Tower Hamlets

Guidance on Research Governance Framework (RGF)

Contents

1. What is Research Governance? 3

2. What is the Research Governance Framework? 3

3. Definition of Research 4

4. What kinds of research does the RGF cover? 4

5. What is not covered by the RGF? 4

6. Who does the RGF apply to? 5

7. What is the Role of the Research Governance Panel (RGP) 5

9. Why do we need it? 6

10. Data Protection and Security……………………………………………………….7

11. What is needed before research can take place? 7

12. What is a Research Proposal? 8

13. What should be submitted to the Panel? 8

14. How will my proposal be assessed? 9

15. What happens if the proposal is approved? 9

16. What happens if the proposal is not approved? 9

17. What happens after the research has taken place? 9

18. For further information, please contact 10

**Appendices**

Appendix 1 Process Flow Chart 11

Appendix 2 Ethical Standards for Research 14

Appendix 3 Caldicott Principles 16

Appendix 4 Research Governance Framework Approval Panel 17

Terms of Reference

Research Governance Framework (RGF)

# 1. What is Research Governance?

## 1.1 Research governance can be defined as the broad range of regulations, principles and standards of good practice that exist to achieve and continuously improve research quality across all aspects of health and social care. Proper governance of research is essential to ensure there can be confidence and derived benefits from quality research, and that high scientific, ethical and financial standards, transparent decision making processes, clear allocation of responsibilities and robust monitoring arrangements are in place.

# 2. What is the Research Governance Framework?

## 2.1 The Research Governance Framework has been developed by the Department of Health and is supported by the Department for Children, Schools and Families.

## 2.2 The Framework brings together principles of good practice and provides guidance for health and social care organizations to implement standards of effective research governance.

## 2.3 The framework sets out key standards under five domains: *(appendix 2)*

* **Ethics:** ensuring the dignity, rights, safety and well-being of research participants;
* **Science**: ensuring that the design and methods of research are subject to independent review by relevant experts;
* **Information**: ensuring full and free public access to information on the research and its findings;
* **Health and safety:** ensuring at all times the safety of research participants, researchers and other employees;
* **Finance:** ensuring financial probity and compliance with the law in the conduct of research.

## 2.4 The Framework also incorporates the Caldicott Principles which govern the use of Personally Identifiable Information (appendix 3).

## 2.5 It is a core standard for healthcare organizations to have systems to ensure the principles and requirements of the Research Governance Framework are consistently applied. Healthcare organizations have to take this standard into account in discharging their duty of quality under section 45 of the Health and Social Care (Community Health and Standards) Act 2003.

2.6 The National Social Care Research Register (NRRSC) managed by the Social Care Institute for Excellence is a new resource for social care research, practice and service user communities. The Research Register will capture all research carried out within, or commissioned by, local Councils with Social Services Responsibilities (CSSR’s). Research will be defined broadly as any activity that utilizes established research methods, such as questionnaires, observation or interviews. Only that which has received independent scrutiny of its methods and ethics, however, including student and practitioner research, will be recorded.

## 2.7 The NRRSC will eventually record all social care research being undertaken within Councils with Social Care Responsibilities (CSSR’s) that has been subject to independent ethical and scientific review, including student projects.

# 3. Definition of Research

## 3.1 Research as defined by the Department of Health is “the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods”. This inclusive definition will cover any activity that involves the collection of information to derive new knowledge, either directly or indirectly, from or about individuals who may be service users, their carers, friends and relatives, or employees of the Council or its contracted agencies. This could range from relatively simple projects to full scale research, for example into adoption involving access to files and interviews with adopters and adoptees.

# 4. What kinds of research does the RGF cover?

## 4.1 The Research Governance Framework will apply to research defined in the Framework.

## 4.2 It will include information gathered through the following mechanisms:

* Surveys;
* Focus groups;
* Evaluations;
* Consultations as part of a wider research project (but see section 6 below – relationship between research and consultation);
* Student projects;
* Observations;
* Review of case files; or
* Group or Individual interviews.

