Mid Essex Hospital Services NHS
NHS Trust

Research & Development Operational Policy	**Type: Policy** **Register No: 04052** **Status Public**

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Consulted With	**Post/Committee/Group**	**Date**
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It is the personal responsibility of the individual referring to this document to ensure that they are viewing the latest version which will always be the document on the intranet

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Appendices:

1. Purpose of Document

1.1 The Research & Development Policy seeks to provide a system for researchers and Trust staff to ensure compliance with good research practice within a regulatory framework as detailed, in the International Conference on Harmonisation Good Clinical Practice (ICH GCP), and the Trust's Standard Operating Procedures (SOP's).

1.2 The management, leadership and administration of all aspects of Research & Development (R&D) is the responsibility of the R&D Office. This office must ensure that all research is carried out in accordance with national and local policies, procedures and guidelines

2.0 Introduction

2.1 All research, including commercial studies, research conducted in collaboration with other organisations, single site research and student research requires ethical review and approval by a NHS Research Ethics Committee (REC), and the approval of the NHS host Trust before it can start.

2.2 REC and Trust approval are required to ensure that the proposed research is:

- ethically sound,
- scientifically robust,
- able to demonstrate financial probity,
- compliant with the Research Governance Framework,
- will not adversely affect service delivery, registered with the Trust and therefore monitored and relevant to the Trusts' R&D strategy

3. Aims

3.1 To develop Mid Essex Hospital Services NHS Trust as an organisation which undertakes high quality Research & Development (R&D), of relevance to both national and local needs, leading to the improvement of patient care. This includes the promotion of clinical trials through investigating new pharmaceutical products.

3.2 To develop the organisation to become and be recognised as a pioneer of research.

3.3 To identify and cultivate appropriate funding opportunities to researchers.

3.4 To develop and maintain strategic links with other research institutions.

4.0 Scope

4.1 This policy applies to all staff employed by or contracted to work with the Trust and to all external agencies connected to the Trust, their staff, patients and their services.

4.2 It applies to **all research and development activity** including student projects, national studies and commercial trials, and includes all staff, both clinical and non-clinical.

4.3 Clinical Audit is specifically excluded from this policy.

5. Definitions

5.1 **Research** is defined as “the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods”.

5.2 **Development** is defined as "the experimental introduction into practice of alternative clinical procedures or methods of care, together with the simultaneous evaluation of their effectiveness, efficiency or both".

5.4 **Projects** which involve “the local assessment of performance and factors which may affect performance within the Trust and are not being conducted as part of a national exercise” are considered as **Operational Change in Practice**. Whilst the ethics of these may need to be considered they fall outside the scope of this policy.

5.5 **Participants** Patients, users, relatives of the deceased, professional carers or members of the public agreeing to take part in the study.

5.6 **Principal Investigator** - the person designated as having overall responsibility within the team of researchers for the design, conduct and reporting of the study. There can only be one Principal Investigator per project.

5.7 **Site Principal Investigator** – a member of staff who acts as the Principal Investigator for Mid Essex Hospital Services NHS Trust – must be a consultant for research directly affecting patient care otherwise a senior member of staff The Mid Essex Hospital Services NHS Trust must employ the Trust Supervisor on a permanent contract. In exceptional circumstances, this requirement maybe varied with the discretion of the R&D Director or Medical Director. The Site Principal Investigator may be the Principal Investigator.

5.8 **Student Researcher** – a person undertaking research as part of an undergraduate or postgraduate degree. This includes, but is not limited to, BSc, BA, MSc, MA, MD, PhD and other professional qualifications. For the avoidance of doubt, student research is subject to the same procedures as all other research in the NHS organisation in relation to notification, approval and monitoring.

5.9 **Academic Supervisor** – a student researcher must have an identified Academic Supervisor, who must be willing and appropriately qualified to assume the role of Principal Investigator and will be responsible for the ethical and scientific conduct of the research. The Academic Supervisor must be employed on a permanent contract by a Partner Organisation and is responsible to ensure the requirements of the Mid Essex Hospital Services NHS Trust are understood and met.

5.10 **Trust Supervisor** – a student researcher must have an identified Trust Supervisor, who is willing and able to ensure that the student researcher is aware of, and complies with, the Trusts’ Policies, Procedures and Guidelines.

5.11 **Researchers** - those conducting the study. Note that all non-Mid Essex Hospital Services NHS Trust staff engaged in a significant amount of research or research activity within or the Trust require an Honorary Attachment Agreement or a Research Passport.

5.12 **Funder(s)** - organisation(s) providing funding for the study through contracts, grants or donations to an authorised member of either the employing and/or care organisation.

5.13 **Sponsor** - the organisation taking primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting; the sponsor is usually, but does not have to be, the main funder.

5.14 **Clinical Research Organisation (CRO)** - the organisation which may have some devolved responsibility for some of the duties of the Sponsor / Funder or other party.

5.15 **Clinical Research Associate (CRA)** – personnel employed to specifically monitor clinical trials.

5.16 **Site Management Organisation** - the organisation which may have some devolved responsibility for some of the duties of the Sponsor / Funder /or other party.

5.17 **Employing Organisation(s) -** the organisation(s) employing the Principal Investigator and/or other researchers. The organisation employing the Principal Investigator will normally hold the contract(s) with the funder(s) of the study. Organisations holding contracts with funders are responsible for the management of the funds provided.

5.18 **Care Organisation** - the organisation(s) responsible for providing care to patients and/or users and carers participating in the study.

