Tower Hamlets

Guidance on Research Governance Framework (RGF)

Application guidance

**Research Proposal Application – Guide to Completion**

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| The following topic areas and questions need to be covered in your proposal to carry out research which involves direct or indirect access to Children’s Directorate service users and pupils, their families and carers and/or staff of the council.  This guide will help you to complete your proposal and help the RGP to make a judgement about your research, so answering as many of the questions as possible will simplify the approval process. |
| **Areas to address in preparing your Application** |
| **1. Background**   * What are you planning to do and what are you hoping to find out through your research? * How will this research add to knowledge in this area? * Will this work duplicate any past efforts? * Why are you carrying out this piece of research (i.e. where did it originate from) * The project timetable may need to be submitted as a draft and updated later. |
| **2. Contact Information**   * It is the researcher’s responsibility to identify a project sponsor * Please provide information about all relevant parties involved in the project. If they are not yet known, this information will need to be provided before research can start. * All researchers are required to hold a current CRB check. |
| **3. Who will be involved?**   * Who are you targeting in this research? Please provide specific details, including age groups, gender, ethnicity, users (e.g. pupils, children in need, adults with mental health problems, and people with disabilities), staff, carers etc. * If you are involving a third sector organisation please provide their details. |
| **4. Methodology and Techniques**   * Please detail how users of services/pupils will be selected (e.g. random selection, through a particular group, forum etc.), and how they will be approached * What method will be used to collect information (e.g. focus groups, citizens panel, complaints scheme, postal survey, user forum, personal interviews, comment at exhibition, LAP event, citizens jury, conference, opinion poll, public meeting, E-polling/Tele-polling, Issue Form, web site survey, case reviews or other methods) * If case reviews are planned how many case files do you intend to read through? * What information will be collected from the participants? (E.g. age, date of birth, background, etc.) Please be clear if the information will contain Personally Identifiable Information. * Will the research take place at a particular location or geographical area in the borough? * How will case files/pupil data or other information be transferred to researchers, and how will they be kept securely? * Previous research/profiles * ADCS application / approval * Approvals from other approving bodies * Other groups. * Questionnaires / surveys * Interview questions * Confidentiality agreement for researchers |
| **5. Ethical Considerations**   * Potential risk areas can include work with vulnerable populations, inexperience of the researcher, collection of sensitive information, issues of privacy and confidentiality, requirement of consent, reluctance of participants and sensitivity of the research. * Where relevant, has the research taken into account age, disability, gender, sexual orientation, race, culture, and religion in its design, undertaking and reporting * What are the plans for informed consent and making sure participants are aware they can opt out of the project at any time or refuse to take part? * Participants must be given information about the Councils (if internal) or the research provider’s complaints procedure. |
| **6. Frequency**  Is the project part of a regular consultation exercise or one off? |
| **7. Resources**  Please provide details of all resources required, including Children’s Services staff time |
| **8.Corporate Research Team Support**   * Please state what help is needed if any from the Corporate Research Team |
| **9. Feedback**   * Please provide details on how your findings will be documented and fed back (e.g. distribution of report, newsletter, public notice, website/intranet, publication) * How will you provide feedback to participants? * It is a condition of approval that research be logged on the council’s database. Feedback and evaluation forms are provided for this purpose. * If you are intending to publish your work, a copy must be provided to the PRS team. * In some circumstances, it may be a condition of approval that the panel approves the report prior to publication, for example to ensure that none of the information contained is traceable to any service user/pupil. |
| **10. Attachments**  Please attach all relevant documentation.   * Research brief * Consent Form- any form (if any) used to verify consent has been obtained. * Participant Information sheet- sheet explaining to participants what the project is about and what will be needed of them as participants. * Topic List- when focus groups are planned or open discussion, please provide a list of the topics which will be covered in the * Questionnaires and interviews schedules etc |

**Using the Risk Assessment Tool**

**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:

1. the age of a child (where the child is very young);
2. the incapacity of an adult due to significant learning difficulties,
3. or mental health issues including dementia;
4. because of barriers to communication arising from language (for people whose first language is not English) or literacy (if people cannot read or write);
5. because of sensory impairments (for example visual impairment, blindness, hearing impairment or deafness);
6. 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:

1. be clearly written so the participant has a full and accurate understanding of exactly what they are consenting to,
2. state that they can withdraw from the study at any time without this affecting the services they receive in any way,
3. provide information about whom they may complain to, 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 to acknowledge the issue as well as offer an account of how any identified barriers will be surmounted. For example, a research study 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:

1. be generally inexperienced – for example, if they are a student or someone who is not a professional researcher;
2. they may lack any real knowledge of the subject under investigation;
3. they may possess little or no experience of working with those people from whom information may be collected;
4. 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 pupils/young people/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:

1. data relating to criminal records;
2. psychiatric history;
3. 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 pupils/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 the findings are reliable and valid. 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:

1. high levels of face to face contact or interaction between the investigator and the subject/participant, or
2. 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:

1. risks to the researcher – for example if the research involves visits to the homes of people who are to be interviewed.
2. 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.
3. a loss of perspective by the researcher arising from a failure to adequately manage fieldwork relationships – for example over-involvement in the research environment.
4. 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 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 Guidance. For example:

1. the security of collected data;
2. the method of analysis;
3. the way that analysed data will be presented;
4. the process by which collected data will be disposed of;

should 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 using codes, changing names, or selecting data that cannot be attributed to source. The research proposal should give a clear account of:

1. how collected data will be stored;
2. who will see the collected data;
3. how it will be analysed;
4. how long collected data will be kept; and
5. how it will be disposed of when no longer needed

**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:

1. ‘Audience effect’ in which participant’s opinions of, or attitudes toward, the researcher affects their behaviour towards the researcher or their response to questions the researcher may ask.
2. An imbalance in power between the researcher and subject/participants may make it very difficult for consent to be withheld.
3. 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.
4. 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 should offer remedies for any potential bias that may occur. For example this might be by ensuring that:

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

**Personally Identifiable Research Data**

Arrangements must be made to control access to any original personally identifiable research data, and to keep it as securely as possible. The more people who will have access to the data, whether by design or potentially by accident through inadequate storage methods, the higher the risk.

Where data is kept on computer, this should, if possible be compliant with BS7799 part 2, which is a set of criteria for the management of information systems, the following basic requirements of which would apply here:

* The system is deployed in a manner compliant with best practice guidance.
* There is a defined change control policy, compliant with best practice.
* Patches to software are deployed in a timely manner compliant with this policy.
* The system has up to date anti-virus software.
* The system is held in a secure area, with adequate air conditioning.
* The system is backed up on a regular basis.
* The system is log-in enabled.

**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.

1. There may be a risk that findings may be misinterpreted, by design or by accident.
2. 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.
3. 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 pupils/users whose first language is not English or who normally communicate using BSL. Questionnaire design should be ‘disability friendly’. 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 defines the potential benefits of the research to enable those responsible for appraising the proposal to weigh up risks against possible benefits.