## 4.3 Any multi-site research activity which involves four or more local authorities also requires the approval of the Association of Directors of Children’s Services (ADCS) Research Group – see <http://www.adcs.org.uk> for how to apply.

# 5. What is not covered by the RGF?

## 5.1 To ensure the Framework is applied appropriately and effectively and promotes the sustainability of internal routine organizational development activity, there are four locally developed exceptions to the Framework:

## Research conducted between London Borough of Tower Hamlets employees, for academic purposes, which do not require access to Children or adult social care Services information regarding current or former service users and pupils.

## Research conducted by specialist staff using existing information for the purposes of audit, inspection and performance management activities

## Research information obtained by Directorates other than Children’s or adult social care Services, for example the Housing Department conducts research using Housing information with users who are also Children’s Service users).

## Internal consultation activity is not covered by the RGF.

# 6. Who does the RGF apply to?

## 6.1 Any employee working within the London Borough of Tower Hamlets wishing to carry out research which requires access to Children and adult social care Services information, subject to the above exceptions.

## 6.2 Any individual/organization requiring access to Children and adult social care Services information for the purpose of research, which may include:

* Voluntary agencies (e.g. NSPCC, Age Concern)
* Other Local Authorities
* Primary Care Trusts
* Research consultants
* University/Social Work students
* Academic researchers

## 6.3 Any organization/individual commissioned by Children and Adult social Care Services to conduct research.

## 6.4 All research carried out in the NHS is subject to research governance through the NHS ethics committees. This framework is necessarily strict, as it would govern clinical trials of new drugs, for example. If a joint proposal for research covering both the NHS and Children or Adult Social Care Services has already been approved by the relevant ethics committee, this would support the decision to approve the proposal, but could not be a guarantee of approval. Such a proposal would therefore still have to be submitted through the Tower Hamlets RGF. Similarly, the Tower Hamlets RGF cannot approve research to be carried out in or through the NHS, for example if patient lists were to be used to access research participants this would have to be approved by the relevant NHS ethics committee.

# 7. What is the Role of the Research Governance Panel (RGP)

## 7.1 The Research Governance Panel (RGP) is responsible for scrutinizing research proposals to ensure that they are in line with good practice and meet ethical standards. The RGP will assess the proposal and will make the decision to approve/reject or modify a research proposal. All research as defined within the Framework will need to obtain approval from the RGP before proceeding with any research or preliminary research activities. Where necessary, the researcher will be asked to amend their proposal and resubmit for further consideration.

## 7.2 The RGP is made up of representatives from Children and Adult Services including the Caldicott Guardian, other members with a background in research and co-opted members who will be a manager or representative of the Service area the research concerns or other staff with specialist expert knowledge of the research subject area. Please refer to the Terms of Reference for the Research Governance Framework Approval Panel (Appendix 6).

## 7.3 The RGP seeks to deal with requests for approval quickly. The RGP will convene a virtual meeting and proposals will need the approval of no less than four members of the panel as detailed in the terms of reference. Approval will normally take no longer than two weeks. Where it is determined that the project poses a high risk to participants a formal meeting will be convened and the proposal may take longer to approve.

## 7.4 Where a research proposal concerning social care covers 4 or more local authority areas and has been approved by the ADCS[[1]](#footnote-1) Research Group, the proposal will still need to be agreed through the Tower Hamlets RGF. Although ADCS approval will indicate a lower level of risk and will support a Tower Hamlets RGF Panel decision to approve, Caldicott Guardian approval to access confidential information will still be required, and specific local arrangements will need to be checked. London local authorities may agree a common RGF approval process for such proposals to eliminate duplication of effort.

# 9. Why do we need it?

## 9.1 All health and social care providers have a duty of care to service users. We have a duty to children, vulnerable adults, their families and carers and for staff who might be the subjects of any research or where research may affect the quality of care or educational services they receive. The RGF aims to ensure that research respects participant’s rights, safety and wellbeing; values diversity within society; and meets ethical standards.

