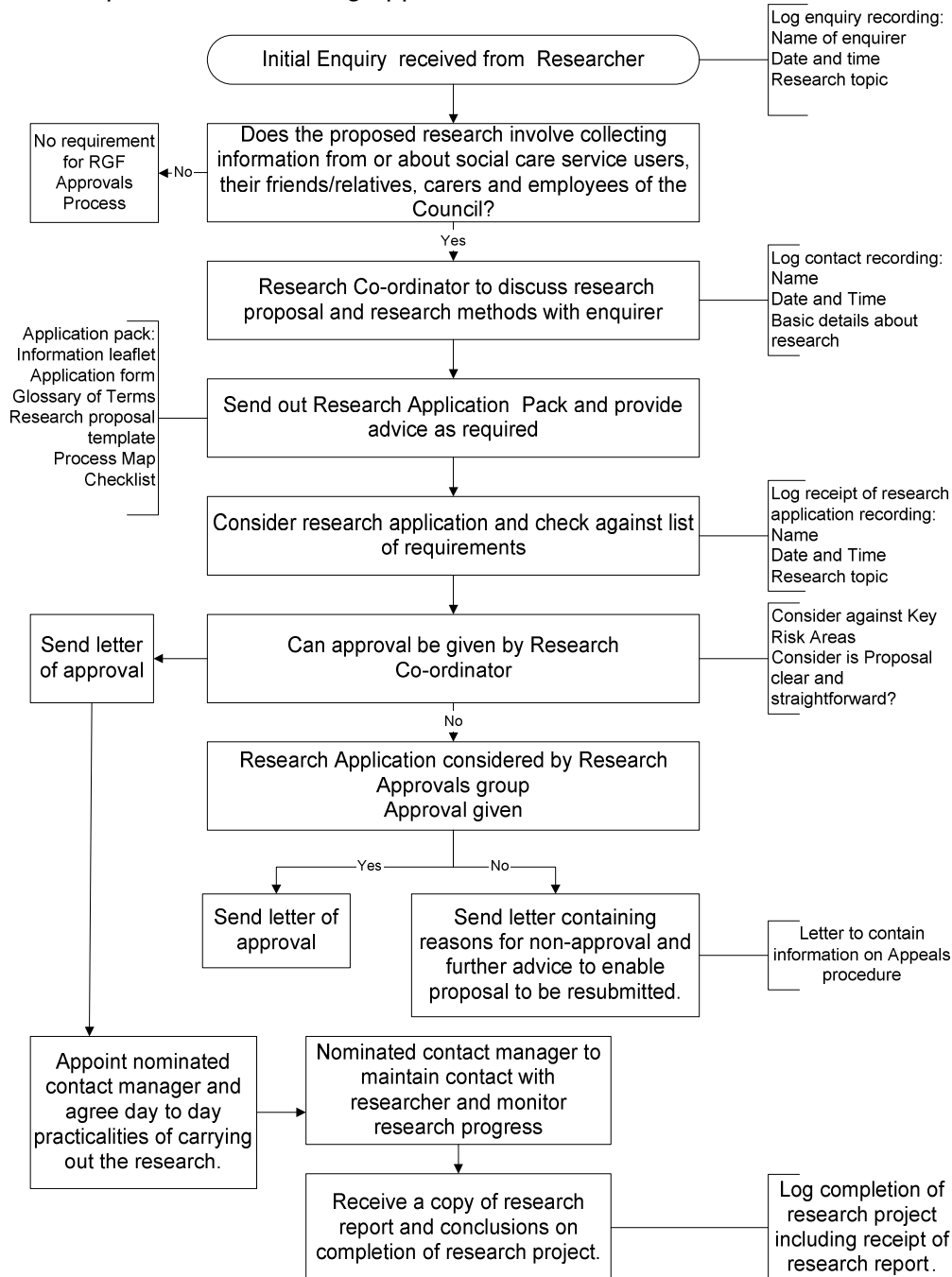
Our research framework is not simply an approval process. Our knowledgeable reviewers will give helpful advice and support to competent applicants if it will improve the methodology, the ethical approach or benefits of a proposal.

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

What happens when I submit a research application?

Research applications pass through our research approval process, which compares proposals with our practice standards and principles.

If an application is straightforward, addresses the required standards and does not involve unacceptable risk to participants and the council, applications should be processed within two weeks. If your application is more complex, it will be referred to the Research Governance Board and this decision might take longer, up to six weeks. This is the process for handling applications:



What happens when approval to proceed is given?

A research project can proceed as soon as the council has supplied the applicant with a notice of approval to proceed. Your research will be registered with the Council and if appropriate on the Social Care Institute for Excellence online database. The named sponsor within the council will also monitor progress.

The council will expect approved research projects to stick to the approved project plan and any conditions that were issued on the notice of approval to proceed. The council will intervene and possibly withdraw its approval to proceed if there is evidence that this is not being done.

If you do not receive approval, you will be given reasons and information about how to appeal the decision. Although applicants can expect contact from the council during the approval process, if an application is refused, advice will be given on the reasons for refusal and any action that could be taken to improve the application.

Who should I contact to find out more?

Contact the council's lead manager for the RGF to discuss your ideas and the best way to make an application.

2. 'Getting Started' – A Checklist

1. Check through this RGF Handbook before making any application.
2. Apply for approval in plenty of time. Don't leave it to the last minute. You may 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 section of the website.
4. Check the sections in this guide on research with people who lack capacity to give consent, and arrangements for monitoring and supervision. Check that you have covered these issues.
5. Contact the council's lead manager for RGF to discuss the application
6. Prepare your research proposal and 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.	

