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Sussex Partnership NHS Foundation Trust

Research Policy

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KEY POLICY ISSUES:

The policy sets out the Trust's policy for the conduct and management of research activity in the organisation. The policy is applicable to all Trust employees and to non-employees who conduct research involving Trust premises or staff.

- The promotion of good research practice in the Trust
- To enhance the ethical and scientific quality of research
- To safeguard the rights and interests of patients
- To prevent poor, wasteful and unnecessary research
- To prevent adverse incidents in research.

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1.0 Introduction

This document explains:

- why the policy is necessary (purpose/rationale)
- to whom it applies and where and when it should be applied (scope)
- the underlying beliefs upon which the policy is based (principles)
- the standards to be achieved (policy)
- how the policy standards will be met through working practices (procedure).

1.1 Definitions

1.1.1 Definition of research

1.1.1.1 The Health Research Authority defines research as 'the attempt to derive generalisable or transferable new knowledge to answer or refine relevant questions with scientifically sound methods'.[1] Broadly speaking, a piece of research has all of the following characteristics:

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

1.1.1.2 Many different types of research are conducted in the NHS. Any project or investigation that (a) meets this definition and (b) involves any of the people, material or facilities listed below is regarded as a research study, and is subject to the provisions of this policy document:

(a) NHS patients (i.e. people recruited to the study by virtue of their past or present treatment or care by this Trust or any other NHS organisation);

(b) Tissue, blood, foetal, IVF material or any other material removed from NHS patients both past and present, and the recently dead in NHS premises;

(c) Data collected from past or present NHS patients, including all information stored in the patient's health records;

(d) The use of NHS premises or facilities;

(e) NHS staff.

1.1.1.3 Common types of NHS research include:

(a) Research on tissue samples and other laboratory-based research;

(b) Imaging and technology research involving, for example, MRI, PET or ultrasound technology;

(c) Clinical trials of interventions, including drugs, surgery, radiotherapy, behaviour change, and screening;

[1] 'UK Policy for Health and Social Care Research' v3.3 Nov 17, Health Research Authority

(d) ‘Health services’ research examining service delivery, health economics and social science studies;

(e) Clinical research, meaning research that directly involves inpatients or outpatients and often affects patient care;

(f) Population-based or epidemiological research, such as retrospective research using data from medical records or databases;

(g) Behavioural and health psychology research

(h) Secondary research, meaning secondary analysis of existing research data or literature, including reviews and meta-analyses.

1.1.2 Clinical Audit, Local Service Development and Evaluation, and Clinical Case Studies

There are a number of activities that, although similar to research in some aspects and sometimes referred to as ‘research’, nevertheless are not classed as research by the Department of Health and therefore are not subject to the provisions in this Research Policy. The most common of these activities are:

1.1.2.1 Clinical Audit

“Clinical audit is a quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria [i.e. a standard that has already been set] and the implementation of change. Aspects of the structure, processes and outcomes of care are selected and systematically evaluated against explicit criteria. Where indicated, changes are implemented at an individual, team or service level and further monitoring is used to confirm improvement in healthcare delivery.”[2] Those conducting clinical audit activity should obtain the necessary authorisation from the relevant Trust officers and refer to the Clinical Audit Policy.

1.1.2.2 Local service development and evaluation

Local service development in itself is not a research activity. The evaluation of a service development may be a research activity. Generally speaking, a small scale evaluation carried out for the purposes of local service monitoring or appraisal is not a research activity. Those conducting local service evaluation activity should obtain the necessary authorisation from the relevant Trust officers.

More complex service evaluations and evaluations of unique or unusual local services might be research activity if they meet the three criteria listed above.

[2] National Institute of Clinical Excellence, ‘Principles for Best Practice in Clinical Audit’, 2002, National Institute for Clinical Excellence: London

1.1.2.3 Clinical case studies

Clinical case studies and case reports are not classed as research. However, in all instances (a) the patient's informed, written consent must be obtained and the consent documented in the patient's health record, and (b) the case report must be anonymised.