## 9.2 Governance is essential to ensure the public have confidence in, and benefit from quality research. Tower Hamlets aims to encourage research as a valuable learning tool which will help to support best practice and improve the quality of service and care provided in the borough. Effective governance will also help to ensure that staff and service user time is not wasted on poorly designed projects from which little or no valid conclusions can be drawn.

## 9.3 The requirement to register the research intentions and results on the corporate database through the Corporate Research Unit will ensure that findings will be widely available. Similarly, the requirement to register with the SCIE[[2]](#footnote-2) administered NRRSC[[3]](#footnote-3) will ensure national availability of research information on social care.

**10. Data Protection and Security**

10.1 Tower Hamlets will not pass any personally identifiable data to a third party unless an informed consent has been obtained from the research participants first.

10.2 Tower Hamlets will only send personally indefinable data to researchers either using Ironkey or through secure email systems e.g. EGRESS.

10.3 We will endeavour to provide accurate data but we will not be held responsible for organisations reaching any wrong conclusion using this data.

10.4 If the research organisations become aware of any errors in the data we request that we are informed of it by contacting dataprotection@towerhamlets.gov.uk

10.5 We expect all research organisations to comply with [Data Protection Act (1998)](http://www.legislation.gov.uk/ukpga/1998/29/contents)

10.6 Data must be stored securely using Ironkey or computer which meets the FIP 140-2 AES 256 Bit encryption.

10.7 Data must be deleted at the completion of the research or at earliest convenience after the publication of the research.

# 11. What is needed before research can take place?

## 11.1 For Tower Hamlets staff any proposed research should first be discussed with the relevant service manager or managers.

## 11.2 Before any research can begin, the RGP must approve the project.

## 11.3 The project should have an identified internal and external sponsor who will oversee the project. It is the responsibility of the researcher to identify a sponsor. The sponsor takes responsibility for confirming there are proper arrangements to initiate, manage, monitor and finance a study. The organisation funding the research will most often act as the sponsor. Where the research is initiated internally the sponsor will need to be identified from within the directorate (e.g. Manager of the Team or Service the research relates to or the manager employing the lead researcher). In the case of a student project, the role of the external sponsor will normally be undertaken by the academic advisor or practice teacher on behalf of the academic institution and the internal sponsor will be as noted above. With regards to joint research for example with other Local Authorities or NHS bodies the sponsor may be from these organisations.

## 11.4 To obtain approval you will have to complete a research proposal form and an initial risk assessment and submit the proposal for approval.

# 12. What is a Research Proposal?

## 12.1 The research proposal details the plans for research activities (appendix 5). The proposal form must be completed for every research project. The form will require information concerning:

* The aims and objectives of the project;
* Who will be involved;
* How the project will be carried out;
* What safeguards have been put in place to protect participants;
* Plans for evaluation of the project.

## 12.2 The Corporate Research Unit is also available to provide advice and support at any stage of the research process. A guide to completing your proposal / application can be found separately.

# 13. What should be submitted to the Panel?

## 13.1 Your research proposal will need to go through an approval process. The RGP will decide whether it can approve your research based on the criteria covered in the application.

## 13.2 The research proposal should include:

* Completed proposal application
* Any consent forms for intended participants(pupils, parents, school, guardian, carer etc)
* Copy of letters to be sent to participants regarding the research
* Copies of any questions to be asked during interviews/focus groups(these can be draft)
* Where informal discussions are planned, a copy of the topics to be discussed
* Copies of any survey or questionnaires used for information gathering
* Copies of any research evaluation forms
* If the project is a continuation of past research copies of past findings
* Copy of any approvals from outside bodies e.g. ADCS Approval for research covering multiple Local Authority sites
* Researchers initial risk assessment
* Project timetable
* Researchers liability insurance information
* Any other relevant information.

