Research Policy and Procedure

Policy type	**Quality Assurance**
Directorate area	**All Directorates**
Policy author/champion	**Theresa Nixon, Director of Quality Assurance**
Equality screened:	**29.09.09** **02.12.10 Reconsidered with no change Dr D Stewart**
Date approved by Executive Team	**23.01.11**
Date approved by Board	**N/A**
Date of issue to RQIA staff	**31.03.11**
Date of review	**February 2013**

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Section 1: Introduction

The Regulation and Quality Improvement Authority (RQIA) is committed to fostering, encouraging and supporting a quality research culture and recognises the value of high quality research to the organisation and to other stakeholders, as a means of promoting continuous service improvement.

The development of a research policy and procedure is an integral part of RQIA's corporate objectives as outlined in the RQIA Corporate Strategy 2009-12.

Research is essential to the successful promotion and protection of health and well-being and to modern and effective health and social care services. At the same time, research can involve an element of risk, both in terms of return on investment and sometimes for the safety and well-being of the research participants.

Proper governance of research in RQIA is therefore essential to ensure that the public can have confidence in and benefit from, quality research in health and social care.

This policy provides a simple, consistent approach for all RQIA staff undertaking research and any research commissioned by RQIA through agreed partnership arrangements. The policy also sets out arrangements for external organisations who wish to access data held by RQIA to support research.

This policy is based and aligned to the principles of research outlined in the Research Governance Framework for Health and Social Care in Northern Ireland (Research & Development Office Northern Ireland, December 2006).

1.1 Definitions

Research is defined by the Research & Development Office Northern Ireland (R&D Office) as a systematic activity that:

- Attempts to answer a clearly defined question
- Employs systematic and rigorous methods, including quantitative and/or qualitative paradigms
- Leads to new knowledge.

For an activity to be classified as research it must meet all three qualifying elements.

Health and social care research activity can be categorised as Service Evaluation, Audit or Research. The National Patient Safety Agency in collaboration with the National Research Ethics Service provides definitions to assist in differentiating these activities as follows:

Service Evaluation is designed and conducted solely to define or judge current care. It measures current services without reference to a standard. It usually involves the analysis of existing data but may include administration of simple interventions or questionnaires.

Audit is designed and conducted to produce information that reports on the delivery of best care. It measures current services against a predetermined standard. It also usually involves the analysis of existing data but may include administration of simple interventions or questionnaires.

Research is the attempt to derive generalisable new knowledge by either generating a hypothesis or testing a hypothesis through qualitative and/or quantitative research. It addresses clearly defined questions, aims and objectives. It usually involves collecting data that is additional to that routinely gathered and can include treatments, samples, or investigations that are additional to routine care. It may also involve randomisation.

Research falls into 2 main types: primary (as undertaken by scientists, social scientists and historians) and secondary (as undertaken by journalists, patent lawyers and Research and Development departments).

Service evaluation and audit do not warrant a mandated Research Ethics Committee (REC) review. However, depending on the nature of research this may be required.

1.2 Purpose and Aims

The purpose and aims of this policy are to:

- Encourage and support the development and promotion of a quality research culture across RQIA

- Introduce mechanisms that will allow research active professionals to conduct research in an environment that facilitates the highest standards of quality, transparency and integrity and in doing so promotes excellence in research quality

- Prevent poor performance, adverse incidents or research misconduct

- Align RQIA's practices with those specified in the Research Governance Framework for Health and Social Care in Northern Ireland (R&D Office December 2006).

Section 2: Scope

This policy is of direct relevance to all RQIA staff who wish to commission, conduct, participate in or fund and manage health and social care research.

It is also relevant to any other external person or organisation who wishes to use information held by RQIA for the purpose of research.

This policy applies to all research carried out by or on behalf of RQIA and includes requests from third party researchers for access to information held by RQIA. In particular, this policy applies to:

- RQIA staff using RQIA data
- RQIA staff using external data
- External staff using RQIA data.

The scope of this policy therefore extends to:

- All clinical and non-clinical research, undertaken by Health and Social Care (HSC) staff using RQIA resources
- All research undertaken by industry, the charities, the research councils and universities associated with health and social care system using RQIA resources.