5.19 **Responsible Care Professional** - the doctor, nurse or social worker formally responsible for the care of the participant while they are taking part in the study.

5.20 **Research Ethics Committee** – the committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards.

5.21 **Partner Organisation** – any organisation that employs staff involved in collaborative research with Mid Essex Hospital Services NHS Trust.

5.22 **CLRN** - Comprehensive Local Research Network.

6.0 Roles and Responsibilities

6.1 **Chief Executive & other Directors**
The Chief Executive & other directors, as accountable officers for Trust Research & Development, have responsibility for granting NHS and local permissions.

6.2 **Research and Development Internal Steering Group**.
This group is designed to steer the R&D and its membership includes representatives of all service support departments and active clinical research areas. **(Appendix 1)**

6.3 **R&D Co-Directors**
As accountable officers for Trust Research & Development they oversee the research governance and management processes prior to granting NHS and local permissions. They ensure the R&D objectives are consistent with Trust objectives, and met.

6.4 **R&D Chief Research Officer**

The accountable officer for Trust research, commercial innovation, activity and service evaluation. Responsibilities extend to ensuring that the strategic, general management and continual development of the Trust's R&D profile is maintained. The R&D Chief Research Officer deputises for the Co-Directors and has overall responsibility for research governance, and ensuring that all projects are fully compliant with governance requirements.

6.5 **Research Coordinator**

The R&D coordinator maintains the Trust database (REDA) for all projects undertaken at the Trust. They will also prepare documents for R&D Approval and assist with progressing new trials. They will also be responsible for arranging the R&D Strategy Group and Steering Group meetings, by arranging the Agenda, taking minutes and distributing all relevant papers.

6.6 **The Chief Investigator (CI)**

- Design, conduct, and reporting of research activities
- Applying for NHS ethical review
- Local R&D approval
- Notifying the NHS REC and R&D Office of significant changes
- In multi-site research, co-coordinating the study at all sites

6.7 **The Principal Investigator (PI)**

6.7.1 The PI is specifically responsible for

- Liaising with the Trust R&D Office
- Liaising between the Trust and the external research team
- Ensuring that information relating to the study is disseminated to appropriate Trust staff
- Ensuring that each external researcher holds an honorary contract/research passport with the Trust
- Assessing the potential impact upon services of hosting the study
- Ensuring that the study is conducted in accordance with Trust and national policies
- Assessing the suitability and capacity of the local research environment and facilities
- Screening Trust service users, carers or staff to assess their suitability for recruitment as per the study's inclusion criteria
- Making the initial contact with suitable service users, carers (if applicable) of staff and establishing a willingness to be approached by the external research team. For users, this must be recorded in the user's case notes
- Ensuring that confidentiality is maintained at all times, and that service users, carers or staff names/details are not passed to any external research organisation or individual without first having established and recorded a willingness to be approached
- Ensuring that participation in a clinical trial (as defined by the EU Clinical Trials Directive 2001) is recorded in a service user's electronic care record

6.7.2 Whilst Central Office for Research Ethics Committees (COREC) guidance states that a PI is only required for studies requiring Site Specific Assessment, please note that

the Trust requires all studies to appoint a local PI who already holds a substantive contract with the Trust. **Honorary contract holders are unsuitable.** The PI must be appropriate for the study e.g. a health professional with suitable experience and knowledge of the service in which the study will take place. The R&D Office can help identify a suitable PI.

6.7.3 The Site Principal Investigator is responsible for taking appropriate measures to ensure Data Protection. Advice may be sought from the Data Protection Officer, Information Manager, Caldicott Guardian, Information Governance Manager or the Information Security Manager or SIRO (Senior Information Risk Owner).

6.8 Research Sponsor

6.8.1 The Research Sponsor is the organisation that accepts overall responsibility for the study. No research may be carried out without a nominated Sponsor. The Sponsor is responsible for the initiation and management of the study and ensuring that systems are in place for monitoring and reporting the research.

6.8.2 The Sponsor can be the lead employer of the Chief Investigator, e.g. academic institute or health care organisation, or the funding body, such as the Medical Research Council, DH or the Pharmaceutical Industry.

6.8.3 There are specific requirements for the sponsorship of clinical trials, and guidance is available on:
http://www.ct-toolkit.ac.uk/route_maps/map_landing.cfm?cit_id=250

6.9 Patient/Public Involvement

6.9.1 Service users, such as patients or members of the public, should, where possible, be involved in the design and/or conduct of research projects. Integrating consumer involvement in the development and design of research projects is essential. These users are represented through the nomination of a representative from the Patient Volunteers Group who will be part of the R&D Strategy Group, which design and discuss objectives for the R&D that feeds to the Board. These meetings take place twice a year.

7. Central Guidance and Legislation

7.1 Research Governance Framework for Health and Social Care (2005)

7.1.1 The Department of Health's Research Governance Framework for Health and Social Care sets legal requirements and recommended guidelines for hosting, conducting and managing research. It defines the roles and responsibilities of individuals and organisations and sets good practice standards. A full copy is available on:
http://www.dh.gov.uk/PolicyAndGuidance/ResearchAndDevelopment/ResearchAndDevelopmentAZ/ResearchGovernance/fs/en

7.2 Mental Capacity Act (2005)

7.2.1 The Mental Capacity Act is designed to empower and protect vulnerable people who cannot make their own decisions. Research involving incapacitated or potentially incapacitated subjects must comply with the Act, which is available

at: http://www.opsi.gov.uk/acts/acts2005/20050009.htm - this should be read in conjunction with the Trust Mental Capacity Act Policy.