## 13.3 The proposal form can be filled in electronically and sent to: RGF@towerhamlets.gov.uk Please send electronic copies (where possible) of all documentation along with your proposal. Alternatively you may send them by post to:

Juanita Haynes

Intelligence and Performance Service

 London Borough of Tower Hamlets

Town Hall,

Mulberry Place

5 Clove Crescent

 London E14 2BG

# 14. How will my proposal be assessed?

## 14.1 The RGP will scrutinise proposals using the ethical standards (appendix 2) as a guide. The research proposal will be assessed in terms of:

* Its viability and whether the project will duplicate past efforts.
* Whether the plan meets the standards set by the Research Governance Framework.
* The potential risks to participants.
* Whether the Caldicott Principles have been addressed.

## 14.2 If the all the areas in the proposal form are addressed, and it does not involve issues of high risk to participants, the application should be processed quickly. If the application or nature of the research is more complex or highlights potential risks, the decision may take longer and you may be asked to provide further information.

# 15. What happens if the proposal is approved?

## 14.1 Once the application is approved, research can go ahead. You must not commence the research without first receiving formal notification of approval.

## 15.2 The Council will arrange for access to participants/data where necessary. Research projects will be registered on the research database and will be monitored by the Corporate Research Unit.

# 16. What happens if the proposal is not approved?

## 16.1 If the proposal is not approved, you will be given reasons and information about how to re-submit the proposal if appropriate. Where possible, you will be given advice on how you might change your proposal to ensure it complies with the council’s and the DH and DCSF requirements.

## 16.2 The Research Governance Panel decision is final.

# 17. What happens after the research has taken place?

## 17.1 All research whether intended for publication or not will need to be copied to Tower Hamlets. Research report should be submitted to the Corporate Research Unit, which will be placed on to the Tower Hamlets research portal sent to the SCIE National Research Register for Social Care. The database will encourage sharing of information and prevent the duplication of research efforts.

## 17.2 In some research projects, e.g. carried out by students, the RGP may make it a condition of approval that the research report is considered by them prior to publication. In this case, the RGF coordinator will distribute it to the Panel for approval.

## 17.3 Where possible, research participants should be provided with the findings of the research.

## 17.4 Research findings will form part of the process of service improvement planning.

# 18. For further information, please contact

Corporate Research Unit

RGF@towerhamlets.gov.uk

020 7364 2239

Caldicott Guardian

Dr Somen Banerjee , Director of Public Health

0207 364 7014

Somen.Banerjee@towerhamlets.gov.uk

Deputy Caldicott Guardian

Judith St John, Divisional Director Sports Leisure and Culture

0207 364 5630

Judith.StJohn@towerhamlets.gov.uk

Other Links:

[www.adcs.org.uk](http://www.adcs.org.uk)

<http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4> 108962

**APPENDIX 1**

**Process for seeking RGF approval for Research**

You will need to follow this process if none of the exemptions detailed in section 14 apply to your research proposal.

No

No

No

Yes

Yes

Yes

Yes

Yes

Applicant forwards the research proposal with supporting documents to the CRU

CRU satisfied that all sections are completed to required standard

CRU Team complete risk assessment on proposal using the RGF Risk Assessment tool

Applicant revises proposal in line with CRU/RGF recommendations / supplies further info

If high risk CRU convene virtual meeting of RGF Approval Panel and send copies of proposal, risk assessment and other documents to members **OR**

CRU Research Officer and CRU Senior Research Officer meet for approval decision

RGF Panel satisfied that all criteria are met, i.e. Risk Assessment, Data Protection, Caldicott Principles, ethical review etc.

RGF Approval Panel approves the proposal – Commence Research

No

No

Does the Proposal cover more than 4 LA boundaries?

Abandon research

Applicant to apply to ADCS

Yes

Approval given by the ADCS?

Abandon research

Is further information required?

Applicant submits further information

CRU input onto the RGF database

Go to stage 3 flowcharts overleaf

No

**Stage 1**

**Stage 2**

**RGF Process: Stage 3**

Research carried out according to proposal

Analyse and provide results/report to CRU by lead researcher

If previously agreed, panel considers and approves report prior to publication

Feedback to participants as per proposal

Evaluation as per proposal

Sponsor complete an evaluation form

CRU feed information into the National Research Register for Social Care

CRU publishes the research / findings on CRU web page

The Social Care institute for Excellence publishes the information on the Internet via the NRRSC

**Non-RGF Process**

You will need to follow this process if your research satisfies one or more exemptions detailed in section 16.