1.2 Purpose/Rationale of this Policy

1.2.1 This document sets out the policy for the conduct and management of research activity within Sussex Partnership NHS Foundation Trust. Research can involve an element of risk, both in terms of return on investment (i.e. the new knowledge gained through the study might not warrant the monies, time and effort invested) and sometimes for the safety and well-being of the research participants. Proper governance of research is essential to ensure that patients and the public can have confidence in, and benefit from, quality research in health care. Patients have a right to expect high standards (scientific, ethical and financial), transparent decision-making processes, clear allocation of responsibilities and robust monitoring arrangements. Research will include those protected characteristics e.g. disability, race, gender,gender identity, age, religion and belief, pregnancy and maternity, sexual orientation and marriage and civil partnership.

1.2.2 Research in the NHS is subject to a large and complex regulatory framework, composed of UK laws, regulations and other statutory requirements, and directives and guidelines issued by a number of government and non-governmental bodies, including the Health Research Authority, the Department of Health and the Medical Research Council. The requirements have been brought together within the UK Policy for Health and Social Care Research.

1.2.3 The UK Policy for Health and Social Care Research sets out standards for research within 19 principles: Safety, competence, scientific and ethical conduct, patient, service user and public involvement, integrity, quality and transparency, protocol, legality, benefits and risks, approval, information about the research, accessible findings, choice, insurance and indemnity, respect for privacy, compliance, justified intervention, ongoing provision of treatment, integrity of the care record, duty of care. It also sets out the specific responsibilities of the different parties that might be involved in NHS research.

1.2.4 The Trust has a statutory responsibility to ensure that all research involving the Trust or Trust patients is conducted in accordance with the UK Policy for Health and Social Care Research. Trust compliance with this requirement is monitored by the Care Quality Commission. Researchers each have an individual responsibility to comply with the UK Policy for Health and Social Care Research in their own research practice. Researchers should refer in particular to the 'Responsibilities' sections in particular of individuals and organisations, chief Investigators, research team.

1.3 Scope

1.3.1 This policy is applicable to all research involving Trust premises or staff, NHS patients to whom the Trust has a duty of care, patient material, or patient data, conducted by Trust employees, independent contractors and other non-employees. The policy is of particular relevance to clinical research activity, but applies equally to all research.

1.4 Principles (Our Beliefs)

This policy aims to promote good research practice in the Trust, to enhance the ethical and scientific quality of research, and to safeguard the rights and interests of patients. It also aims to prevent poor, wasteful and unnecessary research, and adverse incidents. The Policy also ensures that research is inclusive of all protected characteristics e.g. disability, race, gender, age, religion and belief, pregnancy and maternity, sexual orientation and marriage and civil partnership.

2.0 Duties

2.1 Chief Medical Officer (Policy Sponsor)

Responsible for initiating the development and review of this policy. Also responsible for ensuring monitoring arrangements are undertaken and recommendations actioned. Development and review is delegated to the Director of Research.

2.2 Research Manager (Policy Author)

2.2.1 The Research Manager is responsible for ensuring that the policy complies with the Human Rights Act, the Mental Health Act 1983 Code of Practice, the Data Protection Act 2018 and General Data Protection Regulation (GDPR), Freedom of Information Act and any other legislation associated with the document.

2.2.2 The Research Manager is responsible for ensuring that the document is formatted in the correct style and layout according to the organisation-wide policy for the development and management of procedural documents.

2.3 Trust Research & Development Department

Responsible for coordinating local feasibility - this is just one element of the research approvals process that is undertaken by the R&D office. See “R&D Approvals” (SOP03) for further information.

The R&D Governance Office is responsible for assessing, arranging, and confirming local Capacity and Capability for a study to take place in the Trust. The researcher must have written confirmation from the R&D Office that Confirmation of Capacity and Capability has been given before the study can begin. See “R&D Approvals” (SOP03) for further information.

The R&D Governance Office is also responsible for monitoring and audit of active research studies, this includes annual monitoring of all studies and on site monitoring of sponsored or high risk studies – see “Monitoring and Audit for Research Conducted in the Trust” (SOP 05).

The R&D Department is also responsible for ensuring that all new research is in keeping with the Trust research strategy. The R&D Department produce and maintain the information on the Trust’s R&D Operational Capability Statement (see SOP01) which is endorsed by the Trust Board.