7.3 Data Protection Act (1998)

7.3.1 The Trust shall ensure that information held about staff or patients is treated in accordance with:

- The Data Protection Act 1998
- Trust Data Protection Policy
- Trust Confidentiality Policy
- Trust Appropriate Use of IT Policy
- NHS Records Code of Practice
- Protection and use of Patient Information HSC 2000/009
- Data Protection Act 1998 Guidance LASSL(2000)2
- Section 60 of the Health and Social Care Act 2001
- Manual for Caldicott Guardians and the Caldicott Principles
- Approved guidance issued by the R&D Department and Health Records Manager for the use of Patient Records for Research Purposes
- The requirements of the Information Governance Toolkit in relation to trust records including medical records

7.3.2 The Caldicott principles relating to data flow are:

- Justify the purpose(s) for using confidential information
- Only use it when absolutely necessary
- Use the minimum that is required
- Access should be on a need-to know basis
- Everyone must understand his or her responsibilities
- Understand and comply with the law

8.0 Use of patient records for research

8.1 Non-Mid Essex Hospital Services NHS Trust staff may request access to patient Records containing Patient Identifiable Information for research purposes. This could be to:

- Screen patients for possible inclusion into a study
- Obtain patient information relating to disease progression etc; or
- Confirm various details about the patient.

Such actions shall be subject to the following additional requirements

- Written approval from the Caldicott Guardian
- Agreed system of contract, training and induction prior to working on Trust premises, with or without client records
- The signing of a Third Party Confidentiality Agreement
- All those that visit the Trust, including the Patient Record Library, must provide a signed statement that they have received and understood the relevant Trust Policies and Procedures and quote the relevant research number.
- The Library will refuse all requests that are not accompanied by the appropriate number

8.1 Review of patient records for eligibility to a particular research project, unless prior consent is given by patient, can only to be done by a Trust Consultant or a designated clinical member of staff.

9.0 Intellectual Property

9.1 Intellectual Property shall be managed in accordance with the following guidance:

- The NHS as an Innovative Organisation: A Framework and guidance on the management of Intellectual Property in the NHS, Issued by the Department of health, 2002.
- Section 5 of the Health and Social Care Act 2001
- Health Service Circular (HSC 1998/106) Policy framework for the management of intellectual property within the NHS arising from research and development.
- Handling Inventions and other Intellectual Property – A guide for NHS Researchers (NHS Executive July 1998
- The Management of Intellectual property and Related Matters – An Introductory Handbook for R&D Managers and Advisors (NHS Executive July 1998)
- Guidance issued by the R&D Department and approved by the R&D Internal Steering Group

9.2 Staff must not disclose any Intellectual Property that arises in, or could reasonably be expected to arise from, the course of their duties. Under Patent Law, such Intellectual Property belongs to the Trust, unless the terms of an existing contract overrules. All attempts to publish / exploit any such Intellectual Property shall only proceed with the approval of the R&D Internal Steering Group. Net revenue generated by exploitation of Intellectual Property shall be shared with the inventor(s) and the Trust. At the Trust the intellectual property is led by the Director of Finance.

10.0 Commercial / Industrial Research

10.1 Commercial research is designed, organised and usually owned (in terms of intellectual property and often publication rights) by a commercial company, e.g. a pharmaceutical company.

10.2 Special arrangements are required for commercial research to protect the interests of the NHS, research participants and the researchers.

10.3 All commercial research will be contracted by the organisation employing the Chief Investigator. Trust employed staff will be governed by these contracts.

10.4 Contracts will be signed on behalf of the Trust by the nominated authorised person. Commercial research must be fully funded by the Sponsor and not subsidised by the NHS.

10.5 All external organisations including educational bodies and commercial companies must sign a Third Party Confidentiality Form and if the research indicates that the organisation will be collecting and retaining person identifiable data, then that organisation will be asked to provide a copy of their Registration under the Data Protection Act as issued by the Information Commissioners Office

10.6 Income from Commercial Studies is costed using the industry standard NHIR Costing Template (currently Version 2).

10.7 Income is allocated in line with that agreed in the costing template. A Z account (trust research account) is created to which income for the Principal Investigator (PI) is credited.

10.8 If a PI wishes to withdraw income, then they must fill in a form that requires their clinical lead to sign to allow authorisation for the release of funds.

10.9 The form is submitted to the R&D and is reviewed and logged on a system.

10.8 The industry standard Commercial Trial Agreement is used for all contracts, with an Appendix for any financial provision.

11.0 Indemnity

11.1 When commercial research involving a medicinal product is undertaken, a contract of indemnity usually based on Association of British Pharmaceutical Industry (ABPI) guidelines is required.

11.2 If the research involves a clinical research organisation (CRO), a tri-party agreement will be required.

11.3 Arrangements for compensation under such a scheme should be detailed in the patient information and consent form. For non-commercial research, the NHS has no special compensation arrangements for non-negligent harm; indemnity may be available from the academic partner. The participant information sheet and consent form must make clear whether compensation for non-negligent harm is available.

12.0 Informed Consent

12.1 All research requires written informed consent. Participants must be fully informed of the details of the study and what happens after the study finishes via a detailed information sheet before consent is taken.