No

Yes

Yes

Yes

No

Applicant (proposer) discusses research proposal with manager of service area the research relates to.

If Manager agrees that the research is possible and worth pursuing applicant completes proposal form. Manager becomes internal Sponsor for the research

Applicant forwards the research proposal with supporting documents to the CRU Team

CRU Team are satisfied that all sections are completed to required standard

CRU Team complete risk assessment on proposal using the RGF Risk Assessment tool

Applicant revises proposal in line with CRU Team recommendations / supplies further info

CRU Team convene meeting of Research Officer and Senior Research Officer to consider proposal

CRU Team satisfied that all criteria are met, i.e. Risk Assessment, Data Protection, Caldicott Principles, ethical review etc.

Proposal approved – Commence Research

Abandon research or

Once completed CRU Team input onto the research database

Amend proposal and resubmit. Applicants are allowed one opportunity to amend proposal

**APPENDIX 2**

**Ethical Standards for Research**

**1. Ethics**

* The dignity, rights, safety and well-being of participants is the primary consideration in any research study.
* Research involving service users or staff is reviewed independently to ensure ethical standards are met.
* Research respects diversity and the multi-cultural nature of society. Wherever relevant, it should take into account age, disability, gender, sexual orientation, race, culture, and religion in its design, undertaking and reporting.
* Every effort is made to obtain informed consent from participants. With particular consideration given to those who are unable to give consent on their own behalf. The Mental Capacity Act 2005 provides safeguards for a person who lacks capacity to consent to research.
* Where children and vulnerable people are involved every effort is made to respect the wishes of participants. Carers are consulted regarding the participant’s wishes and feelings and informed of their role and responsibilities.
* Where there is a potential for risk in conducting research, the risks must be in proportion to the potential benefit.
* Arrangements are made to ensure that the needs of the participants are met. This may include providing information in alternative formats e.g. providing information in pictorial form and the use of interpreters.
* The Caldicott Principles are applied where personally identifiable information is used and Data Protection guidelines are followed.
* Those involved in designing, conducting and analysing and supervising research should have a full understanding of the subject area.
* Service users and carers or their representative groups are involved wherever possible in the design, conduct, analysis and reporting of research.

**2. Science**

* When planning research, due consideration is made to review existing sources of evidence. Any work which unnecessarily duplicates, or which is not of sufficient quality to contribute to something useful to existing knowledge is unethical.
* Data collected during the course of research is retained for an appropriate period of time if necessary.
* The methodology used to gather information is appropriate and valid. Good research can often use a combination of methodologies, which complement one another.

**3. Information**

* Information regarding research is made available to the public in accordance with the Freedom of Information Act and should be presented in a format understandable to the public.

**4. Health and Safety**

* The safety of participants and of the researcher and other staff must be given priority at all times in compliance with health and safety regulations.

**5. Finance**

* Research should have sufficient and appropriate resources in terms of people, time, transport, money etc. allocated to it.
* Research complies with the law and with the rules set out by HM treasury for the use of public funds.

**APPENDIX 3**

**Caldicott Principles**

The sharing of information between agencies is a major issue within health, social care and education, as there are many inter-dependencies in the provision of services, and there is a need for joined up public services. To address this, a committee was formed, chaired by Dame Caldicott, this committee created a set of principles, called the Caldicott Principles, which govern the use of Personally Identifiable Information. They are broadly similar to those outlined in the [Data Protection Act](http://thhome/LBTHIntranet/Directorates/SocialServices/StrategicServices/DpaBriefSocServs.htm) 1998, but predate it.

