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Related Trust Policies (to be read in conjunction with)	09069 Intellectual Property Policy 11024 Health Records Policy MSBPO 18001 Information Governance and Management Policy 04080 Consent to Examination or Treatment Policy 07063 Conflict of Interest

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3.0	Prof Sandip Pal		27 July 2009
4.0	Laween Al-Atroshi, Chief Research Officer		1 February 2013
5.0	Laween Al-Atroshi, Chief Research Officer		17 May 2016
6.0	Tracey Camburn	Full Review	12th July 2019

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1. Purpose

1.1 "The National Health Service (NHS) aspires to the highest standards of excellence and professionalism – through its commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population" NHS Constitution 2015. Thereby conducting research within the NHS is important not just for business, but also to improve the quality of services delivered to patients.

1.2 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).

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

2. 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), the Health Research Authority (HRA) and a statement of capacity and capability from the NHS host Trust before it can start.

2.2 REC and HRA approval, as well as a statement of capacity and capability from the Trust is required to ensure that the proposed research is:

- Ethically sound;
- Scientifically robust;
- Able to demonstrate financial probity;
- Compliant with the Research Governance Framework;
- Feasible and will not adversely affect service delivery;

3. Aims

3.1 To develop Mid Essex Hospital Services NHS Trust (MEHT) as an organisation which undertakes high quality research and development (R and D), which is relevant to both national and local needs, leading to the improvement of patient care.

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. 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** 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; this is dealt with by the clinical audit team within the Governance department.

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".

5.3 **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.

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

5.5 **Chief 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 Chief Investigator per project.

5.6 **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. 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 Principal Investigator may also be the Chief Investigator.

5.7 **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.

5.8 **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.

5.9 **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.

5.10 **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/Letter of Access.

5.11 **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.

5.12 **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.

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

5.14 **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 **NIHR CRN** - National Institute for Health Research Clinical Research Network. The NIHR provide infrastructure to conduct high calibre research, this can be in the form of funding for staff and/or flexible staff to support research.

5.23 **HRA** - Health Research Authority. The HRA serves to protect and promote the interests of patients and the public in health research by assessing all research for governance and legal compliance.

6. Roles and Responsibilities

6.1 **Chief Executive**
The Chief Executive, Medical Director, Associate Medical Director and R and D -Director, are the accountable officers for Trust Research & Development.

6.2 **Research and Development Internal Steering Committee**.
This committee is designed to steer the R&D and its membership includes representatives of all service support departments and active clinical research areas.

6.3 **Research and Development Co-Directors**
As accountable officers for Trust research and development they oversee the research governance and management processes prior to granting a statement of capacity and capability. They ensure the R and D objectives are consistent with Trust objectives, and met.

6.4 **Research and Development Manager**
The accountable officer for the 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 and D Manager deputises for the Director and has overall responsibility for research governance, ensuring that all projects are fully compliant with governance requirements.

6.5 **Clinical Trial Support Manager**
The clinical trial support manager is responsible for costing studies and reviewing study contracts. They will work with research delivery staff to maintain recruitment, resolve barriers to recruitment and source new research studies with academic and pharmaceutical partners.

6.6 **Research Coordinator**
The research coordinator maintains the Trust database (Edge) for all projects undertaken at the Trust. They will prepare documents in line with the Assess, Arrange, Confirm criteria 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.

6.7 **Research Nurses/ Coordinators**
Research delivery staff are responsible for screening, approaching and where appropriate consenting patients. Research delivery staff will collect study data, manage site files and work with sponsor to complete queries.

6.8 **Research Facilitator**
The research facilitator is responsible for pathology requirements and assisting with amendments and site files.

6.9 **The Chief Investigator (CI)**

- Takes overall accountability for all trial activities;
- Design, conduct, and reporting of research activities;
- Applying for NHS ethical review and HRA approval;
- Local trust capacity and capability;
- Notifying the HRA, NHS REC and R&D Office of significant changes to study protocol;
- In multi centre research, the CI is responsible for co-coordinating the study at all sites.