Section 3: The Policy Statement

RQIA encourages and supports a high quality research culture and the delivery of research within appropriate governance arrangements.

This research policy sets out the research conduct expected of professionals within RQIA, or external to RQIA, when engaged in research.

Section 4: Legislative Framework

All research conducted by RQIA or with RQIA resources must comply with relevant professional standards and guidance including the following:

- **The Research Governance Framework for Health and Social Care in Northern Ireland (R&D Office, Dec 2006).** This framework ensures that any research undertaken and supported is done so properly and sensitively; respecting the rights, dignity, safety and wellbeing of patients and clients. The document identifies the responsibilities that fall to research sponsors, funders, researchers, employing organisations, care organisations, care professionals and participants. Each has a part to play in ensuring that any research undertaken in the area of health and social care meets these standards.

- **EU Directive 2001/20/EC of the European Parliament and of the Council.** This directive covers the approximation of laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. It has significant implications for various aspects of research governance. It aims to simplify and harmonise administrative provisions governing clinical trials, provide a clear transparent procedure and create conditions productive to an effective co-ordination of clinical trials in the EU, facilitating the internal market in medicinal products whilst maintaining appropriate levels of protection for public health. All member states were required to transpose the Directive 2001/20/EC into national law by May 2004.

- **The Data Protection Act,** 1998

- **Medicines for Human Use (Clinical Trials) Regulations**, (DoH, 2004)

- **Human Tissue Act**, 2004

- **Animals (Scientific Procedures) Act**, 1986

- **Protection and Use of Patient Client Information – Guidance for the HPSS**, (DHSSPS, 2006)

- **MRC Guidelines for Good Clinical Practice in Clinical Trials**, (MRC 1998)

- **Consent to Examination, Treatment of Care** (DHSSPS, 2003)

- **HSC Controls Assurance Standards: Research Governance**, (DHSSPS, Apr 2009)

In addition, all research must take apply the principles and best practice recommendations outlined in:

- **Code of Practice for Research - Promoting Good Practice and Preventing Misconduct**, (UK Research Integrity Office, September 2009). This document sets out the responsibilities and values relevant to research. The principles encourage all those involved in research to consider the wider consequences of their work and to engage critically with the practical, ethical and intellectual challenges that are inherent in the conduct of high quality research. The seven principles are:
    - Excellence
    - Honesty
    - Integrity
    - Co-operation
    - Accountability
    - Training and Skills

- Safety

It should be noted that health and social care research is not the province of a single discipline, profession or directorate. Whilst there is a full range of legislation, standards and good practice guidelines available to researchers (as mentioned above) their governance principles can be grouped under five main domains:

- ethics
- science
- information
- health and safety and employment
- finance and intellectual property.

RQIA will monitor and undertake research only when satisfied that the five domains are taken into account and safeguarded throughout the lifetime of the research project.

Section 5: Responsibilities

It is the responsibility of all Directors and Line Managers to ensure that the content of this policy is adhered to and approval given.

The **Board** has overall responsibility for ensuring that the principles of the Research Policy and Procedure are applied within the legislative framework and in a consistent manner. The Board will be kept informed of any relevant research issues.

The **Chief Executive** as "Accountable Officer" has overall responsibility for ensuring that the aims of this policy are met. The Chief Executive is also responsible for disseminating any learning.

The **Executive Team (EMT)** EMT is responsible for ensuring effective research governance within RQIA. EMT has operational responsibility to ensure that the aims of this policy are met and that the policy is applied within the legislative framework and in a consistent manner. EMT is also responsible for developing appropriate partnership arrangements with external organisations and for the dissemination of any learning.

The **Director of Service Improvement** is the designated chair of the RQIA Research Group, and is accountable to EMT.

The **Research Group** is responsible for making appropriate decisions with regards to approval for all research proposals submitted; and also responsible for promoting, encouraging and supporting research in RQIA. (Refer to the Terms of Reference in **Appendix 8**). The Research Group will also ensure that all necessary external approvals have been sought.

Research initiated by RQIA / Request for RQIA information in relation to external research

The **Heads of Programme** are responsible for supporting and encouraging their staff in all aspects of research and have particular responsibility to ensure that all staff adhere to this policy.