12.2 In the event of any type of findings being published where participants could be identified, they must be informed of each planned publication. For example they may consent for their photographs to be published in a journal and used for medical training purposes but not to have any photographs published on the internet or used in any way by a commercial company. This does not apply to aggregated and anonymised data.

13.0 Pharmacovigilance - Clinical Trials & Adverse Incidents

13.1 Researchers must understand the types of untoward occurrences that may occur and how they are managed and communicated:

- Serious Unexpected Suspected Adverse Reaction (SUSAR) - a suspected adverse reaction in a research participant related to an Investigational Medicinal Product (IMP) that is both unexpected and serious.
- Serious Adverse Reaction (SAR) - an untoward and unintended response in a research participant to an IMP which is related to any dose administered.

- Serious Adverse Event (SAE) - an untoward medical occurrence in a research participant to whom an IMP has been administered, including occurrences which may not be related to the IMP.

13.2 All Adverse Events and SAEs should be reported to the trial Sponsor as detailed in the Trial Protocol. The Medicines for Human Use (Clinical Trial) Regulations 2004 requires that the Sponsor (although this may be delegated to Chief Investigator) reports all SUSARs to the MHRA in an expedited fashion.

13.3 Annual reports are required by the MHRA and NHS Research Ethics Committees. All SUSARs and SARs are entered onto the European Clinical Trials Database (EudraCT) by the UK Competent Authority (MHRA).

13.4 The safety of research participants and research staff must be given priority at all times and Health & Safety regulations strictly observed.

13.5 Research staff must report any adverse event affecting their research staff, research subjects or members of the public immediately, using the Trust standard risk event form available from the front page of the intranet.

14.0 Record Keeping

14.1 The Principal/Chief Investigator must keep a comprehensive, accurate and up to date study file for each research project, containing all study related documents and correspondence.

14.2 Any data must be available for audit, and the handling of data must comply with the Data Protection Act. Research data collected from study participants should always have any patient identifiable data removed or blacked out to avoid unnecessary identification and wherever possible anonymised or pseudonymised for confidentiality.

14.3 For clinical trials there is a comprehensive list of essential documents that must be held in an Investigator Site File or Trial Master File study file and be available for auditing by the MHRA. These documents are stipulated in the Guidelines for Good Clinical Practice issued by The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and are available on: http://www.emea.eu.int/pdfs/human/ich/013595en.pdf

14.4 At the end of a project, records should be kept until they are no longer required or the sponsor gives authorisation to destroy the records. Data verification may be requested after the study has closed during review of research findings and records must be available and accessible for this purpose. Clinical Trial data may need to be kept for 10 or more years after the close of the project for review by the licensing authority, and the period should be clearly stated in the protocol.

14.5 The R&D Office has a duty to maintain accurate central records of all R&D projects and related activities conducted in the Trust. This information and all research related activity documentation, e.g. minutes of R&D group meetings etc, has to be available for auditing. All trials at the Trust are logged on an electronic database system called REDA.

15.0 Amendments to the already agreed protocol

15.1 All substantial amendments must be submitted to the main REC for a favourable opinion and studies involving a Clinical Trial of an Investigational Medicinal Product (CTIMP) must be submitted to the MHRA.

15.2 All amendments must be submitted by the Principal Investigator to the R&D office for research governance approval prior to local implementation by sending, where appropriate, copies of the EU notification of amendment, the MHRA acceptance letter, the NRES notice of amendment and the REC favourable opinion. In addition we require one copy of the amendment protocol and any other revised document. When a protocol amendment is approved by the R&D office and approval letter is sent to the PI who must sign it to acknowledge receipt. This can be done electronically.

16.0 Reporting Requirements

16.1 Researchers are required to deliver progress and final reports, as stated in approval letters from funders, NHS REC and R&D Office. For clinical trials there is a legal requirement for the Sponsor to report the end of a trial to the MHRA and therefore the Chief Investigator must inform the Sponsor as soon as the trial finishes.

17.0 Local approval mechanism and implementation

17.1 All research must be approved by the Trusts' R&D Office before it can commence, prior to starting any form of research. A notification form must be completed to ensure the R&D office is aware of the intent, and guide where appropriate. (Appendix 2)

17.2 An R&D approval flowchart and R&D Checklist details the information required (**Appendix 3 & 4**). Information required by the Trust includes:

- Evidence that the appropriate clinical lead(s) or service manager(s) has
- agreed to support the study, and if applicable a PI has been appointed;
- A copy of the completed Ethics application form and any supporting
- documents;
- For studies involving IMPs, a copy of the notice of acceptance from the
- MHRA and if appropriate agreement from the dispensing pharmacy;
- A letter from an independent expert.

17.3 If the research is approved, the CI and PI will be sent an acceptance of responsibility to ensure adherence to agreed research protocol **(Appendix 5**). If the research is not approved, the CI and PI will be sent a notification outlining the reasons why and inviting resubmission.

17.4 Notification Requirements.
For any ongoing study the CI must inform the NHS REC and R&D Office if changes are made to any of the following:

- research personnel or protocol
- start/finish dates
- funding arrangements
- serious unexpected adverse events

17.5 If any research amendment is approved, the CI and PI will be sent an amendment approval letter. **(Appendix 6**). If the amendment is not approved, the CI and PI will be sent a notification outlining the reasons why and inviting resubmission.