2.4 Trust Research Assurance Committee

The purpose of the Research Assurance Committee is to stimulate and support best practice in research activity, ensure best research practice and the effective dissemination of findings, develop stronger links between the Trust and local academic centres and keep the Board and its partners, the Leadership Team and the Effective Care Domain informed.

The Trust Research Assurance Committee is responsible for initial approval of this policy.

The Design Forum, Delivery Forum and Leadership Forum feed into the RAC via quarterly updates.

2.5 All staff undertaking research

All staff undertaking research have a responsibility to comply with the UK Policy Framework for Health and Social Research, all conditions of research approval and this policy.

All researchers must obtain a Good Clinical Practice (GCP) certificate and update this regularly for Clinical Trials of an Investigational Medicinal Product (CTIMP). The R&D Department will facilitate and support researchers in attaining this certification where required.

All researchers need to make reasonable adjustments in their methodology to ensure people with disabilities are able to have equal access and input to research studies.

All staff employed by Sussex Partnership NHS Foundation Trust are required to complete the Trust's Equality and Diversity training. All researchers must read and comply with the Trust Policy on Equality and Diversity. Lead Researchers are responsible for ensuring researchers in their team have read, and comply with this policy.

3.0 Procedure

3.0.1 An approvals guide illustrating the process for approval of research proposals can be obtained from the R&D department. This process applies to all research studies conducted within the Trust.

3.1 Research Governance Standards

3.1.1 Ethics – general

3.1.1.1 The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. The Department of Health requires that, generally speaking, research involving patients, service users, or their organs, tissue or data, is reviewed independently to ensure it meets ethical standards.

3.1.1.2 It is the responsibility of the researcher to ensure that the study is ethical and meets all the requirements specified by the Health Research Authority for ethical and regulatory review, including compliance with requirements for informed consent.

3.1.1.3 Ethics committees consider the eligibility and exclusion criteria set out by the researchers as to who can and cannot take part in any given research study. This is due to the design of the research and the requirements of the research questions. If either inclusion or exclusion criteria were unethical or excluded people unjustly this would be raised by ethics.

3.1.2 Ethics – consent

3.1.2.1 Informed consent is at the heart of ethical research. Researchers are required to ensure that the study has appropriate arrangements for obtaining consent that have been approved by an NHS research ethics committee and Health Research Authority.

3.1.2.2 In the case of research that affects a patient's clinical care, the researcher must ensure that the patient's participation in the study is noted in the patient's health record, preferably by including a copy of the patient's consent form in the record.

3.1.2.3 Consent in Clinical Trials of Investigational Medicinal Products (CTIMPs)

Anyone conducting Clinical Trials of Investigational Medicinal Products has a duty to act in accordance with the principles and provisions for consent of The Medicines for Human Use (Clinical Trials) Regulations 2004, The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, and the Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006. These regulations make specific provisions for consent in research involving minors and for consent in research involving incapacitated adults.

3.1.2.4 Consent in research involving minors

Consent in research involving minors is a complex issue for which the statutory requirements change periodically. Researchers planning research involving minors must (a) notify the Trust at an early stage of planning, and (b) obtain and follow the advice of the Health Research Authority regarding consent and other ethical issues.

3.1.2.5 Consent in research involving adults lacking mental capacity

Anyone conducting research involving adults lacking mental capacity (excluding clinical trials covered under the Medicines for Human Use (Clinical Trials) Regulations 2006) has a duty to act in accordance with the principles and provisions for consent of The Mental Capacity Act 2005.

3.1.2.6 Consent in research involving human organs and tissue

The Human Tissue Act 2004 sets out the statutory provisions for research involving human organs and tissue. The main requirements of the Act in relation to research involving human organs or tissues are:

- Consent must be obtained for any storage and use of tissue removed after death for research purposes;

- Consent is required for the storage and use of tissue from living individuals for research unless:

    - The material has been anonymised, such that the person carrying out the research does not know the identity of the donor (there may still be a link to the donor via third party), and

    - The research project has been granted approval not to seek consent by the "Health Research Authority"

3.1.3 Science: scientific quality

3.1.3.1 A project of good scientific quality is one that uses an appropriate and rigorous method to answer a valid and specific question. Researchers have an obligation to design and conduct work to the highest possible standard, to ensure that the study is of sufficient quality to contribute something useful to existing knowledge. Research of a limited scope is acceptable within the boundaries of research being carried out in part fulfillment of an educational qualification. Such research must still be of a sufficient quality to contribute to the local knowledge base.