The **Researcher** bears the day to day responsibilities for the conduct of research including:

- Ensuring that any research they undertake follows the current version of the agreed protocol
- Helping care professionals to ensure that participants receive appropriate care while involved in research
- Reporting any adverse events
- Protecting the integrity and confidentiality of clinical and other records and data generated by the research and by reporting any failures in these aspects or suspected misconduct thorough appropriate systems.

The **Chief Investigator** is responsible for the overall design, conduct and reporting of the research project, including:

- Developing proposals that are scientifically sound and ethical
- Submitting the design for independent expert review
- Submitting the study (or proposal) for independent ethical review
- Conducting a study to the agreed protocol (or proposal) in accordance with legal requirements, guidance and accepted standards of good practice
- Preparing and providing information for participants
- Ensuring participants' welfare while in the study
- Arranging to make findings and data accessible following expert review
- Feeding back results to research participants
- Conducting the study in accordance with agreed funding arrangements.

More information on the roles and responsibilities of the funder, the sponsor and the host organisation are found in **Appendix 7**.

Note: The provision of information held by RQIA in regard to external organisations, in accordance with the procedure set out in this policy, does not imply any shared responsibility by RQIA in ensuring that the conduct of the research is carried out in keeping with good research governance procedures. This remains solely the responsibility of the researcher.

Section 6: Training

All staff will be informed of the new policy and procedures by the chair of the Research Group via the monthly staff meeting and internal email.
Heads of Programme and Line Managers should raise awareness of this policy and procedures in their team meetings and in appraisal meetings with their staff.
The Research Group will determine the training needs of RQIA staff in respect of promoting, encouraging and supporting research and informing regarding the requirements needed for research approval.

Section 7: Equality

This policy has been screened for equality implications as required by Section 75, Schedule 9, of the Northern Ireland Act, 1998. Equality Commission for Northern Ireland Guidance states that the purpose of screening is to identify those policies which are likely to have a significant impact on equality of opportunity so that greatest resources can be targeted at them.

Using the Equality Commission's screening criteria, no significant equality implications have been identified. This policy will therefore not be subject to an equality impact assessment.

This policy has been considered under the terms of the Human Rights Act, 1998, and was deemed to be compatible with the European Convention Rights contained in that Act.

This policy will be included in the Authority's register of screening documentation and maintained for inspection whilst it remains in force.

Section 8: Monitoring/ Evaluation

The implementation and adherence to this policy will be monitored and reviewed by the Research Group.

Section 9: Review of Policy

This policy will be reviewed in February 2013.

Section 10: Development and Stakeholder Consultation

This policy was developed in consultation with:

- Research and Development Office Northern Ireland
- Southern Health and Social Care Trust Research Manager
- Executive Team Policy Sub Group
- Quality Assurance Directorate
- Policy Group
- RQIA Staff

Section 11: The Procedure

11.1 Research Application

As of April 2009, all health and social care research applications must be completed using the **Integrated Research Application System** (IRAS) Form. IRAS is a single system for applying for permission and approval of health and social care/community care research across the United Kingdom which:

- Enables the researcher to enter the information about the project once instead of duplicating information in separate application forms
- Uses filters to ensure the data collected and collated is appropriate to the type of study
- Helps to meet regulatory and governance requirements
- Retains many of the familiar aspects of the previous National Research Ethics Service (NRES).

IRAS captures the information needed for the relevant approvals from the following bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Gene Therapy Advisory Committee (GTAC)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Ministry of Justice
- NHS/HSC Research and Development (R&D) Offices
- NRES/NHS/HSC Research Ethics Committees
- National information Governance Board (NIGB)
- Social Care Research Ethics Committee.

Appendix 1 lists the questions to be completed in the IRAS online Research Form.

11.2 RQIA Procedures

RQIA will consider for approval all research proposals as defined on pages 4 and 5 of this policy - proposals that sustain and enhance RQIA's Value Proposition as outlined in the Corporate Strategy 2009-12.

All researchers must demonstrate to RQIA that they have adopted the Code of Practice for Research - Promoting Good Practice and Preventing Misconduct's checklist. Please refer to **Appendix 2** for the full details of the checklist.

When a research proposal is registered the Chair will convene the group to process the proposal.

