RESEARCH MANAGEMENT POLICY
Policy Title: Research Management Policy

Executive Summary: This document sets out East Cheshire NHS Trust’s policy on the undertaking of any research study within the organisation to enable assurance that the principles and practices of research governance are followed.

Supersedes: Research & Development Management Policy v.4

Description of Amendments(s) Change to Issued by and Author Section 3. Principles – change to reflect current approval process Section 5. Organisational responsibilities and duties – changes to reflect current responsibilities of key staff. Section 6. Inclusion of summary detail on the Research Governance Framework Section 7. Measuring performance and audit – changes to reflect reporting mechanism to Trust SQS Committee.

This policy will impact on: All corporate Trust policies and procedure documents relating to the undertaking of research within the Trust.

Policy Area: Trustwide Document Reference: ECT002816
Version Number: V5 Effective Date: April 2017
Issued By: Lorraine Jackman, Deputy Director of Corporate Affairs & Governance Review Date: April 2020
Author: Fiona Smith, Head of Integrated Governance Impact Assessment Date: July 2017

APPROVAL RECORD

Consultation: Clinical Audit Research & Effectiveness (CARE) Group March 2017
Approved by Committees: Clinical Audit Research & Effectiveness (CARE) Group
Safety Quality and Standards Committee May 2017
Approved by Director Director of Corporate Affairs & Governance March 2017
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1. **Purpose**

The government has introduced the concept of Research Governance\(^1\) as a quality assurance system for improving the standards of research practice across health and social care and reducing unacceptable variations. It follows a standard model for defining and communicating quality standards; introducing mechanisms to ensure those standards are met; and monitoring adherence to the standards.

All individuals and organisations involved in research associated with health and social care have responsibilities within research governance. The Trust has varying responsibilities in its capacity as healthcare provider, employer, and in some cases, research sponsor to ensure that the principles and practices of research governance are followed.

Accordingly, the Trust has a series of specific policies and Standard Operating Procedures covering different aspects of research governance. These documents are linked through to this overarching policy on research governance, which sets out the arrangements for conduct and management of research activity at East Cheshire NHS Trust.

2. **Definition of Research**

Research is defined within the Research Governance Framework for Health and Social Care, 2005, as "the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods"\(^1\). This definition includes studies that aim to generate hypotheses, as well as studies that aim to test them.

Generally, research studies have the following characteristics:

- It follows an established method of data collection and analysis;
- It is designed to elicit information that will be applicable to and of interest to people outside the immediate research context/organisation;
- It will be publicly disseminated (e.g. via conference presentation or publication)

3. **Principles**

This policy aims to promote good research practice in the Trust, to enhance the ethical and scientific quality of research, and to safeguard the rights and interests of patients. It also aims to prevent poor, wasteful and unnecessary research, and adverse incidents.

1. All research involving East Cheshire NHS Trust must be registered with the Trust's Clinical Effectiveness, Research and Development Department.

2. A research study involving East Cheshire NHS Trust patients, staff, or undertaken on its premises, cannot proceed until written explicit approval has been granted by the Head of Integrated Governance.

3. All research is subject to the Trust's Research Governance policies and must be carried out in accordance with the appropriate legislation e.g. Clinical Trials Regulations\(^2\), the Human Tissue Act 2004, Mental Health Act 2007 etc.
4. **Scope**

The above principles apply to:
- all research undertaken on East Cheshire NHS Trust premises, with its staff; NHS patients, to whom the Trust has a duty of care; patient material or patient data
- all individuals involved in the conduct of research either taking place within or in conjunction with the Trust, its patients or staff whether a Trust/NHS employee, holding an honorary contracts or a research passport.

Failure to abide by this policy could lead to the halting of a study and disciplinary action.

5. **Organisational Responsibilities and duties**

5.1 The **Chief Executive** is responsible for ensuring that the Trust meets its legal and policy obligations under the Research Governance Framework and the implementation of the Research Strategy. The Chief Executive may delegate responsibility for ensuring compliance to an appropriately qualified and senior member of staff.

5.2 The **Medical Director** has Trust Board responsibility for Research.

5.3 The **Director of Corporate Affairs and Governance** is responsible for ensuring effective research governance processes are in place working closely with the executive lead for research and development and is also Chair of the Clinical Audit and Research Effectiveness Group.

5.4 The **Deputy Director of Corporate Affairs and Governance** is responsible for overseeing the implementation of the Operational Research Governance.

5.5 The **Clinical Lead for Research (Deputy Medical Director)** acts as a champion for Clinical Research at the Trust. They engage with clinical colleagues to promote research and to define priority areas inline with the Clinical Strategy.

