Isle of Wight Council

Research Governance 2024

Contents

1 Undertaking social care or related research on the Isle of Wight

1.1 Determine whether what kind of research approval is needed

Research is a core function of health and social care. It is essential for our health and wellbeing and for the care we receive. Research benefits our knowledge or our community and the impact of what we do. It also improves the evidence base, reduced uncertainties and leads to improvements in care. If undertaken responsibly, competent research can improve lives and benefit our environment.

All research proposals must comply with the UK Policy Framework for Health and Social Care Research. This policy sets out the principles of good practice in the management and conduct of social care research, taking into account legal requirements and other standards. The policy framework should be read in conjunction with guidance provided by the NHS Health Research Authority (HRA). The HRA has held formal responsibility for research in adult social care since January 2015.

The UK policy framework defines research as the attempt to derive generalisable or transferrable knowledge to answer or refine relevant questions with scientifically sound methods. The council therefore regards 'research' as any study, survey or consultation, intended to gather information, which involved access to people in contact with public or community services. This access may be either direct or indirect. This framework applies to all health and social care research that falls within the responsibility of the HRA. This includes:

- Research conducted with the protection and promotion of public heath
- Research undertaken in or by a UK health department, its non-departmental public bodies or the NHS and social care providers
- Clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care providers and any research undertaken within the health and social care systems.

All research proposals must be approved before commencing. Research in adult social care may require approval from the Social Care Research Ethics Committee, in particular if it will involve adults who lack capacity.
To establish if your study is considered research, and to identify if your study requires Research Ethics Committee (REC) approval please follow the steps below:

1. Complete the HRA tool: Is my study research?
2. Complete the HRA tool: Do I need NHS REC approval?

Studies requiring REC approval must have an application submitted via the Integrated Research Application System (IRAS).

If your study is classified as research, but you do not need REC approval, you need to complete the Isle of Wight Council research application form. This form will be sent to you when you enquire.

1.2 Research submissions where no REC approval is required

Research applications that are not required to be processed via the IRAS will pass through the Isle of Wight Council research approval process.

If the 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.

1.3 What happens if 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 the named sponsor within the council will monitor its 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 procced. 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.

1.4 Who should I contact to find out more?

Contact the councils lead for research governance to discuss your ideas and the best way to make an application PMO.aschn@iow.gov.uk

2 Getting started

2.1 Getting started checklist

1. Read this handbook before making an application
2. Apply for approval in plenty of time. You will not be permitted to proceed without approval.
3. Be clear about the research governance principles and standards.
4. Check that you have covered the requirements for research with people who lack capacity to give consent.
5. Contact the council's lead manager for research governance.
6. Prepare your research proposal and gather the documents that you need.

2.2 Document checklist

- A completed project proposal
- Research timetable
- Information for participants
- Participant consent forms
- References
- CRB checks (yourself and any other researchers)
- Copy of approval from any relevant ethical research committee.
- Additional optional documents can include:
    - Literature review
    - Letters confirming sponsorship and academic support
    - A communication and dissemination plan for the final report
    - Other documents that will support your application

3 Preparing a principled application

Our standards are common to all good research or study, particularly where the project involves vulnerable people, their families, carers 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 prove 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 and 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 and 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 on 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 hard, discomfort or distress, 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 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 involved 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, however, 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	• 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	• Will you be doing this research on your own or with others? • Have you provided full details of anyone else you intent to carry out this research with, including fieldworkers? • Who are you targeting in this research? • How many people or case files do you intent 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 of 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? • Is 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 make against you by participants? • How will you deal with any sensitive matters that may be raised during your research? • What follow-up support will be available to participants, should they require it? • What will you do it 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 the 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?

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.

5.1 The Sponsor

The sponsor is the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report the research project. All health and social care research has a sponsor. The sponsor is normally expected to be the employer of the chief investigator in the case of non-commercial research or the funder in the case of commercial research. An employer or funder is not automatically the sponsor as the responsibilities of being a sponsor have to be explicitly accepted.