All proposals for research within or external to RQIA including requests for assistance with a research project, or access to information held by RQIA for the purpose of research, must be registered initially with the Chair of the RQIA Research Group. An initial draft research proposal should be completed on the template attached to **Appendix 3/Appendix 4 [if applicable]**. The applicant

should clearly state how the project meets the definition of research rather than service evaluation or audit as set out in Section 1.1 above.

RQIA will consider granting approval to proceed with the research once the RQIA Executive team and RQIA Board are satisfied that the research application:

- Is compliant with the R&D Research Governance Framework for Health and Social Care principles,
- Is compliant with the Data Protection Act (1998) and Human Rights Act (1998)
- Has received full REC approval (when this is required)
- Is compliant with any other legislative requirements such as:
    - Administration of Radioactive Substances Advisory Committee (ARSAC)
    - Gene Therapy Advisory Committee (GTAC)
    - Medicines and Healthcare Products Regulatory Agency (MHRA)
    - Ministry of Justice
    - NHS/HSC Research and Development (R&D) Offices
    - NRES/NHS/HSC Research Ethics Committees
    - National information Governance Board (NIGB)
    - Social Care Research Ethics Committee.
- Has build in appropriate mechanisms to safeguard data and information as well as the sources of the data
- Has clearly defined the different roles and responsibilities of the Researcher, the Chief Investigator, the Host organisation, the Sponsor and the Funder.

Following provisional approval by the RQIA Research Group (see **Appendix 5**) to continue with the research approval process, the researcher should seek approval from IRAS, secure funding and sponsors. This process will include seeking any other relevant approval requirements (e.g. Research Ethics Committee and/or MHRA approval).

The progress of the research application and its constituent parts will be discussed at regular intervals with the RQIA Research Group. The Research Group will inform the RQIA Executive team and RQIA Board of any developments.

When the final approval from IRAS has been received, the researcher should forward a copy of the signed and approved application form to the RQIA Research Group who will issue a final RQIA Research Project Approval Form (see **Appendix 6**).

Section 12: Glossary

Literature

Department of Health, (2005), "*Research Governance Framework for Health and Social Care*", Second Edition

Institute for Research and Innovation in Social Services, (Apr 2008) "*Towards a Research and Development Strategy for Social Services in Scotland*"

King's College London, (2008), "*Research in the Workplace*"

National Research Ethics Service and National Patient Safety Agency, (2008), "*Defining Research*", Issue 3

Research and Development Office Northern Ireland, (Dec 2006), "*Research Governance Framework*"

Scottish Executive, (2003), "*Research Strategy for health and Healthcare*", TSO

Southern Health and Social Care Trust (Dec 2008), "*Policy for the Management of Research and Development*"

Southern Health and Social Care Trust, (Jan 2009), "*Research and Development Strategy"*

UK Research Integrity Office, (Sep 2009), "*Code of Practice for Research. Promoting Good Practice and Preventing Misconduct*"

UK Research Integrity Office, (Aug 2008), "*Procedure for the Investigation of Misconduct in Research*"

Walker D., (Aug 2008), "*Strategic Plan for the development and Promotion of IADI Research, Guidance and Core Principles: 2008/10*", Consultation version

Web Sites

IRAS
https://www.myresearchproject.org.uk/

Kings College
http://www.kcl.ac.uk/research

National Research Ethics Service
http://www.nres.npsa.nhs.uk/

Office for Research Ethics Committees in Northern Ireland
http://www.orecni.org.uk/display/home

Research and Development Office Northern Ireland
http://www.centralservicesagency.com/display/rdo

Legislations and Standards

United Kingdom: Research Governance Framework
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_088293

Northern Ireland: Research Governance Framework
http://www.dhsspsni.gov.uk/research_governance_framework.pdf

Northern Ireland: Research Governance Research Standard
http://www.dhsspsni.gov.uk/research_gov_controls_assurance_standard__pdf_162kb_.pdf

Patient Confidentiality and Caldicott Guardians

http://www.dh.gov.uk/en/Managingyourorganisation/Informationpolicy/Patientconfidentialityandcaldicottguardians/DH_4084181

