# Policy on Chief Investigators and Principal Investigators in Research

**CATEGORY:** Policy  
**CLASSIFICATION:** Governance

**PURPOSE**
To set out the responsibilities of Chief Investigators (CI) and Principal Investigators (PI) in research and the conditions for approving an individual as CI or PI

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**Distribution:**

- **Essential Reading for:** Clinical Researchers, Divisional Directors, Clinical Service Leads, Divisional Directors of Operations, Senior Trust Managers, Service Managers
- **Information for:** All staff who are involved in research
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1 Policy Statement

1.1 This policy sets out the principles for accepting an individual to act as Chief Investigator (CI) or Principal Investigator (PI) for a clinical research study undertaken in the Trust, and the responsibilities of CIs and PIs. The purpose is to ensure that there is appropriate leadership and accountability for research studies involving patients and resources of the Trust.

1.2 This policy may be amended from time to time by authority of the Executive Director of Delivery, provided that such amendments are compliant with the Policy on Controlled Documents.

2 Scope

2.1 This policy applies to all clinical research as defined in Appendix 1 of the Trust’s General Policy on Research Governance.

2.2 All clinical research studies must have a Chief Investigator and most research studies will need a local Principal Investigator (see paragraphs 3.5 for exceptions).

3 Framework

3.1 Under the Department of Health’s Research Governance Framework and the Medicines for Human Use Act (2004), the terms ‘Chief Investigator’ and ‘Principal Investigator’ have clear defined and prescribed roles. NHS Trusts have a primary duty to care for patients and it is essential that this duty is not compromised in clinical research.

3.2 Chief Investigator (CI)

3.2.1 The Chief Investigator is the person designated by the Sponsor to provide overall leadership for the conduct of a study. They would usually be the person who was primarily responsible for designing the research study and writing the protocol.

3.2.2 The Chief Investigator is accountable to the Sponsor for overall conduct of the study.

3.2.3 It is for the Sponsor to decide who should act as Chief Investigator.

3.2.4 Where the Trust is asked to act as sponsor, the Chief Investigator would normally be employed by the Trust. If the proposed CI was employed by another organisation, that organisation would be expected to act as sponsor.

3.3 Principal Investigator (PI)

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1 The Chief Investigator is also sometimes referred to as the Coordinating Investigator.
3.3.1 The local Principal Investigator is the person in the Trust who takes responsibility for implementing the clinical components of a study in the Trust and is accountable through usual clinical management structures for overseeing the conduct of the study in the Trust.

3.3.2 Because most clinical activity in the Trust is consultant-led, and to avoid potential conflicting authorities, the following set of principles generally apply when considering whether someone is appropriate to act as Principal Investigator for a study:

a) The PI must have direct first-line responsibility for the care of patients. The following would generally be eligible to act as PIs:

   (i) Consultant (including Nurse Consultant)
   (ii) Service lead
   (iii) Head of Therapy
   (iv) Clinical Nurse Specialists
   (v) Associate Specialist

b) The PI should be employed by the Trust or hold an honorary clinical contract with the Trust; and

c) The PI must be able to provide evidence of appropriate up-to-date training (see below paragraphs 3.6).

3.3.3 There can be only one PI for a study even if the study involves several disciplines.

3.3.4 There will be circumstances where it is appropriate that someone who does not meet 3.3.2a) or 3.3.2b) should act as PI; in particular where no consultant would normally be expected to be involved in the care of the patient. In such circumstances suitable senior staff such as a head of department, senior manager, senior scientist or equivalent may act as PI. The Divisional Director appropriate for the proposed PI must approve their appointment.

3.3.5 The PI need not necessarily be involved in managing or directing the day to day conduct of the study, but the PI must maintain oversight of the study and will be accountable to the Chief Executive and the Board of Directors for the conduct of the study.

3.3.6 The CI and PI may be the same person if the CI meets the eligibility criteria for PI or is otherwise approved to act as PI for the Trust.

3.4 Changes in PI or CI
3.4.1 If the existing PI leaves the Trust, or is otherwise unable to continue to act as PI (which may include reasons connected with concerns over the governance of a study), a replacement PI must be identified and authorised in accordance with paragraphs 3.3.2 to 3.3.4. Wherever possible, the handover of PI responsibilities should occur before the previous PI leaves. If this is not possible then the research study must be suspended until a new PI has been approved.