6.10 **Principal Investigator (PI)** is specifically responsible for:

- Liaising with the Trust R&D Office;
- Liaising between the Trust and the external research team;
- Ensuring staff working on the study are adequately trained and work within the constraints of both the delegation log and study protocol;
- Ensuring that information relating to the study is disseminated to appropriate Trust staff;
- Ensuring that each external researcher holds an honorary contract/research passport/letter of access 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 medical records;
- 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 the service user's electronic care record;
- Ensure that all patient's data is recorded in line with European Union General Data Protection Regulation and the Data Protection Act 1998.

6.10.1 Whilst HRA 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,** unless in exceptional circumstances which are to be assessed by the R&D Director. 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 and D Office can help identify a suitable PI.

6.10.2 The 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).

6.11 **Research Sponsor**

6.11.1 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.

6.11.2 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.

6.11.3 There are specific requirements for the sponsorship of clinical trials, and guidance is available on: http://www.ct-toolkit.ac.uk/routemap/sponsorship/

6.12 **Patient/Public Involvement**
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.

7. Central Guidance and Legislation

7.1 **UK Policy Framework for Health and Social Care Research** 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:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

7.2 **Mental Capacity Act (2005)** 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: https:/www.legislation.gov.uk/ukpga/2005/9/contents - this should be read in conjunction with the Trust Mental Capacity Act Policy.

7.3 **Data Protection Act (2018) and European Union General Data Protection Regulations**
The Trust shall ensure that information held about staff or patients is treated in accordance with:

- European Union General Data Protection Regulations (EU GDPR);
- The Data Protection Act 2018;
- MSBPO 18001 Information Governance and Management Policy;
- MSBPO 18015 User Access and Acceptable 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.

7.3.1 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. 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.

8.2 Such actions shall be subject to the following additional requirements:

- Written approval from the Caldicott Guardian;
- Written approval from the Data Protection Officer;
- 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;
- Where appropriate complete training for accessing electronic health records;
- All those that visit the Trust, including the Health Records 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 Health Records Library will refuse all requests that are not accompanied by the appropriate number.

8.3 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. 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;

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 and D Committee. Net revenue generated by exploitation of Intellectual Property shall be shared with the inventor(s) and the Trust. At the Trust intellectual property is led by the Director of Finance.
(Refer to the Intellectual Property Policy, register number 09069, for further details)

10. 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 All commercial research will be contracted by the organisation employing the Chief Investigator. Trust employed staff will be governed by these contracts and will use the standard model clinical trial agreement which can be found on the IRAS website. https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Contracts-Agreements

10.3 Contracts will be signed on behalf of the Trust by the nominated authorised person. At the time of writing this includes the R&D Manager and R&D Director.

10.4 All commercial research must be fully funded by the Sponsor and not subsidised by the NHS in any way.

10.5 All external organisations including educational bodies and commercial companies must sign a contract to agree roles and responsibilities of both parties to include payment and data protection of parties and patients.

11. Indemnity

11.1 When commercial research involving a medicinal product is undertaken, a statement of indemnity is usually based on Association of British Pharmaceutical Industry (ABPI) guidelines and is incorporated into the study contract.

11.2 If the research involves a clinical research organisation (CRO), a tri-party agreement will need to be written into the contract.

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. Informed Consent

12.1 In line with ICH-Good Clinical Practice (ICH GCP) 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 Consent is an ongoing process, and verbal consent should be sought throughout the patient's participation in clinical research.

12.3 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. Pharmacovigilance - Clinical Trials and Adverse Incidents

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

- Adverse Event (AE) – an untoward medical occurrence in a research participant to whom an IMP has been administered.
- 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) – a serious untoward medical occurrence in a research participant to whom an IMP has been administered, including occurrences which may not be related to the IMP. SAE's are life threatening and/ or result in hospitalisation and/ or result in significant disability and/ or death.

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 Medicines and Healthcare products Regulatory Agency (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. 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 2018 and the EU General Data Protection Regulations. 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: https://www.ich.org/home.html

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 EDGE.