Confidentiality - NHS Code of Practice

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4069253

Data Protection Act

http://www.opsi.gov.uk/acts/acts1998/19980029.htm

Access to health records

http://www.opsi.gov.uk/acts/acts1990/Ukpga_19900023_en_1.htm

Use of Human Tissue and Organs

http://www.opsi.gov.uk/acts/acts2004/20040030.htm

Medicines for Human Use (Clinical Trials) Regulation 2004

http://www.opsi.gov.uk/si/si2006/20062984.htm

Informed Consent

http://www.nres.npsa.nhs.uk/applications/guidance/

Guidance on Information sheets and consent forms

http://www.nres.npsa.nhs.uk/applications/guidance/

Research ethics

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/Browsable/DH_088297

APPENDIX 1

Questions on IRAS Online Application Form

PART A - Core Study Information

1. Administrative Details

Title of research
Student project details
Chief Investigator for Student project
Chief Investigator details
Central study coordinator details
Research reference numbers
Other linked studies or applications

2. Overview

Lay Summary
Overview of study purpose and design

3. Purpose and Design

Methodology description
Type of CTIMP
Phase of CTIMP
Principal research question/objective
Secondary research question/objective
Scientific justification
Summary of design and methodology
Patient/Public Involvement
Consulting patients/public on use of data without consent

4. Risks and ethical issues

Sample group or cohort
First time in humans
Inclusion/exclusion criteria

5. Research procedures, risks and benefits

Details of non-clinical interventions or procedures
Details of clinical interventions or procedures
Withholding of clinical interventions or procedures
Potential risks and burdens
Potential for distress in interviews, questionnaires, or group discussions

Potential benefits
Arrangements for continued provision of intervention after research finished
Potential risks for researchers
Identification of potential participants
Screening personal data
Methods/ resources
Access to personal data outside the care team
Consent to access identifiable data
Details of recruitment through posters or adverts
How and by whom potential participants will be approached
Informed consent
Recording Consent
Use of data without consent
Time to decide on participation
Participants' involvement in other research
Participants with inadequate English language skills or special communication needs
Welsh language
Providing information to participants during the research
Loss of capacity to consent during the study

Confidentiality

Checklist of data processing activities
Physical security of data storage
Confidentiality of data
Separation/encryption of identifiers
Access to identifiable data during the study
Analysis of data and location
Data custodian
Retention of identifiable data at the end of the study
Period of data storage
Long term arrangements for data storage

Incentives and Payments

Financial payments/incentives (participants)
Financial payments/incentives (researchers)
Conflicts of interest

Notifying other health professionals

Notifying GP or other health professional
Permission to notify

Publication and dissemination

Trail registration
Dissemination of study results

Ensuring the anonymity of published data
Informing participants of the study result

6. Science

Scientific critique
Assessment by Expert Advisory Group and commission on Human Medicine
Statistics critique
Primary outcome measure
Secondary outcome measure
Sample size
Sample size determination
Randomisation
Methods of analysis

7. Management of Research

Key collaborators
Lead Sponsor
Sponsor's contact point
Legal representative in EEA
External funding
Subcontractors
Previous rejection by REC
Lead R&D contact
Duration of study
Definition of the end of the study
Overview of host organisations
Identification of participants
NHS participant identification centres (PICs)
Resources for PICs
Monitoring and auditing the conduct of the research
DMC and stopping rules
Insurance/indemnity - management of study
Insurance/indemnity - design of study
Insurance/indemnity - conduct of study
No fault compensation
Intellectual property
Level of commercial participation

PART B - Additional information for specific applications

Investigational medicinal products
Medical devices (populates the MHRS Devices Form)
Exposure to ionising radiation (populates ARSAC form)
Use of existing human tissue samples
Use of new human tissue samples

Adults unable to consent for themselves
Children
Additional information NIGB (populates NIB) form
Additional information for Ministry of Justice (populates the MoJ forms)

Part C - List of Research Sites

List of research sites NHS participants' identification centres (for R&D offices only)

Part D - Declarations

Chief Investigator
Sponsor's representative
Academic supervisor
Information Guardian (NIGB only)

APPENDIX 2

Recommended checklist for researchers

Before conducting your research:

1. Does the proposed research address pertinent question(s) and is it designed either to add to existing knowledge about the subject in question or to develop methods for research into it?
2. Is your research design appropriate for the question(s) being asked?
3. Will you have access to all necessary skills and resources to conduct the research?
4. Have you conducted a risk assessment to determine:
    a. whether there are any ethical issues and whether ethics review is required?
    b. the potential for risks to the organisation, the research, or the health, safety and wellbeing of researchers and research participants? and
    c. what legal requirements govern the research?
5. Will your research comply with all legal and ethical requirements and other applicable guidelines, including those from other organisations and/or countries if relevant?
6. Will your research comply with all requirements of legislation and good practice relating to health and safety?
7. Has your research undergone any necessary ethics review (see 4(a) above), especially if it involves animals, human participants, human material or personal data?
8. Will your research comply with any monitoring and audit requirements?
9. Are you in compliance with any contracts and financial guidelines relating to the project?
10. Have you reached an agreement relating to intellectual property, publication and authorship?
11. Have you reached an agreement relating to collaborative working, if applicable?
12. Have you agreed the roles of researchers and responsibilities for management and supervision?
13. Have all conflicts of interest relating to your research been identified, declared and addressed?
14. Are you aware of the guidance from all applicable organisations on misconduct in research?

When conducting your research:

1. Are you following the agreed research design for the project?
2. Have any changes to the agreed research design been reviewed and approved if applicable?
3. Are you following best practice for the collection, storage and management of data?
4. Are agreed roles and responsibilities for management and supervision being fulfilled?
5. Is your research complying with any monitoring and audit requirements?

When finishing your research:

1. Will your research and its findings be reported accurately, honestly and within a reasonable timeframe?
2. Will all contributions to the research be acknowledged?
3. Are agreements relating to intellectual property, publication and authorship being compiled with?
4. Will research data be retained in a secure and accessible form and for the required duration?
5. Will your research comply with all legal, ethical and contractual requirements?

APPENDIX 3

Initial RQIA Research Proposal

Project/Research Title:

_____
_____
_____

Name(s) of Applicants:

1. _____

2. _____

Contact Details of Principal Investigator

Name	Address	Telephone Number
Job Title	**Employer**	**Employer Address**

Research Questions or Hypothesis

Abstract

Please provide a concise statement of what you are going to do, why and how appropriate it is. Please also provide a brief description of the research area and how you arrived at the research question or hypothesis. (250 words maximum)

Plan of Investigation

Using the six categories below, give a short, high level description of your methodology and sample.

1. Study Design	
2. Planned Interventions	
3. Estimated Duration	
4. Type of Participants	
5. No. of Participants	
6. Inclusion/Exclusion Criteria	

Resources

Please detail below, what resources will be required and how and by whom these will be provided.

Resources Required	**Provided by whom and how**

Project Funding

Has a potential funder been identified	**Y**		**N**		If yes please give details below

Project Sponsor

Signatures

Applicant: _____ Date: _____

Applicant: _____ Date: _____

Line Manager: _____ Date: _____

FOR OFFICE USE ONLY

Approved by RQIA Research Group

Reason for additional funding if applicable

Reason for non approval (if appropriate)

Final report received

Copy received:

Hard Copy ☐ E Format ☐ None ☐

Publications:

APPENDIX 4

Request for Access to Information held by RQIA

Project/Research Title:

_____
_____
_____

Name(s) of Applicants:

1. _____

2. _____

Contact Details of Principal Investigator

Name	Address	Telephone Number
Job Title	**Employer**	**Employer Address**

Research Questions or Hypothesis

Abstract

Please provide a concise statement of what you are going to do, why and how appropriate it is. Please also provide a brief description of the research area and how you arrived at the research question or hypothesis. (250 words maximum)

Plan of Investigation

Using the six categories below, give a short, high level description of your methodology and sample.

1. Study Design	
2. Planned Interventions	
3. Estimated Duration	
4. Type of Participants	
5. No. of Participants	
6. Inclusion/Exclusion Criteria	
7. Specific Information Requested from RQIA	
8. Purpose	
9. Description of Information Request	
10. Information Governance Arrangements	
11. Time Period	
12. Geographic Coverage	

Resources

Please detail below, what resources will be required and how and by whom these will be provided.