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 on the section in this guide that covers the content of a research proposal, and the run through the reviewers checklist at appendix 2 and the risk assessment tool at appendix 3.
9. Prior to submitting an application, call the council's lead manager for RGF and give notice of its arrival.
10. Print off the completed application form and send it with all of the required documents to the council's lead manager for RGF.

3. Research Standards - Preparing a Principled Application

Our standards are common to all good research or study, 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 it is possible that participants will lack mental capacity to give informed consent, applicants must seek advice from the council's lead manager for RGF 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 as appropriate.
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 be applied. 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 workplaces, families and communities.

13. Researchers must have an understanding of the actions that will be taken should the possibility of risk or abuse be identified during the research process.

14. Applicants are expected to participate in the project approval process and comply with any conditions added to the notice of approval to proceed, engaging in a positive and constructive way with any advice, criticism or support that may be offered.

4. Foundations - Writing The Research Proposal

In addition to completing your online application, you will be expected to submit a Research proposal. You should prepare this proposal before making an application, as it forms the foundation for all aspects of your application and research.

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 addressing the questions in this guide 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	<ul style="list-style-type: none">• 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?• Why is this research important?• What other studies have there been in this area?• How will this research add to knowledge in this area?
How you will do your research	<ul style="list-style-type: none">• 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?
Timetable	<ul style="list-style-type: none">• Who will be funding your research?• 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?

Dissemination

- 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?
- 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?

5. Access, Monitoring and Supervision Arrangements

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 Local Authority as Sponsor'*.

Supervision

The researcher must identify 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.

6. The Role of the Sponsor

As the research sponsor for the local authority or host partner organisation, this person has responsibility for overseeing the research, ensuring that 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 guide. 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.

7. Managing Risks

The RGF is all about managing risks. As well as considering the research proposal and the application form, the approval process also considers the following risk related issues.

The vulnerability of research participants.

Some prospective participants including children, people with learning difficulties or service users with mental health issues, cannot give informed consent. With children, it is essential that consent is obtained from a responsible person with the legal ability to consent on the subject's behalf. If you think your project will involve adults who cannot give informed consent, or who do not have the mental capacity to do so, applicants must discuss how to manage this with council's lead manager for RGF. Please also see section 8, '*Research that involves adults who lack capacity to give consent*'.

The researcher's experience.

The researcher's experience is likely to have a bearing on methods and the impact on participants. This is affected by experience, being a student, knowledge of the subject, client group insight or limited knowledge of research methods. It is essential to consider the level to which the researcher's qualifications and experience are relevant and appropriate to the research area and methodology. Other related issues may arise, For example, research requiring participants to be interviewed in their homes means increased levels of disclosure of personal information and potential physical risks.

Collection and safe storage 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? Equally as important are arrangements for storage and the destruction or return of information.

Privacy and confidentiality.

Are the proposals for ensuring anonymity and confidentiality adequate? Does the information collection process conform to the data and information safety standards?

The benefits of giving consent.

All research requires information to be provided to participants and informed consent to be given before study can be carried out. Proposal must define how the potential benefits of participation are explained, along with how consent will be obtained. Participants are more willing to take part if they believe the study has wider benefit.

Risk Assessment Tool

The RGF uses a tool for assessing risks to research and study participants. This tool is always used when deciding on the level of review needed for applications, and plays a significant role in then decision to give consent to proceed.

You can pre-assess the level of risk that your project may have, and consider how risks can be controlled by looking at the tool used by assessors (appendix 3 to this guide).

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

The implementation of the Mental Capacity Act 2006 has resulted in changes and new obligations for researchers.

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

Recent guidance has led to a national a framework for the handling of applications for research that fall into this category. The Isle of Wight Council works closely with NHS colleagues to ensure that researchers are referred on to the correct research governance process as effectively as possible.

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 Act.

If you think your project may involve participants who are unable to give informed consent, please investigate the process that you may have to follow, or contact the council's lead manager for RGF.

9. Appeals and Complaints

The Research Governance Framework (RGF) Board has a working draft Appeals and Complaints process.

If an applicant disagrees with an RGF decision, they have access to appeal.

The applicant can also make a complaint to the IW council about the process used.

Taking Action

The council will welcome appeals, concerns, comments or complaints about the process, conduct or standards of the RGF. The RGF is a multi agency partnership committed to dealing with appeals and complaints promptly and at the most practical level.

Applicants can appeal against a decision, with a view to seeking a changed decision or improvement to the Research Governance Process.

Complaints received by those involved with the RGF that reflect on the conduct of the Council and the RGF process, will be dealt with as part of the council's policy and procedures for dealing with complaints.

Complaints may be referred to other organisations with a responsibility for dealing with complaints about aspects of their service.

Complaints About Research Projects

The council will have a continuing interest in 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 council for investigation. The Council's complaints management standards will be applied as appropriate.

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

Making an Complaint or Appeal

Comments, concerns, appeals or complaints should be addressed to council's lead manager for RGF.

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

The council 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.

Applicants are invited to appeal in writing, setting out the reasons for re-consideration of a decision. Appeals should be addressed to the council's lead manager for RGF.

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

The council will arrange a review of the processing of the original application, decisions made or withdrawal of consent to proceed. The review will 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 RGF Board for final consideration and decision. The Board will invite the applicant to make representations to the Board.

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

Who should I contact to find out more?

Contact the council's lead manager responsible for the RGF

10. 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 (RGF). The process relies on the help and assistance of people with research expertise.

The RGF 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 Who should I contact to find out more?
Contact the manager in the council responsible for the RGF to discuss your ideas and making an application.