18.0 Fees for Commercial Research

18.1 All costs associated with commercial research must be recouped from the industry Sponsor. This includes the cost of processing commercial research applications. The NIHR clinical research industry costing template Version 2 18th December 2012, is used. Further information can be found at http://www.crncc.nihr.ac.uk/Life+sciences+industry/tools/costing
National costing templates provide cost transparency and predictability when negotiating local site budgets in the UK, helping to prevent delays during study set-up.

19.0 Training and Education

19.1 The R&D Department will act as the first point of contact for researchers and staff, to provide advice and training. It will expose researchers to wider training opportunities including those via the Anglia Ruskin University and the CLRN.

20.0 Stakeholder and Involvement

20.1 Key stakeholders are members of or are represented on the Research and Development Strategy Group and Research and Development Internal Steering Group. **(Appendix 6 & 7)**

21. Key Performance Indicators

21.1 All studies are to be recoded on the electronic REDA database and monitored through the R&D meetings and reviewed via the minutes

21.2 All studies to have been invoiced and accounted for, with any discrepancies explained to the R&D internal steering Group. Findings should be reviewed via the minutes and scrutinised further by the R&D strategy group, where appropriate**. (Appendix 7)**

22.0 Monitoring Compliance with and effectiveness of this document

22.1 The R&D department maintains a database of all studies. There will be an investigation into concerns and queries regarding a study or potential study. The Clinical Audit Department will be open to audit up to 10% of studies annually.

22.2 To ensure effective monitoring, minutes of meetings, individual study records and reviews of database should be recorded and kept for up to ten years.

22.3 Any risks or incidents, including near-misses, or any breaches of compliance with this policy must be recorded on a risk event form and investigated appropriately

22.4 In the event of non-compliance, the Medical Director and any other senior responsible officer involved must be alerted.

22.5 Any error, complaints, systems failures, or other incidents, and learning points from such incidents will be addressed by the Chief Research Officer or R&D Directors who are working closely with the researchers, particularly the Principal Investigator.

22.6 The R&D Reporting Structure details chain of authority within the Trust. (Appendix 8)

22.7 Any suspicions of fraudulent behaviour will be reported to the Trust's Local Counter Fraud Specialist for consideration and may lead to criminal proceeding being undertaken against the individual(s) involved'.

23.0 Implementation & Communication

23.1 On ratification by DRAG, this policy will be notified to staff via Focus magazine and uploaded to the intranet and website

25.2 It is the responsibility of the author to ensure that personal copies reach all staff where the policy applies and to be aware of the contents of the policy.

24 Declarations, Conflicts of Interest,

The situation where one may be exposed to an actual or potential conflict of interest is covered in the Trust Conflict of Interest Policy (Register No 07063), which must be adhered to.

25 Bribery Act 2010

Under the Bribery Act 2010, any money, gift or consideration received by an employee from a personal company seeking a contract within the Trust will have been deemed to have received under a bribe. Any gift received from a supplier, such as pens, pencils or calendars may not be declared but if unsure, clarification should be sought from your Line Manager. Any hospitality, other than meals or buffets, provided by suppliers must be declared in writing.

Appendix 1 - R&D Internal Steering Group Terms of Reference

Research and Development Internal Steering Group
Terms of Reference

1 Constitution

The Research & Development (R&D) department has established an internal steering Group, hereby referred to as the R&D Internal Steering Group. The members have no executive powers other than those specifically delegated in these Terms of Reference.

2 Terms of Reference

2.1 Purpose

To provide strategic direction in ensuring the Trust has a robust framework for R&D, and to ensure compliance with good research practice and the R&D Operational Policy.

2.2 Objectives

The primary objective of the group is to provide assurance to the Trust that the policies, regulations and 'orphan' areas are covered in the Trusts SOP's.

To develop and agree on a R&D 5 year Strategy Plan.

To advise the finance department and monitor financial income relating to research activity and agree on a finance model for research.

To develop links and discuss channels of funding for research.

To develop and enhance strategic links with local academic institutions and other relevant statutory and voluntary organisations.

In addition, the group will address issues surrounding research and monitor action plans devised within the group in relation to promotion of research, clinical governance and MHRA audit reviews.

3 Membership

Mr Bruce Philp	R&D Director, **Chair**
Tracey Camburn	R&D Director, **Deputy Chair**
Dr Kevin Kiff	Associate Medical Director
Laween Al-Atroshi	Chief Research Officer
Mandy Austin	Research Coordinator
Mary Atkins	Charity Fundraising Manager
Prof Peter Dziewulski	Burns & Plastics Consultant
Prof Saad Tahir	Clinical Lead for Oncology
Mr Jeremy Tuite	Clinical Lead for Muscular skeletal
Mr Ranjan Thilagarajah	Clinical Lead for Urology
Dr Steve Jenkins	Respiratory
Dr Gerald Clesham	Cardiology Consultant
Mr Nigel Richardson	Clinical Lead for Surgery
CLRN	Senior Trials Coordinator
	CLRN / RM&G Facilitator
Dr Udaiveer Panwar	Research Consultant Oncology
Jane Giles	Chief Pharmacist
Christian Barnett	Clinical Trials Support Manager
Daniel Pilgrim	Assistant Finance Manager
Emma Rafferty/Frances Cairns	Clinical Trial Pharmacist
Dr Peter Davis	Clinical Director for Diagnostics & Therapies
Sarah Smailes	Consultant Physiotherapist
Michael French	Nuclear Medicine
Kate Thompson	Head of IT

4 Attendance by Members

Members are expected to attend all meetings or to send a representative in the event a member can not be present.