15. Amendments to the Already Agreed Protocol

15.1 All substantial amendments must be submitted to the main REC and HRA for a favourable opinion. Studies involving a 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 HRA and REC favourable opinion. In addition we require one copy of the amendment protocol and any other revised document.

16. Reporting Requirements

16.1 Researchers are required to deliver progress and final reports, as stated in approval letters from funders, NHS, HRA, 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. Local Approval Mechanism and Implementation

17.1 All research must receive a statement of capacity and capability by the Trusts' R&D Office before it can commence, prior to starting any form of research.

17.2 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 IRAS application form and any supporting documents;
- For studies involving IMPs, a copy of the notice of acceptance from the MHRA and agreement from the dispensing pharmacy;

17.3 If the research is approved, the CI and PI will be sent a statement of capacity and capability to ensure adherence to agreed research protocol (refer to Appendix 1). 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 REC, HRA 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 (refer to Appendix 2). If the amendment is not approved, the CI and PI will be sent a notification outlining the reasons why and inviting resubmission.

18. 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 (updated every year) is used. Further information can be found at https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm

18.2 National costing templates provide cost transparency and predictability when negotiating local site budgets in the UK, helping to prevent delays during study set-up.

18.3 All fees for all NHS services used in commercial research must be covered. The Trust will not operate commercial research at a loss to the Trust's income.

19. Training and Education

19.1 The R and 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 CRN.
Any staff in the trust who conduct clinical research must obtain a Good Clinical Practice (GCP) certificate. The GCP certificate will need to be refreshed every two years. The trust will provide staff with access to GCP training (face to face or online) to ensure this is not a barrier to individuals.

20. Key Performance Indicators

20.1 All studies are to be recorded on the electronic EDGE database and monitored through the R and D meetings and reviewed via the minutes.

20.2 All studies to have been invoiced and accounted for, with any discrepancies explained.

21. Monitoring Compliance with and Effectiveness of this Document

21.1 The R and D department maintains a database of all studies on EDGE. Any concerns or queries regarding a study or potential study will be investigated further.

21.2 To ensure effective monitoring, minutes of meetings, individual study records and reviews of database should be recorded and kept for up to ten years in accordance with EU GDPR.

21.3 Any risks or incidents, including near-misses, or any breaches of compliance with this policy must be recorded on a datix form, submitted to the clinical governance team and investigated appropriately.

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

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

21.6 The R and D Reporting Structure details chain of authority within the Trust.
(Refer to Appendix 3)

21.7 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

22. Implementation and Communication

22.1 On ratification by DRAG, this policy will be notified to staff newsletter and uploaded to the intranet and website.

22.2 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.

23. Declarations, Conflicts of Interest

23.1 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.

24. Bribery Act 2010

24.1 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.

25. Equality Impact Assessment

25.1 Mid Essex Hospital Services NHS Trust is committed to the provision of a service that is fair, accessible and meets the needs of all individuals.
(Refer to Appendix 4)

26. References

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Available at: https://www.legislation.gov.uk/ukpga/2001/15/contents

Integrated Research And Systems application guidance for researchers Available at: https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Contracts-Agreements

Integrated Research Application System (2019) Templates for supporting documents [online] Available at Available at: https://www.myresearchproject.org.uk/help/hlptemplatesfor.aspx#Contracts-Agreements accessed 4/6/2019

NIHR costing template
Available at: https://www.nihr.ac.uk/funding-and-support/study-support-service/early-contact-and-engagement/commercial-study-costing-templates.htm

Appendix 1: Capacity and Capability letter

National Institute for Health Research

Mid Essex Hospital Services NHS Trust

TRUST APPROVAL LETTER

Research and Development Department
Broomfield Hospital
West Wing 2
Court Road
Broomfield
Chelmsford
Essex CM1 7ET
Main Switchboard: 01245 443673
R&D Department: 01245 515136
Mandy.austin@meht.nhs.uk

Letter prepared on
Effective from date of signature

Dear

Re: R&D IRAS:

We are writing on behalf of Mid Essex Hospital Services NHS Trust (MEHT) to advise that the above study was given R&D approval. MEHT has NOT agreed to act as sponsor. The following documents were reviewed by the R&D Department:

Description	Version	Date

We are pleased to confirm that site recruitment at MEHT can commence after a Site Initiation Visit. You will need to ensure that as patients are recruited the instructions detailed on the bottom of the Consent Form are adhered to. The patient should sign the Consent Form, with a copy returned to the patient. A further copy should be placed in the patients' notes and the original placed in the Site File.