3.1.3.2 The Trust's research approval process ensures that all research is designed at the appropriate level of scientific quality, and that the study protocol has undergone peer review commensurate with the nature and scale of the study.

3.1.3.3 Trust researchers are encouraged to publish their work and to make the work open to critical review through the accepted scientific and professional channels. Researchers are advised to follow the guidance of the International Committee of Medical Journal Editors regarding authorship.[3] Authorship credit should be based only on substantial contribution both to the study and to the manuscript. Participation solely in the acquisition of funding, or the collection of data, or the clinical care of research participants does not justify authorship. Instead, following the guidance of the *British Medical Journal*, a full list of contributors should be provided at the end of the paper, giving details of who did what in planning, conducting, and reporting the work.

3.1.4 Science: fraud and misconduct

3.1.4.1 Any significant breach by an investigator of the principles and standards set down in the UK Policy Framework for Health and Social Care Research and associated regulations and guidelines shall be considered research misconduct. Research fraud or misconduct constitutes professional misconduct and is grounds for disciplinary action and/or reporting to the appropriate professional bodies.

[3] International Committee of Medical Journal Editors, Uniform requirements of manuscripts submitted to biomedical journals. Medical Education, 1999. 33(1): p.66-78

3.1.4.2 Detailed procedures and responsibilities for the handling of suspected fraud and misconduct are set out in a separate Trust Procedure 'Handling Suspected Fraud and Misconduct' (SOP 06).

3.1.5 Information: data protection

3.1.5.1 Personal information means information of any type about individuals, living or dead, held in any form by the Trust or its employees or independent contractors. This includes written and electronic records, opinions, images, recordings, and information obtained from samples. Identifiable information is information from which the individual to whom the information pertains might be identified by a person viewing the information (e.g. unique ID number, date of birth, telephone number). Researchers should refer to the *NHS Confidentiality Code of Practice* (2003). Anonymised data are data prepared from personal information, but from which the individual cannot be identified by a person viewing the information (eg. age, height, Body Mass Index). Linked anonymised data (also referred to as pseudonymised data) are anonymous to the people who receive and hold it but contain information or codes that would allow others (eg. the Chief Investigator) to identify people from it. Linked data are typically used where it may be necessary to refer back to an original data source for further information or verification. Confidential information is any information obtained by a person on the understanding that they will not disclose it to others, or obtained in circumstances where it is expected that they will not disclose it.

3.1.5.2 The confidentiality of information provided by patients or collected from or on patients as part of their healthcare is central to the public's trust in the NHS and health care professionals. The appropriate use and protection of personal information is paramount. All those involved in research must be aware of their legal and ethical duties in this respect; it is a legal requirement that personal information remains confidential, including information associated with tissue and biological samples.

3.1.5.3 All research project information should be recorded, handled and stored in a way that allows its accurate reporting, interpretation and verification.

3.1.5.4 All NHS care records should be maintained in compliance with the NHS Care Records Guarantee.

3.1.5.5 Researchers are responsible for ensuring that research data is held securely; this is a legal obligation under the Data Protection Act 2018 and GDPR. The Act requires that all personal identifiable information relating to living individuals must be anonymised as far as is possible and consistent with the needs of the study, and as early as possible in the data processing. Whenever possible and as soon as possible, researchers should store personal data as unlinked anonymised data. When this is not possible, personal data should be stored as linked anonymised data. This should be done by attaching a code – such as a serial number – to all data from each individual participant or dataset. The key to this code should be held in a single, locked file (the 'link' file), separate from the main data files.

3.1.5.6 Paper documents with identifiable personal data should not be left unattended in an unsecured area, and must be locked within a secure area overnight. Electronic files should be password protected, with the password known only to legitimate research staff. Personal identifiable information held on laptops whether temporary or not should have an encrypted hard drive where if lost it would be impossible to unscramble the information. On no account should identifiable data be held without encryption. Anonymised data must be kept for a 10 year period of time from the date of completion of the study in a secure location as just described.