5 Accountability and Reporting Arrangements

The Chair of the group will be Bruce Philp, the Senior Responsible Officer hereby referred to as the SRO will be Tracey Camburn. The group minutes will feed to the R&D Internal Steering Committee that effectively feed to the Trust Board. Minutes will be recorded and sent out to members within a week of the meeting. In the event that the Chair is absent then the R&D Co-Director will deputise and in the event both are absent the Chief Research Officer will chair the meeting.
The Group will report to the Board at least annually in an R&D Report, such report to include matters considered by the R&D Strategy Group.

6 Frequency

The group will meet every 8 weeks. Additional meetings may be arranged when required to fulfil the obligations of the R&D department to the Trust.

7 Review

The Group will review its Terms of Reference on an annual basis as a minimum.

RESEARCH AND DEVELOPMENT NOTIFICATION FORM

All research in the NHS must be carried out in accordance with the Research Governance Framework and in line with the Mid-Essex NHS Trust R&D Operational Policy which can be accessed via the Trust Intranet or website. For each research project that you intend to undertake within the Trust then it is a requirement to submit the notification form.

The notification forms should be sent via email to the Research Coordinator, Mandy Austin (Mandy.Austin@meht.nhs.uk)

Project Title	
R&D Number	

Chief Investigator Name	
Address	
Email	
Speciality	
Name of Sponsor	

Does the Chief Investigator hold a substantive contract with the Trust
(Please be advised, an honorary contract is not sufficient)

Yes	**No**

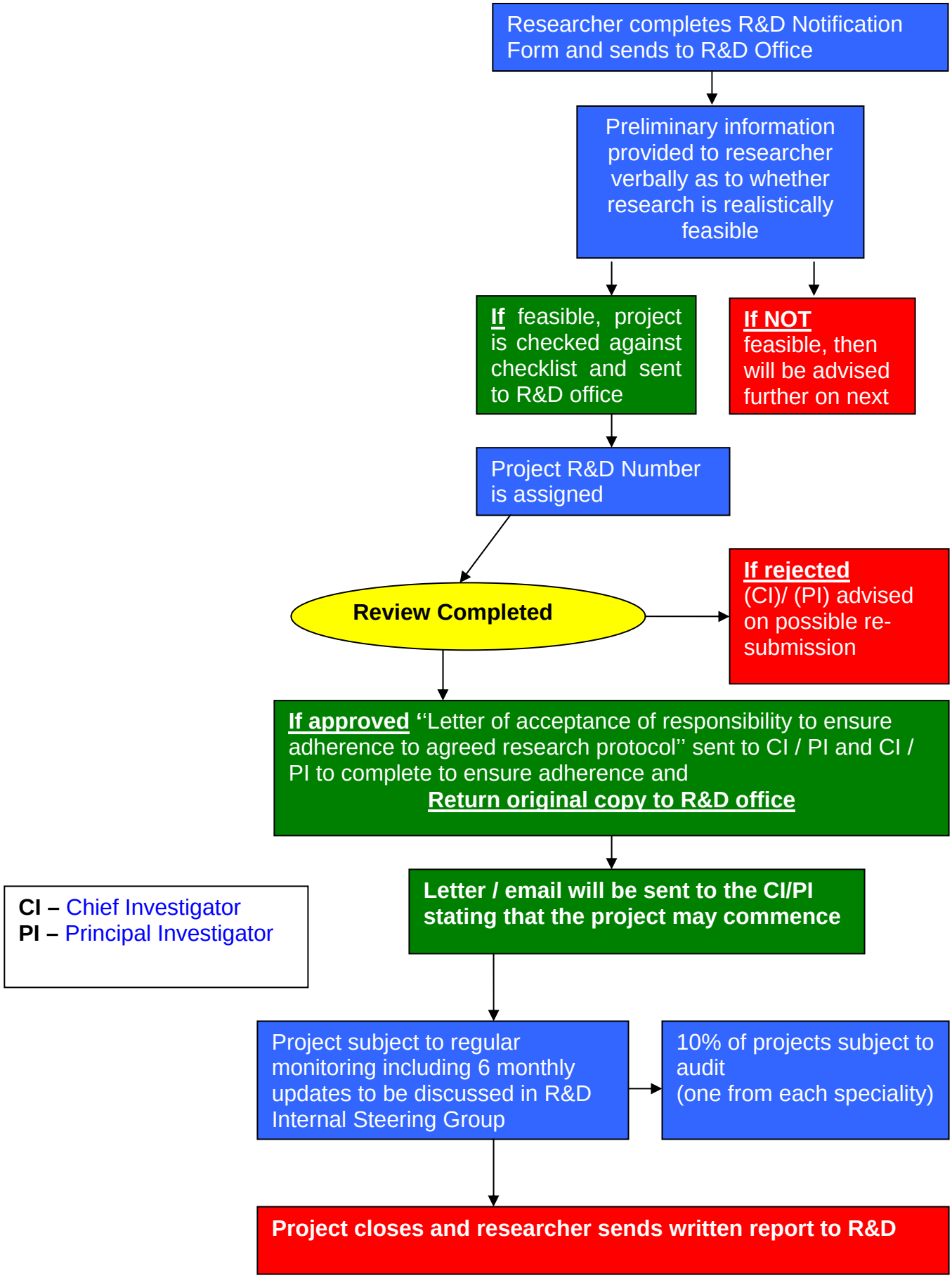
If No, please provide the name and contact details of a Principal Investigator employed within the Trust.