5.6 The **Principal Investigator** is responsible for approving that the research project is appropriate to be carried out and accommodated within the service. This ensures any likely impact on services has been considered throughout the conduct of the study.

5.7 The **Head of Integrated Governance** is responsible for management and monitoring of compliance with research governance processes, policies and standards.

5.8 The **Research Governance Facilitator** – The Research Governance Facilitator is responsible for ensuring appropriate governance arrangements are implemented and risks to patient safety are mitigated. This includes delegated authority for approval of minor amendments to study protocols.

5.9 The **Southern Sector Partnership** is expected to enhance research and help to ensure:
- Common administrative and shared governance processes to ensure rapid approval of applications and oversight
- Broader collaboration
- Improved resilience
- Greater skill mix
5.10 **Research staff** are responsible for operational implementation of research governance whilst undertaking research activity and identifying gaps in controls/assurance that may impact on patient safety, experience and care effectiveness.

5.11 Each patient is selected for participation in a clinical research trial/study by a trained **Principal Investigator**, who will apply the inclusion/exclusion criteria that have been approved by National Ethics Committee.

6. **Research Governance Standards**

The Trust has a statutory responsibility to ensure that all research involving the Trust or Trust patients is conducted in accordance with the Research Governance Framework\(^{(3)}\). Trust compliance with this requirement is monitored by the Care Quality Commission. Researchers each have an individual responsibility to comply with the Research Governance Framework in their own research practice. A summary of the requirements is given below:

(a) **General Management Arrangements**

(i) The Trust should be notified of, and approve, all research which is proposed to be undertaken in the Trust. The progress of research projects will be monitored.

(ii) There should be clear documented agreements with research partners about the allocation of responsibilities for research.

(iii) Staff should be made aware and kept informed of the Research Governance Framework.

(iv) Research governance is a component of the wider issue of clinical governance and appropriate links should be set in place to ensure compatibility.

(v) Honorary contracts or letters of access should be awarded, where appropriate, to non NHS researchers involved in research within the Trust. Employment contracts and honorary contracts should include compliance with the Research Governance Framework.

(b) **Ethics**

(vi) All research should have research ethics committee approval, where appropriate.

(vii) Arrangements should be set in place to monitor that the procedures in the protocol approved by the research ethics committee, for example informed consent, are being adhered to.

(c) **Science**

(viii) The ‘sponsor’ of research should be explicitly stated. This can include externally funded research, research funded by the Trust and research which is indirectly sponsored by another agency.

(ix) Clinical trials research should be conducted in accordance with the principles of good clinical practice (GCP).

(x) Clinical trials involving Investigational Medicinal Products (IMPs) must comply with the Medicines for Human Use (Clinical Trials) Regulations 2004

(xi) Prospective research project should be subjected to expert independent review.
(xii) Appropriate public and patient involvement should be sought at various stages in the development and execution of research projects. Consideration will be given to ensuring equality issues are considered when recruiting people for PPI.

**Information**
(xiii) Systems should be set in place to ensure that all researchers are aware of the Data Protection Act and other guidance related to handling information.

(xiv) Research should be both published in peer reviewed academic journals and appropriately disseminated to the relevant target audiences.

**Health & Safety**
(xv) Adverse events associated with research should be recorded and reported in line with incident reporting policy and study protocol.

(xvi) Systems should be set in place to detect and deal with research misconduct and fraud.

**Finance**
(xvii) There should be written agreements with sponsors for all funded work in the Trust.

(xviii) There should be systems to ensure the appropriate costing and financial management of research.

(xix) Intellectual property arising from research should be identified and registered with appropriate agreements for ownership, exploitation and income of arising from that intellectual property.

7. **Measuring performance and audit**

The key performance indicator identified which relates to this policy is as follows:
All research studies will achieve 100% compliance when audited against the Research Governance Audit Tool. This will be reported via quarterly reports to Trust SQS Committee.

8. **Review (this policy)**

This policy will be reviewed every 3 years.

9. **References**


(2) The EU Clinical Trials Directive (2001/20/EC) came into force on 1 May 2004 and has been transposed into UK law by the Medicines for Human Use (Clinical Trials) Regulations 2004. and all subsequent amendments up to, and including, The Human Medicine’s Regulations 2012.

Equality Analysis (Impact assessment)

Please START this assessment BEFORE writing your policy, procedure, proposal, strategy or service so that you can identify any adverse impacts and include action to mitigate these in your finished policy, procedure, proposal, strategy or service. Use it to help you develop fair and equal services.