**What is 'Personally Identifiable Information' (PII)?**

 Personally Identifiable Information, also known as PII, is anything that can identify an individual; this includes, but is not limited to:

* Name
* Contact details
* Date of Birth
* Racial or Ethnic Origin
* Political Opinions, Religious or other Beliefs
* Trade Union membership
* Physical or mental health
* Sexual Orientation & sexual history
* Offences or alleged offences

**The Principles**

1. **Justify the purpose(s)**: Every proposed use or transfer of PII within or from an organization should be clearly defined and scrutinized, with continuing uses regularly reviewed by the Caldicott Guardian
2. **Don't use Personally Identifiable Information (PII) unless it is absolutely necessary**: PII should not be used unless there is no alternative
3. **Use the minimum necessary PII**: Where use of PII is considered to be essential, each individual item of information should be justified with the aim of reducing identifiability
4. **Access to PII should be on a strict need-to-know basis**: Only those individuals who need access to PII should have access to it, and they should only have access to the information items they need to see for a specific purpose
5. **Everyone should be aware of their responsibilities**: Action should be taken to ensure that those handling PII are aware of their responsibilities and obligations to respect an individual's confidentiality
6. **Understand and comply with the law**: Every use of PII must be lawful. Each organization must identify a person responsible for ensuring that the organization complies with legal requirements

APPENDIX 4

Research Governance Framework Approval Panel

Terms of Reference

**Purpose**

The purpose of the RGF Approval Board is to ensure that all proposed research, whether initiated externally or internally within the organisation, meets the standards required by Tower Hamlets Research Governance Framework. Particularly:

* Proper arrangements are in place to initiate, manage, monitor and finance the study
* There is a sponsor overseeing the above
* Best practice is being followed in relation to ethical and scientific considerations
* Information governance arrangements comply with data protection legislation and Caldicott requirements
* The health and safety of participants, researchers and staff will be secured

**Membership**

Caldicott Guardian Dr Somen Banerjee Director of Public Health

Deputy Caldicott Guardian Judith St John Divisional Director Director Sports Leisure and Culture

Corporate Information Governance Deputy Manager (Robert Wingate)

Senior Intelligence and Performance Manager (Juanita Haynes)

Specialist Practitioner, Children’s Social Care, Team Manager\*\*

Specialist Practitioner, Adult Social Care Team Manager\*\*

**Responsibilities**

* + - 1. To scrutinise research proposals, within agreed timescales to ensure that the research will meet the agreed RGF standards.
			2. To be familiar and keep up to date with all best practice guidance and research governance systems.
			3. To comment and / or suggest approval / rejection of the research proposal within agreed timescale.
			4. To meet as necessary to consider research proposals identified in the risk assessment as ‘high risk’ projects.
			5. To scrutinise reports of research findings prior to publication, if necessary.
			6. To annually review research carried out.

**Operation**

1. Research proposals should be sent to rgf@towerhamlets.gov.uk
2. The RGF coordinator will check that the proposal has been completed correctly and return for further information where necessary.
3. The Corporate Research Officer will complete a Risk Assessment, to be approved by the relevant panel members.
4. Where the risk assessment indicates a low or medium risk, Corporate Research Officer and Corporate Senior Research Officer will meet and consider the proposal and will approve the research if all requirements are met.
5. Where the risk assessment indicates a high risk, the Corporate Research Officer will convene a meeting of the RGF Approval Board, supplying all the relevant information. A quorum of 4 panel members must agree the research proposal. This must include either the Caldicott Guardian or Deputy Information Governance Manager; Corporate Research Officer; and the Specialist Manager or deputy / nominated alternative officer. The Chair will also consider whether to invite the researcher/sponsor to the meeting.
6. The Panel Chair will consider and address any concerns that panel members may have, and inform the proposer either that the research is approved and can go ahead, that further information is needed, or that the research cannot be approved, and why.
7. The Corporate Research Officer will register the research on both the corporate RGF database, and the CSCI research register.
8. The researcher will send the report of the research findings to the relevant email address as above, and the Corporate Research Officer will distribute this to the panel for approval prior to publication if necessary.
1. Association of Directors of Children’s Services [↑](#footnote-ref-1)
2. Social Care Institute of Excellence [↑](#footnote-ref-2)
3. National Research Register for Social Care [↑](#footnote-ref-3)