Please advise if the project is any of the following: (Please Tick)

	Yes	**No**
1. Student Research		
2. Part of a commercial Clinical Trial		
3. Part of a project with one of the research networks.		

When this form is received by the R&D office, a liaison member will guide and advice you further through the governance & documentation process.

Appendix 3 – Approval Flowchart



CI – Chief Investigator
PI – Principal Investigator

Appendix 4 - R&D Checklist

Checklist for submission of documentation for Trust Approval
Version 11 dated September 2012

Project Title (short)	
Contact Person	
Tel Number	
Email	

Please complete and submit this with your application for Trust Approval to the R&D Office, Broomfield Court, Court Road, First Floor, Chelmsford, CM1 7ET, Tel 01245 515136 mandy.austin@meht.nhs.ukl

For all research	
• A complete protocol with date and version number (this should be the same version as supplied for Ethics approval).	☐Yes ☐No
• A complete hard copy of the Integrated Research Application System (IRAS) application with all relevant signatures.	☐Yes ☐No
• A complete electronic copy of IRAS application emailed to mandy.austin@meht.nhs.uk .	☐Yes ☐No
• A complete hard copy of the Site Specific Information Form (SSI) with all relevant authorisation signatures .	☐Yes ☐No
• A complete electronic copy of the SSI emailed to mandy.austin@meht.nhs.uk.	☐Yes ☐No
• Copies of Patient information sheets, consent forms, GP letters, adverts, patient diaries, etc on Trust headed notepaper emailed to mandy.austin@meht.nhs.uk.	☐Yes ☐No
• A signed declaration by an organisation willing to Sponsor to project. (if this has not already been signed on the IRAS form).	☐Yes ☐No
• Evidence of peer review.	☐Yes ☐No
• If any of the research team does not hold a contract with the Trust then an Honorary Attachment Contract/Research Passport may be required. Please contact the R&D office for further information.	☐Yes ☐No ☐N/A
• Copies of Ethics approval letter must be submitted.	☐Yes ☐No
• A copy of Good Clinical Practice (GCP) Certificate is also compulsory (please note that this is only for certain studies and please contact R&D for further details). This is renewable every two years.	☐Yes ☐ No
• Any other relevant documents such as contracts, evidence of funding awards.	☐Yes ☐No
For student research only (inc BSc, MA, MSc. MD and PhD) please also include:	☐N/A
• A signed letter of support from the **Academic Supervisor**. This must include contact details and CV	☐Yes ☐No
• A signed letter of support from a **Trust Supervisor** (may be line-manager, if employed by the Trust)	☐Yes ☐No

• Confirmation that the Educational Organisation is willing to sponsor or co-sponsor this research (if this has not already been signed on the IRAS form)	☐Yes ☐No
For Clinical Trials of Medicinal Products/ Commercial research only please also include as relevant:	☐N/A
• Three draft copies of the Clinical Trial agreement / Study Agreement, including any Financial Payment details (emailed to R&D)	☐Yes ☐No
Notes: Commercial Studies 1 The use of NHS/ABPI model Clinical Trial Agreements (mCTAs) is recommended 2 If the mCTAs are not used for commercial research then additional fees may be applicable if legal review is required. 3 The name of the Trust is **Mid Essex Hospital Services NHS Trust** and the signatory of behalf of the Trust is **Mr Bruce Philp and Tracey Camburn, Directors of R&D.** The R&D office will arrange signature when the contract is agreed. 4 All fees will incur R&D Levy of 15% and exclusive of VAT, unless VAT exempt. 5 Trust R&D set up fees and Amendment fees, will be applicable for all Commercial Projects. The current R&D set up fee is £700 and the Amendment fee is £300 (per Amendment). 6 All contracts to be submitted with details of the Trust, Investigator etc. Blank generic contracts will not be reviewed. 7 All payments will be administered via R&D using formal VAT invoices in compliance with NHS & MEHT Standing Financial Instructions and no other person within the Trust should be responsible for raising invoices.	
• The proposed form of indemnity (if not within the Clinical Trial Agreement) and insurance statement	☐Yes ☐No
• A copy of the Clinical Trial Authorisation from the MHRA	☐Yes ☐No

Please note that your application will <u>not</u> be reviewed unless a complete and accurate submission is received. The R&D Office will review applications for completeness and will aim to review a complete application within five weeks.

If the correct documentation is not received this could delay your research. **The above checklist should help you to help us.**

****Important: Research can not start until a Trust approval letter is issued from R&D****

Appendix 5 - Acceptance of Responsibility to ensure adherence to agreed research protocol

TRUST APPROVAL LETTER

Research and Development
Ground Floor
West Wing 2
Broomfield Hospital
Chelmsford
Essex, CM1 7ET
Tel: 01245 516599 / 515136
Fax: 01245 516149

Address 1
Address 2
Address 3
Address 4

Date

Dear

Re: Title
Description

We are writing on behalf of the R&D Department to advise that the above study was given R&D approval. The following documents were reviewed:

Description	Version	Date

We are pleased to confirm site recruitment at Mid Essex Hospital Services NHS Trust can commence after a Site Initiation Visit.