Eg. If there is an impact on Deaf people, then include in the policy how Deaf people will have equal access.

1. What is being assessed?

Research Management Policy

Details of person responsible for completing the assessment:

- **Name:** Fiona Smith
- **Position:** Head of Integrated Governance
- **Team/service:** Governance

State main purpose or aim of the policy, procedure, proposal, strategy or service:

(usually the first paragraph of what you are writing. Also include details of legislation, guidance, regulations etc which have shaped or informed the document)

This document sets out East Cheshire NHS Trust’s policy on the undertaking of any research study within the organisation to enable assurance that the principles and practices of research governance are followed.

2. Consideration of Data and Research

To carry out the equality analysis you will need to consider information about the people who use the service and the staff that provide it. Think about the information below – how does this apply to your policy, procedure, proposal, strategy or service

2.1 Give details of RELEVANT information available that gives you an understanding of who will be affected by this document

Cheshire East (CE) covers Eastern Cheshire CCG and South Cheshire CCG. Cheshire West & Chester (CWAC) covers Vale Royal CCG and Cheshire West CCG. In 2011, 370,100 people resided in CE and 329,608 people resided in CWAC.

Age: East Cheshire and South Cheshire CCG’s serve a predominantly older population than the national average, with 19.3% aged over 65 (71,400 people) and 2.6% aged over 85 (9,700 people).

Vale Royal CCGs registered population in general has a younger age profile compared to the CWAC average, with 14% aged over 65 (14,561 people) and 2% aged over 85 (2,111 people).
Since the 2001 census the number of over 65s has increased by 26% compared with 20% nationally. The number of over 85s has increased by 35% compared with 24% nationally.

Race:
- In 2011, 93.6% of CE residents, and 94.7% of CWAC residents were White British
- 5.1% of CE residents, and 4.9% of CWAC residents were born outside the UK – Poland and India being the most common
- 3% of CE households have members for whom English is not the main language (11,103 people) and 1.2% of CWAC households have no people for whom English is their main language.

Gender: In 2011, c. 49% of the population in both CE and CWAC were male and 51% female. For CE, the assumption from national figures is that 20 per 100,000 are likely to be transgender and for CWAC 1,500 transgender people will be living in the CWAC area.

Disability:
- In 2011, 7.9% of the population in CE and 8.7% in CWAC had a long term health problem or disability
- In CE, there are c.4500 people aged 65+ with dementia, and c.1430 aged 65+ with dementia in CWAC. 1 in 20 people over 65 has a form of dementia
- Over 10 million (c. 1 in 6) people in the UK have a degree of hearing impairment or deafness.
- C. 2 million people in the UK have visual impairment, of these around 365,000 are registered as blind or partially sighted.
- In CE, it is estimated that around 7000 people have learning disabilities and 6500 people in CWAC.
- Mental health – 1 in 4 will have mental health problems at some time in their lives.

Sexual Orientation:
- CE - In 2011, the lesbian, gay, bisexual and transgender (LGBT) population in CE was estimated at 18,700, based on assumptions that 5-7% of the population are likely to be lesbian, gay or bisexual and 20 per 100,000 are likely to be transgender (The Lesbian & Gay Foundation).
- CWAC - In 2011, the LGBT population in CWAC is unknown, but in 2010 there were c. 20,000 LGB people in the area and as many as 1,500 transgender people residing in CWAC.

Religion/Belief:
The proportion of CE people classing themselves as Christian has fallen from 80.3% in 2001 to 68.9% in 2011 and in CWAC a similar picture from 80.7% to 70.1%, the proportion saying they had no religion doubled in both areas from around 11%-22%.
- **Christian:** 68.9% of Cheshire East and 70.1% of Cheshire West & Chester
- **Sikh:** 0.07% of Cheshire East and 0.1% of Cheshire West & Chester
- **Buddhist:** 0.24% of Cheshire East and 0.2% of Cheshire West & Chester
- **Hindu:** 0.36% of Cheshire East and 0.2% of Cheshire West & Chester
- **Jewish:** 0.16% of Cheshire East and 0.1% of Cheshire West & Chester
- **Muslim:** 0.66% of Cheshire East and 0.5% of Cheshire West & Chester
- **Other:** 0.29% of Cheshire East and 0.3% of Cheshire West & Chester
- **None:** 22.69% of Cheshire East and 22.0% of Cheshire West & Chester
- **Not stated:** 6.66% of Cheshire East and 6.5% of Cheshire West & Chester

**Carers:** In 2011, nearly 11% (40,000) of the population in CE are unpaid carers and just over 11% (37,000) of the population in CWAC.