3.4.2 Any proposed change in PI must be notified to the Research and Development Office and cannot come into effect until approved by the Research and Development Office.

3.4.3 Paras 3.4.1 and 3.4.2 also apply for CIs for Trust-sponsored studies.

3.4.4 A change in Principal Investigator must be notified to the NHS Research Ethics Committee that reviewed the original application. If the study is a clinical trial of a medicine this is regarded as a substantial amendment and cannot be implemented until the amendment has received a favourable opinion from the Research Ethics Committee.

3.4.5 A change in Chief Investigator is always regarded as a substantial amendment and cannot be implemented until a favourable opinion has been received from the original NHS research ethics committee and, if the study is a clinical trial of a medicine, authorisation from the Medicines and Healthcare Products Regulatory Agency (MHRA).

3.5 Studies without a PI

3.5.1 Where the Trust is providing a routine clinical treatment or procedure for patients recruited into a study from outside UHB then it may not be necessary to have a local PI. In these cases it is sufficient for the Research and Development Office to have confirmation from the appropriate service lead that the procedures are consistent with standard care for the patients.

3.5.2 However, if any of the procedures are specific to the study protocol or if the study would result in more patients receiving the treatment or procedure than would otherwise be the case then a local PI is required.

3.6 Experience and Training

3.6.1 A PI must be able to demonstrate sufficient education, experience and training appropriate to the particular study on which they are leading.
3.6.2 All active clinical researchers should have a basic level of training in the principles of Good Clinical Practice (GCP) and the UK legislation implementing the EU clinical trials directive.

3.6.3 Online and face-to-face training courses accredited by a University, pharmaceutical company or the National Institute for Healthcare Research (NIHR) are widely available. A list of approved courses is available from the Research and Development Office. If other training has been undertaken, the investigators should seek confirmation from the Research and Development Office that this meets the criterion.

3.6.4 Refresher training in GCP is required every 5 years, or earlier if recommended by the Research and Development Office. For example if the Research and Development Office obtain evidence of poor investigator compliance with research governance standards.

3.6.5 If there is a significant change in legislation relevant to research governance then the Research and Development Office will ensure an appropriate update is provided to all principal investigators.

3.6.6 Evidence of training in other areas may be required as appropriate (e.g. consent, mental capacity, or study specific procedures).

4 Duties

4.1 Chief Investigators

The outline list of CI responsibilities is set out in Appendix 2. This includes some duties of the sponsor that have been delegated to the CI. This may be amended from time to time and an up-to-date list is available from the Research and Development Office.

4.2 Principal Investigators

4.2.1 The outline list of PI duties is set out in Appendix 3. This may be amended from time to time and an up-to-date list is available from the Research and Development Office.

4.2.2 The PI may delegate some or all of their duties. However, this must be documented in the study file with clear evidence that those who have been delegated duties have accepted them.

4.3 Executive Director of Delivery

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2 The GCP principles are set out by the International Committee on Harmonisation (ICH) and incorporated into EU Directive 2005/28/EC
The Executive Director of Delivery is responsible for the development of the research strategy for the Trust and overseeing its implementation and effective governance.

4.4 **Divisional Directors and Clinical Service Leads**

Divisional Directors and Clinical Service Leads are required to ensure that they keep abreast of all research within their area of responsibility. They should satisfy themselves that the researchers are sufficiently qualified and trained to undertake the research proposed, that the individual research studies fit with any broadly defined research strategy for the clinical service or division, and that adequate resources are available to enable the research to take place.

4.5 **Head of Research & Development Governance**

The Head of R&D Governance:

4.5.1 ensures all research projects are assessed and, when appropriate conditions have been met, duly authorised in accordance with the principles of the NHS Research Governance Framework and all relevant UK legislation;

4.5.2 checks the appropriateness of individuals to act as Chief Investigators and Principal Investigators on studies;

4.5.3 puts in place procedures to maintain effective oversight of the progress of individual research projects;

4.5.4 may require a PI to undergo refresher training if significant governance issues are identified during auditing or monitoring of a study; and

4.5.5 oversees appropriate monitoring and auditing of individual research studies against established principles of good research practice, and to check compliance with Trust policies.