As always within the NHS, approval for this study is granted on the understanding that you will abide by the requirements of the Research Governance Framework issued by the Department of Health and all other relevant legislation. It is your responsibility to ensure that this project is conducted in accordance with the agreed protocol and that all storage and transfer of data complies with the Data Protection Act 1998. We would be grateful if you would ensure compliance with these instructions.
With regard to patient recruitment firstly you need to ensure that as patients are recruited the copying instructions detailed on the bottom of the Consent form are adhered to. The patient should sign the consent form, with a copy given back to the patient. A further copy should be placed in the patient's notes and the original placed in the Site file.

For trials involving patients you need to be aware of Trust R&D policy and the importance of placing a copy of the signed consent form and associated Patient Information Sheet in the patient's main NHS hospital notes. This is to ensure that other clinicians are informed about the patient's participation in the research project; together with documenting any details in the patient's main NHS hospital notes regarding specific research visits, treatments or interventions that are undertaken.

In accordance with the Department of Health requirements regarding NHS Medical Notes retention any patients involved in research must have their NHS Medical Notes 'flagged' with a trial sticker and marked for retention for a minimum of 15 years. For each patient recruited one of the enclosed stickers needs to be completed and placed on the front cover of the patients' NHS Medical Notes.

Once the study is underway you will need to keep us informed of its progress. Your prompt assistance in completing annual progress reports issued by the MEHT R&D department would be much appreciated. Additionally, you should be aware that you might be required to participate in the audit of compliance to the Research Governance Framework, which is undertaken in a proportion of projects each year. Finally when your project has reached completion you will be expected to complete an R&D end of project form.

You will also need to inform the MEHT R&D department if there are any changes to personnel, the protocol or any other documentation involved in the study. Additionally any adverse events should be reported to the MEHT R&D department and also via the MEHT electronic Datix system.

Furthermore please note that any individual or members of a team intending to conduct research within MEHT, in accordance with Trust policy and Department of Health Research Governance Framework, must have undertaken Good Clinical Practice (GCP) training. This has to be undertaken every two years.
You are reminded that failure to comply with any of the specifics detailed within this formal R&D approval letter could result in withdrawal of R&D approval. If you have any queries about any of the arrangements for this study, Mandy Austin, R&D Administrator, who is based in the R&D department at MEHT will be happy to assist you (Extn 5136).

Please find enclosed a second copy of this letter for you to sign and return to the R&D Office (for the attention of Mandy Austin) to acknowledge receipt of this letter and confirmation that you will adhere to the above Trust requirements.

We wish you every success with the project.

Yours sincerely

Mr Bruce Philp & Mrs Tracey Camburn
R&D Directors

Please sign and return to the R&D Office

Name:……

Date: ……

Appendix 6 - Amendment approval letter

TRUST APPROVAL FOR AMENDMENT

Research and Development
Ground Floor
West Wing 2
Broomfield Hospital
Chelmsford
Essex, CM1 7ET
Tel: 01245 516599 / 515136
Fax: 01245 516149

Address 1
Address 2
Address 3
Address 4

Date

Our Ref: Research

Dear

Re: Title
Description

The Directors of R&D are pleased to confirm that the following documents:

:

Description	Version	Date

Have been reviewed and approved by Mid Essex Hospitals Services NHS Trust and as in the Trust Approval Letter dated MEHT has NOT agreed to act as sponsor.

The approval of amendments is subject to any conditions in the Trust Approval Letter dated XXXXXX

Yours sincerely

Mr Bruce Philp & Mrs Tracey Camburn
R&D Directors

Research and Development Strategy Group
Terms of Reference

1 Constitution

The Research & Development (R&D) department has established a Strategy Group, hereby referred to as the R&D Strategy Group. The members have no executive powers other than those specifically delegated in these Terms of Reference.

2 Terms of Reference

2.1 Purpose

To provide strategic direction in ensuring the Trust has a robust framework for R&D, by ensuring patients and researchers receive the best levels of care and a positive experience.

2.2 Objectives

The primary objective of the group is to provide assurance to the Trust that the policies and regulations are adhered to, including but not limited to:

- Ensuring that the key objectives of the 5 year plan are delivered to further develop the Trust status.
- Ensuring research management is more effective.
- Ensuring that the department is accessible for all staff.
- Ensuring we are investing time in our researchers
- Increase self generated income.

3 Membership

Mr Bruce Philp	R&D Director, **Chair**
Tracey Camburn	R&D Director
Manny Lewis	Non Exec Director
Dr Ronan Fenton	Medical Director
Dr Kevin Kiff	Associate Medical Director
Paul Reeves	Chief Nurse
Angela O'Connor	Head of Governance
Lynn Thomas	Head of Patient Experience and Public Engagement
Nick Gerard	Finance Director
Laween Al-Atroshi	Chief Research Officer
Mandy Austin	Research (R&D) Coordinator
Maureen Hindle	Patient Information Group

4 Attendance by Members

Members are expected to attend all meetings or to send a representative in the event a member cannot be present.

5 Accountability and Reporting Arrangements

The R&D Strategy Group will be chaired by the Director of R&D and made up of senior representatives from a whole range of roles within the Trust. Minutes will be recorded and sent out to members within a week of the meeting. In the event that the Chair is absent the Chief Research Officer will deputise and in the event both are absent the Chief Research Officer will chair the meeting. Reporting shall be to the Trust Board, not less than annually in an R&D Report, incorporating matters considered by the R&D Internal Steering Group.

6 Frequency

The group will meet every 6 months. Additional meetings may be arranged when required to fulfil the obligations of the R&D department to the Trust.

7 Review

The Group will review its Terms of Reference on an annual basis as a minimum.

Reporting Structure