**2.2 Evidence of complaints on grounds of discrimination:** (Are there any complaints or concerns raised either from patients or staff (grievance) relating to the policy, procedure, proposal, strategy or service or its effects on different groups?)

None

**2.3 Does the information gathered from 2.1 – 2.3 indicate any negative impact as a result of this document?**

None

LB comment - 6.c/xii states that patient and public involvement is required, there is therefore an equality consideration here as to how this is achieved so as to give people with protected characteristics an equal opportunity to be involved. This could be mentioned at this point in the policy – that ‘consideration will be given to ensuring equality issues are considered when recruiting people for PPI.’ This would then cover how people are selected to participate and also the reasonable adjustments you may need to make to make it happen.

Policy amended by author to reflect this issue and strengthen the policy. LB 31.7.17

**3. Assessment of Impact**

Now that you have looked at the purpose, etc. of the policy, procedure, proposal, strategy or service (part 1) and looked at the data and research you have (part 2), this section asks you to assess the impact of the policy, procedure, proposal, strategy or service on each of the strands listed below.

**RACE:**

From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, racial groups differently?  

Yes ☐  No ☑

**Explain your response:**

The policy is applied equally to all groups of staff.

**GENDER (INCLUDING TRANSGENDER):**

From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect, different gender groups differently?  

Yes ☐  No ☑

**Explain your response:**

The policy is applied equally to all groups of staff.
**DISABILITY**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, disabled people differently?  
Yes □ No x □

**Explain your response:**
The policy is applied equally to all groups of staff. However as it is a public written document there could be an impact on those with visual impairment, therefore the document can be made available in other formats such as large print if required. It can also be made available in easy read.

**AGE:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, age groups differently?  
Yes □ No x □

**Explain your response:**
The policy is applied equally to all groups of staff.

**LESBIAN, GAY, BISEXUAL:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, lesbian, gay or bisexual groups differently?  
Yes □ No x □

**Explain your response:**
The policy is applied equally to all groups of staff.

**RELIGION/BELIEF:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, religious belief groups differently?  
Yes □ No x □

**Explain your response:**
The policy is applied equally to all groups of staff.

**CARERS:**
From the evidence available does the **policy, procedure, proposal, strategy or service** affect, or have the potential to affect, carers differently?  
Yes □ No x □

**Explain your response:**
The policy relates only to staff members
OTHER: EG Pregnant women, people in civil partnerships, human rights issues. From the evidence available does the policy, procedure, proposal, strategy or service affect, or have the potential to affect any other groups differently? Yes □ No x □

Explain your response:
The policy is applied equally to all groups of staff.

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4. Safeguarding Assessment - CHILDREN

<table>
<thead>
<tr>
<th>a. Is there a direct or indirect impact upon children?</th>
<th>Yes □</th>
<th>No x □</th>
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</table>

b. If yes please describe the nature and level of the impact (consideration to be given to all children; children in a specific group or area, or individual children. As well as consideration of impact now or in the future; competing / conflicting impact between different groups of children and young people:

c. If no please describe why there is considered to be no impact / significant impact on children

The policy relates to staff members only

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5. Relevant consultation

Having identified key groups, how have you consulted with them to find out their views and that the made sure that the policy, procedure, proposal, strategy or service will affect them in the way that you intend? Have you spoken to staff groups, charities, national organisations etc?

Consultation of Medical Director, Director of Corporate Affairs & Governance and Clinical Audit and Research Effectiveness group

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6. Date completed: 13/06/2017 Review Date: March 2020

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7. Any actions identified: Have you identified any work which you will need to do in the future to ensure that the document has no adverse impact?
<table>
<thead>
<tr>
<th>Action</th>
<th>Lead</th>
<th>Date to be Achieved</th>
</tr>
</thead>
<tbody>
<tr>
<td>LB comment - 6.c/xii states that patient and public involvement is required, there is therefore an equality consideration here as to how this is achieved so as to give people with protected characteristics an equal opportunity to be involved. This could be mentioned at this point in the policy – that 'consideration will be given to ensuring equality issues are considered when recruiting people for PPI.' This would then cover how people are selected to participate and also the reasonable adjustments you may need to make to make it happen. Policy amended by author to reflect this issue and strengthen the policy. LB 31.7.17</td>
<td>FS</td>
<td>31.7.17</td>
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8. Approval  – At this point, you should forward the template to the Trust Equality and Diversity Lead lynbailey@nhs.net

Approved by Trust Equality and Diversity Lead:  

Date: 31.7.17