A Site File should be prepared for each study.

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 and the Trust R&D Operational Policy, which can be found on the Intranet.

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 what are undertaken.

Once the study is underway you will need to keep us informed of its progress. You will be required to complete a Project Annual Status Form issued by the MEHT R&D Department. 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 the projects each year. Finally when your project has reached completion you will be expected to complete an R&D Project Closure 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. If the Principal Investigator (PI) retires, leaves the Trust or abdicates responsibility for this trial there must be a clear handover to the new PI which much be communicated in writing to the R&D Department. Additionally any adverse events or unexpected serious adverse reactions 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 is valid for 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 please contact Mandy Austin, R&D Coordinator on Ext 5136, who will be happy to assist you.

This letter has been sent via email, with a read receipt requested. This will act as acceptance to the conditions outlined above, unless the R&D Department is informed of any issues within 48 hours of receipt of this document.

We wish you every success with the project.

Yours sincerely

Lauren Perkins
R&D Manager

Cc **Tracey Camburn, R&D Co Director and Lead Research Nurse**
Stuart Craig, Radiology Manager
Richard Green, Wael Elamin, Emily Leach, Sarah Linstead, Pathology
Ajay Sinha, Ophthalmology Lead
Emma Cannon & Lucy Cooper, Pharmacy
Christian Barnett, Clinical Trials Support Manager
Beth Farr, Clinical Research Set Up Assistant
Mandy Austin, R&D Coordinator and Governance Facilitator
Sponsor contact details
Sss.crnnorththames@nihr.ac.uk

Appendix 2: Amendment letter

Trust Approval for Amendment

Date **Letter prepared on 12 July 2019**
effective from date of signature
Our Ref **R&D XXXX**

C254 Research and Development
Broomfield Hospital
Chelmsford
Essex
CM1 7ET
Tel: 01245 515136
research@meht.nhs.uk

XXXXX
XXXXXXX
Broomfield Hospital
Court Road
Chelmsford
Essex
CM1 7ET

Dear

RE: Title

R&D: **IRAS:**

Substantial Amendment XX – **The reason for this amendment ……**

I am pleased to confirm that the following documents have been reviewed by Mid Essex Hospital Services NHS Trust and as in the Trust Approval letter dated xxxxx MEHT has NOT agreed to act as Sponsor.

The following documents are to be implemented on **XX XXX XXXX**

Description	Version	Date

The implementation of amendments is subject to any conditions in the Trust Approval letter dated XX/XX/XX

