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

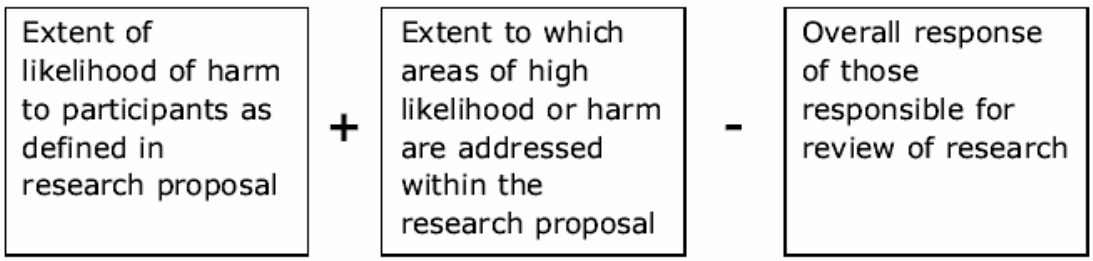
be assessed. The *left hand column statements* are those representing the highest likelihood of harm to participants. Statements found in the *right hand column* are those representing the lowest chances of harm occurring Research proposals can be appraised against each of the statements contained in 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:

- It could be used as an administrative tool to separate out and fast-track research in which likelihood of harm to participants, and degree of risk is low and a more rigorous review may be unnecessary. Where concerns about likelihood of harm or risk are identified, the tool may be used to determine the level of review that may be needed.
- It could be used within the review process itself.
- It might also be used as a self-assessment tool by the researcher or principal investigator – though a formal review process will always be needed to review research proposals.
- It could be used by Quality Assurance staff in some contexts.

In general terms it is envisaged that the tool might be used at an early stage in a defined research application process to decide who might be best placed to review the proposal, or to assist in a decision about whether to approve or not approve any proposed study.

Title of Proposal					**Date**.....
Name of Researcher/Principal Investigator.....					**Ref No** .....
Area	**Likelihood of harm (tick boxes to indicate judgement)**				**Areas of high likelihood of harm addressed?**
	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 ☐	Informed consent & ability to withdraw from study possible with support to overcome communication barriers e.g. advocates, translators/interpreters, signers, or technology ☐	Informed consent and ability to withdraw from study fully possible ☐	⇨	Concerns about informed consent and communication barriers are fully identified & addressed Concerns are not fully identified or addressed
Researcher competence	Researcher(s) not well qualified with little or no experience or knowledge of either the topic of investigation, the participants or the methods to be used e.g. undergraduate researcher/student project ☐	Researcher(s) reasonably well qualified with experience and knowledge of two out of the three following factors – topic of investigation, the participants/subjects or the methods to be used e.g. non-researcher who has had formal research training who may work in a professional domain offering relevant experience and knowledge ☐	Researcher(s) well qualified with experience and knowledge of all three of the following factors – topic of investigation, the participants/subjects and the methods to be used. e.g. formal research training and/or qualification and/or experience and knowledge gained from working in an appropriate environment ☐	⇨	Any lack of competence by the researcher(s) fully addressed Any lack of competence is not addressed

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 ☐	The topic or the kinds of information being sought include items likely to be considered slightly personal or sensitive by some people e.g. age, ethnicity, income ☐	The topic and kinds of information being sought do not focus on personal information at all e.g. opinions about services received ☐	⇨	The need to collect any personal information is fully justified The need to collect this information is not fully justified
Appropriateness of method to subject & quality of research design	The methods are neither appropriate to the subject of the proposed study or the research questions being asked, the need for the study is not established and the project does not have the resources to properly address the research question(s) ☐	The methods may not be appropriate either to the subject of the proposed study or to the main research questions, or the need for research is not established, or the project does not have the resources to properly address the research question(s) ☐	The methods are fully appropriate to the subject of the proposed study and to the research questions being asked, there is a demonstrable need for the study and the resources to carry out the study are sufficient ☐	⇨	The case for & resources to do the study exist & methods are fully appropriate to the subject or main research questions The case for & resources to do study are absent & methods are not appropriate to subject or main research questions

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 ☐	Some face-to-face contact and interaction for limited amounts of time ☐	No face to face interaction between investigator and participant ☐	⇨	Possible risks arising from high level of contact are identified and fully addressed Possible risks are not identified or addressed
Level of privacy to participant	Not confidential ☐	Confidential ☐	Anonymous ☐	⇨	If the study is not anonymous or confidential reasons for this are fully justified & conform to Data Protection Act principles Study is not anonymous or confidential and reasons for this are not fully justified

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 ☐	Limited information about subjects/participants is provided to the investigator to make the study possible or more reliable ☐	Subjects/participants are unknown to the investigator and cannot be identified ☐	⇨	Conflicts of interest are fully described & consideration given to how to minimise possible effects on study Conflicts of interest are not fully described. Proposal does not adequately consider how to minimise effects on study
External considerations	Study is likely to be extremely sensitive ☐	Parts of study may be sensitive ☐	No known sensitivities ☐	⇨	Sensitivities have been fully identified and adequately addressed Sensitivities have not been adequately addressed.

	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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