5.2 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 supervisors agreement to undertake this task. Is 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:

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

The sponsor has overall responsibility for the research including:

1. Identifying and addressing poorly designed or planned research and poor-quality research proposals, protocols or applications and ensuring that research proposals and protocols:
    - Take into account systematic reviews of relevant existing research evidence and other relevant research in progress
    - Make appropriate use of patient, service user and public involvement and
    - Are scientifically sound (e.g. through independent expert review), safe, ethical, legal and feasible and remain so for the duration of the research, taking account of developments while the research is ongoing.
2. Satisfying itself that the investigators, research team and research sites are suitable,
3. Ensuring that roles and responsibilities of the parties involved in the research and any delegation by the sponsor of its tasks are agreed and documented.
4. Ensuring adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project, and
5. Ensuring appropriate arrangements are made for making information about the research publicly available before it starts (unless a deferral is agreed by or on behalf of the research ethics committee); agreeing appropriate arrangements for making data and tissue accessible, with adequate consent and privacy safeguards, in a timely manner after it has finished; and ensuring arrangements for information about the findings of the research to be make available, including, where appropriate, to participants (For education research, registration, accessibility of data and tissues, and dissemination may be limited to institutional arrangements).
6. Ensuring that, where expected or required, the research has approval from a research ethics committee (whether outright or following a provisional opinion, resubmission or appeal) and any other relevant approval bodies before it begins.
7. Verifying that regulatory and practical arrangements are in place, before permitting the research to begin in a safe and timely manner.
8. Putting and keeping in place arrangements for adequate finance and management or the research project, including its competent risk management and data management.
9. Ensuring that effective procedures and arrangements are kept in place and adhered to for reporting (e.g. progress reports, safety repots) and for monitoring the research, including its conduct and the ongoing suitability of the approved proposal or protocol in light of adverse events or other developments.

Universities and colleges should accept the role of sponsor for all educational research conducted by their own students, unless the student is employed by a health or social provider that prefers to take on this role. Sponsors of educational research should ensure that supervisors can and do carry out the activities involved in fulfilling this role. Where the academic supervisor cannot adequately satisfy the sponsor's oversight responsibilities due to location or expertise, the sponsor should agree co-supervision arrangements with a local care practitioner.

7 Managing risks

Research governance 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:

7.1 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 research governance. Please also see section 8, *'Research that involves adults who lack capacity to give consent'.*

7.2 The researchers' experience

The researchers' 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 with the researchers' qualifications and experience are relevant and appropriate to the research are 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.

7.3 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.

7.4 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?

7.5 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. The 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.

7.6 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 for applications and plays a significant role in the decision to given consent to proceed.

8 Appeals and complaints

The Research Governance (RG) Board has a working draft Appeals and Complaints Procedure. If an applicant disagrees with a decision, they have access to appeal. The applicant can also make a complaint to the IW council about the process used.

8.1 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.

8.2 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 choses 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.

8.3 Making a Complaint or Appeal

Comments, concerns, appeals or complaints should be addressed to the council's lead 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:

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

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 the conclusion reach through review.

The lead reviewed can make a number of decisions:

1. Reverse or amend a previous decision
2. Establish new conditions for approval
3. Refer the outcome of the review to the Board for decision

The lead reviewers decision will normally over-ride the previous decisions. Any decision to refer the review to the Board for decision will be taken in association with the Research Governance coordinator.

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.

8.4 Who should I contact to find out more?

Contact the councils lead for research governance to discuss your ideas and the best way to make an application. Email: PMO.aschn@iow.gov.uk

9 Guaranteeing high standards of research on the Isle of Wight

All social care research and evaluation projects must be passed through the council's Research Governance procedure. The process relies on the help and assistance of people with research expertise.

The process ensures that projects are well planned and executed, ethical and of benefit. As small group of volunteers with varied experience or research support the process by undertaking peer reviews of research and evaluation applications. New peer reviewers are always welcome.

9.1 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.

9.2 Can you help?

Masters level research or previous involvement on the business end of research programs would qualify anyone to join the peer review group. Experience of social care or education research is desirable but not essential. If you are interested, please contact the manager in the council who is responsible for the research governance to discuss your ideas and make an application.

10 Glossary of Terms

Main/Principal Researcher	The person designated as taking overall responsibility for the design,conduct and reporting of the study.
Nominated LinkOfficer	A named council officer, usually an experienced manager, appointed by the sponsor organisation to act on its sponsor responsibilities. Theperson 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 serviceusers, 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 routinecollection of management information.
Research Governance Coordinator	The Council Officer who is the official point of referral for all prospective research applicants.
Research Governance Board	The body responsible for considering any research proposals that involve direct or indirect access to service users, their families/friends or carers. The Board is only convened as required.
Research Supervisor	The person responsible for the management of the researcher(s) andthe research.
Research Team	Other researchers who, with the Main Researcher, comprise the people conducting the study and includes field workers.
Sponsor	An organisation (often likely to be the council) taking the primary responsibility for ensuring the design of the study meets applicable standards and that arrangements are in place to ensure appropriate conductand reporting. The sponsor ensures that all the necessary agreements are in place and are documented. The sponsor is usually the main funder and could be a local authority, a University or a research foundation.