Resources Required	**Provided by whom and how**

Project Funding

Has a potential funder been identified	**Y**		**N**		If yes please give details below

Project Sponsor

Signatures

Applicant: _____ Date: _____

Applicant: _____ Date: _____

Line Manager: _____ Date: _____

FOR OFFICE USE ONLY

Approved by RQIA Research Group

Reason for additional funding if applicable

Reason for non approval (if appropriate)

Final report received

Copy received:

Hard Copy ☐ E Format ☐ None ☐

Publications:

APPENDIX 5

RQIA Provisional Approval to Research Proposal

Project/Research Title: _____ _____ _____ _____
Project Reference Number:
Date Form 1 submitted to RQIA Research Group:
Having reviewed your research proposal, the Research Group confirms that the proposed project: • Aligns with our Corporate strategy • Has included all the major resource components, and • It appears feasible for the research to be carried out On that basis, provisional approval is granted for the project to proceed to the next stage. You should now proceed to complete the OREC application Form and submit for ethical approval* and submit your full submission **(Form 3)**, funding and sponsorship arrangements for final approval to the Research Group.
Signature: _____ **(Chairperson Research Group)** **Date: _____**

APPENDIX 6

Research Project Final RQIA Approval

PROJECT DETAILS			
Principal Investigator:		**Project Reference Number:**	
Research Title:			
Directorate:			
Date of planned commencement:			
Date of planned completion:			
Sponsor:			
Funding Organisation:	**Funding Category:**	**Own Account**	
		HSC Funded	
		Non-commercial Externally Funded	
		Commercially Funded	

Documentation	Received/Comment
RQIA Form 1 - proposal	
RQIA Form 2 - Approval to proceed with application	
IRAS Application Form	
Funding Confirmation	
Sponsorship Agreement	
Ethical Approval Confirmation	
Statutory Body Approval(s), if applicable	
Commercial Agreement(s), if applicable	
Copy of Contract Details, if applicable	
Honorary Contracts for non-RQIA staff working on RQIA's premises	

Research Staff involved in Project	Indemnity provided by

SECTION 1: Final Approval to be completed by Chairman of RQIA Research Group

Having reviewed the project documentation presented, I can confirm that the proposed project:

- Aligns with our research strategy,
- Has included all the major resource components, and
- It appears feasible for the research to be conducted in this Authority
- Has been Peer Reviewed internally/externally* (Delete as appropriate)
- Has received a favourable ethics opinion

On that basis, I grant approval for project to proceed

Signed: Date:

SECTION 2: Financial Approval to be completed by the relevant Director/Deputy Director

Having reviewed the financial details contained within the project information presented, I confirm that:

- All reasonably foreseeable resources required and other costs have been identified and included,
- Correct values have been applied for all standardised costs, and
- Non standard costs have been correctly qualified

On that basis, I grant financial approval for the project

Signed: Date:

SECTION 3: Indemnity Arrangements to be completed by the Director of Corporate Services
(Please delete (a) or(b) as appropriate)

Having reviewed the documentation of project presented, providing the researchers adhere to and abide by the conditions set out within the research management process, I am satisfied that:

(a) the indemnity arrangements provided by external source are acceptable,

(b) that the Trust agrees to provide indemnity in the event of a claim by, or on behalf of, participants for negligent harm.

Signed: Date:

SECTION 4: Approval to be completed by the Chief Executive of RQIA

Having reviewed the documentation of the project presented, I can confirm that the proposed project meets the requirements of the Research Governance framework, has received ethical approval by HPSS Research Ethics Committee.

On that basis I authorise RQIA's Research Group to grant approval to the Chief Principal Investigator.