5 **Implementation and Monitoring**

5.1 The Trust's research authorisation process ensures that an assessment has been made of the appropriateness of individuals to act PIs and CIs and that they have formally acknowledged their responsibilities to the Trust for the conduct of the study.

5.2 The Trust Research and Development Office maintains a library of investigator CVs and requests an updated copy from a PI if it is more than 3 years old.
5.3 Trust Learning and Development Department maintains a record of staff who have undergone GCP training through the Birmingham Research Training Collaborative.

5.4 A report on compliance with this policy is included in the annual Research Governance report to the Research and Development Committee from the Head of Research and Development Governance.

5.5 If concerns are raised about the conduct of a study and these cannot be resolved by the PI, then the study may be suspended by the Head of Research and Development Governance and an investigation will take place via the Research and Development office. A decision of action will then be approved by the Board of Directors.

6 References

Department of Health

Statutory Instrument 2004/1031
The Medicines for Human Use (Clinical Trials) Regulations 2004

7 Associated Policy and Procedural Documentation

7.1 General Policy on Research Governance

7.2 Research Passport Policy

7.3 Policy on Scientific Misconduct

7.4 Policy on Reporting Research Incidents and Breaches
## Appendix 1

### Monitoring Matrix

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<th>MONITORING OF IMPLEMENTATION</th>
<th>MONITORING LEAD</th>
<th>REPORTED TO PERSON/GROUP</th>
<th>MONITORING PROCESS</th>
<th>MONITORING FREQUENCY</th>
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<tr>
<td>Trust Research and Development Database</td>
<td>Research and Development Administrator</td>
<td>Head of R&amp;D Governance</td>
<td>Trust Research and Development Database flags if proposed PI meets standard criteria or not. Record of latest CV and evidence of GCP training maintained on Research and Development database. Database will not allow Trust authorisation letter to be generated if a study doesn’t have a suitable PI, or the CV is out of date or there is no evidence of GCP training within the past 5 years. A recommendation to undertake refresher training is flagged if the PI has not provided evidence of training in the past 3 years.</td>
<td>Continuous</td>
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<td>Training records and delegated duties logs reviewed as part of governance audits of studies.</td>
<td>Research and Development Governance Facilitator</td>
<td>R&amp;D Committee</td>
<td>Annual programme of random study audits. ‘For-cause’ audits where concerns have been raised. Monitoring visits for Trust-sponsored clinical trials</td>
<td>Approximately 5-10% of studies each year for random audits. 1 monitoring visit per year for Trust-sponsored trials.</td>
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<td>Annual Research Governance report to the Research and Development Committee</td>
<td>Head of R&amp;D Governance</td>
<td>Research and Development Committee</td>
<td>Outcome of audits reporting by exception</td>
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Appendix 2

Chief Investigator Duties

1) Administration

a) The Chief Investigator is responsible for submitting a request for authorisation to undertake the study to the competent authority (MHRA) on behalf of the Trust (as sponsor) – where appropriate.

b) The Chief Investigator is responsible for requesting an opinion from the National Research Ethics Service (NRES) on behalf of the Sponsor.

c) The Chief Investigator is responsible for submitting amendments and reports, including annual reports and the final report, to the MHRA and NRES as required subsequent to authorisation of a study.

d) The Chief Investigator must ensure that all copies of correspondence relating to the study between the Chief Investigator and the ethics committees and regulatory authorities are sent to the Trust’s Research and Development Office.

2) Pharmacovigilence

a) The Chief Investigator is responsible on behalf of the sponsor for reporting, within the statutory timeframes, to the MHRA, NRES and Principal Investigators at participating sites, details of any Suspected Unexpected Serious Adverse Reactions (SUSARs)

b) The Chief Investigator must therefore ensure that all adverse events occurring at any of the approved centres are reported to themselves promptly. The Chief Investigator must also ensure that an assessment has been made, by themselves or a competent expert, and documented, of the seriousness of each event and its relatedness and expectedness to the medicinal product or procedures used in the study in order to determine whether the event is classed as a SUSAR.

c) The Chief Investigator is responsible for generating and submitting an Annual Safety Report (ASR) to the MHRA.

d) The Chief Investigator must ensure that copies of all pharmacovigilence reports sent to the MHRA and ethics committees are also sent to the Trust’s Research and Development Office.