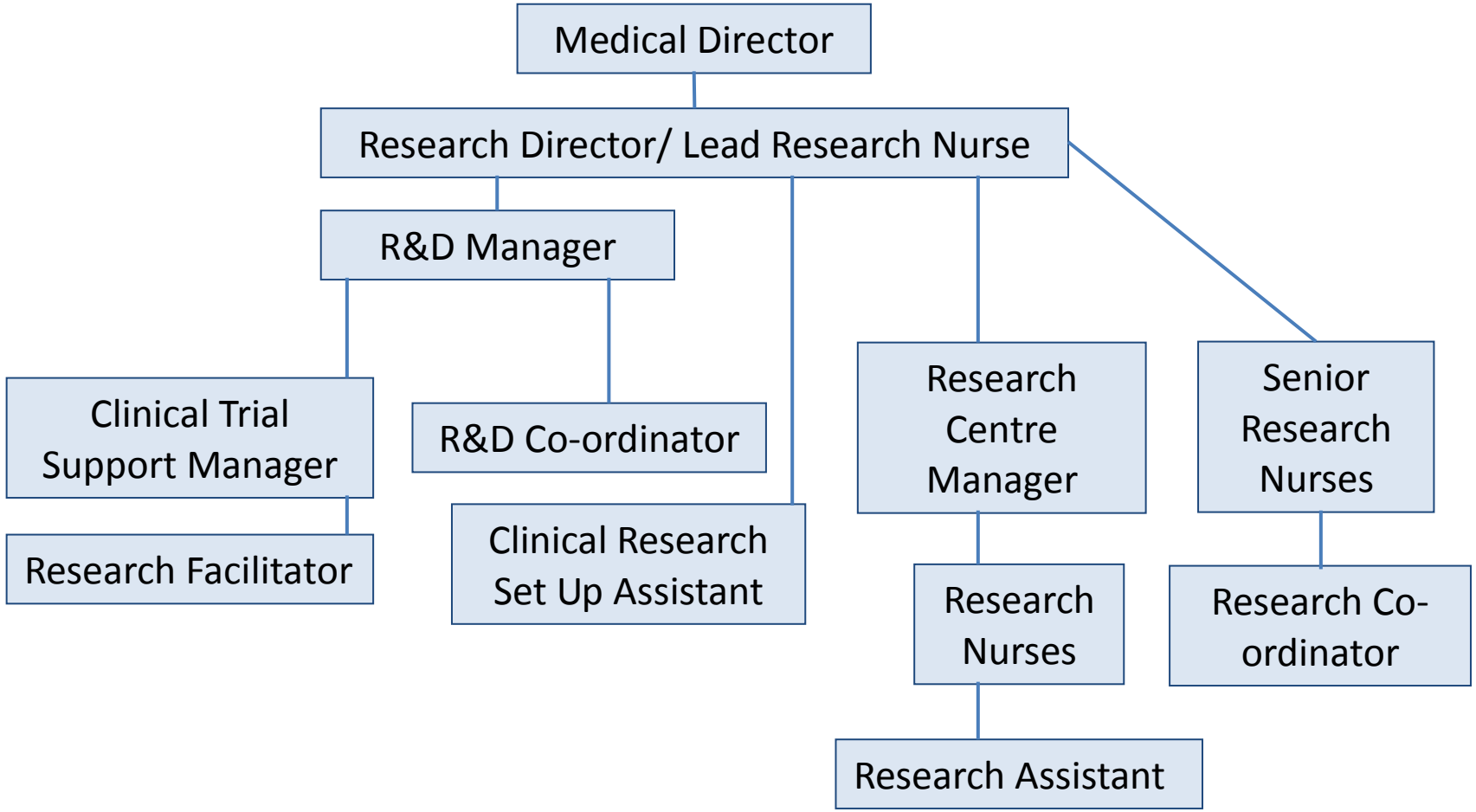
Yours Sincerely

CC: **Tracey Camburn,** R&D Co Director
Lauren Perkins, R&D Innovation Manager
Christian Barnett, Clinical Trial Support Manager
Emma Cannon, Pharmacist

……
Kevin Beaton
Medical Director

Appendix 3

R&D reporting structure



Appendix 4: Preliminary Equality Analysis

This assessment relates to: Research & Development Operational Policy / 04052

A change in a service to patients		A change to an existing policy	**X**	A change to the way staff work	
A new policy		Something else (please give details)			

Questions	Answers
1. What are you proposing to change?	Full Review
2. Why are you making this change? (What will the change achieve?)	3 year review
3. Who benefits from this change and how?	Patients and clinicians
4. **Is anyone likely to suffer any negative impact as a result of this change?** If **no**, please record reasons here and sign and date this assessment. If **yes**, please complete a full EIA.	No
5. a) Will you be undertaking any consultation as part of this change? **b) If so, with whom?**	Refer to pages 1 and 2

Preliminary analysis completed by:

Name	Lauren Perkins	**Job Title**	Research and Development Manager	**Date**	June 2019