Signed:

Name:

Date:

This Certificate of Approval/Indemnity has been issued by the Research Group provided the researcher(s) involved adhere to and abide by the conditions below:

- The researcher(s) must adhere strictly to the research management policy and research protocol
- There must be no changes to research protocol without prior consent of RQIA
- There must be no changes in research staff without prior consent of RQIA. In the event of changes of staff, the Principal Investigator must request a reissue of this Certificate of Indemnity.
- There must be no increase in the resources required without prior consent of RQIA
- Researcher(s) must report all untoward incidents and/or adverse events to RQIA
- Any concerns in relation to the research protocol must be reported to RQIA
- Any matter of interpretation in relation to the research protocol to be referred to RQIA
- Researchers adhere to good research practice principles in line with the Code of Practice for Research - Promoting Good Practice and Preventing Misconduct, (UK Research Integrity Office, Sep 2009)
- Researchers adhere to the requirements of the ORECNI Research Governance Framework

Any changes invalidate this certificate

APPENDIX 7

Roles and Responsibilities in Research Projects (R&D Office, 2006)

Responsibilities of the researcher

Researchers bear the day to day responsibilities for the conduct of research. They are responsible for:

- Ensuring that any research they undertake follows the current version of the agreed protocol
- Helping care professionals to ensure that participants receive appropriate care while involved in research
- Reporting any adverse events
- Protecting the integrity and confidentiality of clinical and other records and data generated by the research and by reporting any failures in these aspects or suspected misconduct thorough appropriate systems

Responsibilities of the Chief Investigator

The Chief Investigator is the person who takes overall responsibility for the design, conduct and reporting of the research project:

- Developing proposals that are scientifically sound and ethical
- Submitting the design for independent expert review
- Submitting the study (or proposal) for independent ethical review
- Conducting a study to the agreed protocol (or proposal) in accordance with legal requirements, guidance and accepted standards of good practice
- Preparing and providing information for participants
- Ensuring participants' welfare while in the study
- Arranging to make findings and data accessible following expert review
- Feeding back results to research participants
- Conducting the study in accordance with agreed funding arrangements

Responsibilities of Main Funder

The main funder is the organisation providing funding for the research project (through contracts, grants or donations):

- Assessing the scientific quality of the research proposed
- Establishing the value for money of the research proposed
- Considering the suitability of the research environment in which the research will be undertaken, particularly the experience of the Chief Investigator and other key researchers involved
- Ensuring that appropriate sponsorship arrangements are in place before the research begins

Responsibilities of Main Sponsor

The sponsor is the individual, organisation or group taking on the responsibility for securing the arrangements to initiate, manage and finance the research project, confirming that everything is ready for the research to begin by:

- Taking on responsibility for putting and keeping in place arrangements to initiate, manage and fund the study

- Satisfying itself that the research protocol, research team and research environment have passed appropriate scientific quality assurance processes
- Satisfying itself that the study has ethical approval before it begins
- For clinical trials involving medicines, seeking a clinical trial authorization and making arrangements for investigational medicinal products
- Satisfying itself that arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reactions

Responsibilities of the organisation providing care/responsible care professional

This is the organisation responsible for providing health and social care to patients and/or services users and carers participating in a study:

- Arranging for an appropriate person to give permission for research involving patients, service users, carers or staff, before the research starts.
- Ensuring that any research is conducted to the standards set out in the Research Governance Framework for Health and Social Care in Northern Ireland (R&D Office, 2006)
- Requiring evidence of ethical review before recruitment to any research that affects the organisation's duty of care
- Before recruitment to trials with medicines, requiring evidence of a positive ethical opinion and a clinical trials authorisation
- Retaining responsibility for the care of participants to whom the organisation has a duty

APPENDIX 8

RQIA RESEARCH GROUP
TERMS OF REFERENCE

The Terms of Reference of the RQIA Research Group are to:

1. Promote, encourage and support research with all staff in RQIA.

2. Consider all research proposals received, and make appropriate decisions with regard to approval to the next stage.

3. Agree a process to consider appeals made by researchers/chief investigators for research proposals which have been declined by the Group.

4. Quality assure and monitor research governance monitoring outputs prior to consideration by RQIA's Governance Committee.

5. Promote and encourage a multidisciplinary research culture within RQIA and with other agencies, which will secure implementation of policies and procedures for effective research management and enable the creation of new knowledge and implantation of existing knowledge for the good of current and future patients/clients/users.

6. Identify and support the identification of research training needs of staff in RQIA and ensure that these are met.

7. Liaise with outside bodies that have a statutory or advisory role in research matters including the research and development structures within the HSC in Northern Ireland.

8. Monitor funding from commercial and non-commercial funders and ensure that all research funding within RQIA is managed to a high standard of cost-effectiveness and accountability to the public.