3) Investigational Medicinal Products (IMPs)

a) The Chief Investigator is responsible for ensuring appropriate supply of IMPs to all study sites in accordance with the protocol

b) The Chief Investigator is responsible for ensuring that the labelling of IMPs conform to Article 15 of EU Directive 2003/94/EC

4) Protocol Breaches
a) The Chief Investigator must ensure that any serious breaches in the protocol or principles of good clinical practice at any of the sites (including their own) are reported to the Research and Development Office within 5 days of becoming aware of the breach. A serious breach is one which is likely to affect to a significant degree the safety or mental or physical health of the participants or the scientific value of the study.

5) Documentation and Archiving

a) The Chief Investigator is responsible for ensuring that a trial master file conforming to the Medicines for Human Use (Clinical Trials) Regulations 2004 is created, maintained and secured throughout the duration of the study and that this file is available for inspection by the sponsor or regulatory authorities with 24 hours notice.

b) The Chief Investigator is responsible for ensuring that site files are created, maintained and secured at each site participating in the study and that these files are available for inspection by the sponsor, regulatory authorities and local NHS management with 24 hours notice.

c) The Chief Investigator is responsible for arranging appropriate archiving of the master file, all site files, raw study data and details of all analyses for a minimum of 5 years after the end of the study.

d) Unless explicitly agreed otherwise with the Trust’s Head of Research and Development Governance, the Chief Investigator shall act as the nominated Archivist for the study in accordance with section 31(A) of Statutory Instrument 2006/1928.

e) The Chief Investigator must ensure each participating site nominates a named archivist who is responsible for provide the Trust Research and Development Office with details of a single named archivist
Appendix 3

Principal Investigator Duties

The Principal Investigator takes overall responsibility for the study ensuring that the design of the study is appropriate, that the study is well conducted according to a written protocol, and that reasonable efforts are made to disseminate the results of the research. The PI must be fully conversant with the details of the study protocol and the drugs, devices and procedures used in the study, and be satisfied that the objectives of the study are appropriate and the methods used are valid.

In maintaining an overview of the conduct and progress of the study the Principal Investigator is responsible for ensuring that:

*Conduct of the Study*

- all those involved in the study are aware of, and abide by, the Trust’s policies on Research Governance
- all those involved in the study are given details of the aims, objectives and plan of the research
- those involved in the study are clear about their roles and duties in the study and are sufficiently qualified and experienced to undertake these duties
- all members of the research team have appropriate experience and training
- a project file is set up and maintained for the study as set out in the Clinical Study Project File document

*Patient Involvement*

- all research subjects have freely given consent to their participation in the study, having been given detailed information about the aims and objectives of the study, the risks and benefits and any alternatives
- a confidential record is maintained of all research subjects invited to take part in the study, whether or not they did agree to take part
- adverse events and serious adverse events will be reported according to the Trust’s policy on reporting research-related adverse events
- those involved in the study are aware of, and abide by, the Data Protection Act (1998), with particular reference to confidentiality, and any Trust policies on data protection and confidentiality
- if randomisation and blinding are used to assign patients to different treatment options there is an agreed procedure for breaking the code in an emergency to identify which treatment a particular patient received
- subjects enrolled in a trial involving medicines are given a card bearing information that identifies that they are involved in a clinical trial
- patient notes are clearly marked to indicate that the patient has been entered into a trial (patient records that relate to research must be retained for longer than routine patient records)

*Data collection, analysis and publication*

- data collected is accurate and complete
- reasonable efforts are made to publish, or disseminate in other ways, the results of the research and that these accurately reflect the findings of the research
- the Trust’s policy on Scientific Misconduct is followed
Health and Safety

- medicines are stored and dispensed through Pharmacy or by some other mechanism that has been agreed with the Director of Pharmacy
- any equipment used for the study is compatible with other equipment in the Trust, preferably purchased through the Trust’s Supplies Department. Electrical equipment must be checked and approved by Medical Engineering. All equipment must be serviced regularly
- where appropriate any hazardous material is handled in accordance with COSHH guidelines and that appropriate notifications and risk assessments have been made