3.1.5.7 Research involving recordings and transcripts of interview, focus groups or any research activity should ensure these are kept for 10 years from the date of completion of the study. Digital recordings of research activity should be password protected.

3.1.5.8 Lead Investigators are responsible for ensuring that all other research staff under their supervision understand fully the standards expected, and the importance of confidentiality.

3.1.6 Information: use of existing personal information for research purposes

3.1.6.1 The Data Protection Act 2018 and GDPR requires that when people give information they should be told what it will be used for and to whom it will be passed. The Trust is a research-active organisation and it is possible that researchers may want to access and process a patient's personal information at a later date for research purposes. This later processing may be unlawful without the patient's further consent. There are three routes to processing these data lawfully; these are set out below.

3.1.6.2 (1) The preferred route is for researchers to obtain consent from each individual patient whose data they wish to access or process. This consent must be obtained on a study-by-study basis, i.e. for each individual study.

3.1.6.3 (2) The Health Research Authority Confidentiality Advisory Group (CAG) have advised that a person from within the patient's clinical care team would legitimately be able to access identifiable information without consent in order to prepare a fully anonymised data set. This means undertaking the minimum necessary data processing required to extract and immediately anonymise the information. This person must be a member of the patient's clinical care team – i.e. a person directly involved in the diagnosis, care and treatment of an individual: people external to this team are not permitted to process data, regardless of their contractual status with the NHS organisation and regardless of the data protection registration status of the organisation or database involved. If it is not clear whether or not a researcher is a member of the patient's clinical care team, advice should be sought from the Trust's Caldicott Guardian.

3.1.6.4 (3) When it is neither reasonably practicable to gain each individual's consent nor for a member of the patient's clinical care team to process the information, then the researcher is required to gain permission for their activity from the Health Research Authority Confidentiality Advisory Group (CAG) ('Section 251 approval').

3.1.6.5 From 2016, all new patients to adult services in the Trust have been given a 'Research Leaflet' (Appendix 2) outlining how R&D staff members may send them information about research studies. All patients are given the option to opt out of hearing more about research studies.

3.1.7 Health and safety: reporting of adverse events and incidents

3.1.7.1 Researchers must report to the study Sponsor any adverse events and safety incidents arising in research, as defined and required by the study protocol.

3.1.7.2 In addition, in line with the Trust's own incident reporting policy, researchers must report to the NHS site / organisation any events and incidents that cause injury to a patient (i.e. Clinical Incident reporting) or any 'near misses', this being any incident that had the potential to cause harm but was avoided.

3.1.7.3 Protocol violations in clinical studies should be reported as incidents or near misses, as appropriate.

3.1.7.4 Researchers conducting Clinical Trials of Investigational Medicinal Products must comply with the specific regulatory requirements for pharmacovigilance as set out in The Medicines for Human Use (Clinical Trials) Regulations 2004, The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, and The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006.

3.1.8 Health and safety: indemnity

3.1.8.1 It is the responsibility of the researcher to ensure that arrangements for compensation in the event of negligent or non-negligent harm are agreed with the Trust Research & Development Office prior to commencement of the study. These arrangements will vary depending upon the type of research and research Sponsor.

3.1.8.2 In commercial research, the Sponsor must indemnify and hold harmless the Trust and its employees against all claims and proceedings made or brought (successfully or otherwise) by or on behalf of research subjects against the Trust for personal injury arising out of any procedure required by the protocol to which the subjects would not have been exposed but for their participation in the study. Researchers must ensure a Form of Indemnity, properly agreed by a Trust authorised signatory, is in place for any commercial research study.

3.1.8.3 Typically this indemnity does not apply to any claim to the extent that such personal injury is caused by the negligent or wrongful acts or omissions or breach of statutory duty of the Trust or the individuals conducting the study, including the failure of the researchers to conduct the study in accordance with the protocol. Existing arrangements for NHS Indemnity cover harm caused to patients or healthy volunteers by clinical negligence in research, when that research has been approved by the Trust and follows the approved protocol.[4]

3.1.8.4 NHS indemnity does not extend to cover for independent contractors or their employees, who instead must ensure they are covered by satisfactory professional indemnity policies.

3.1.8.5 NHS bodies may not offer advance indemnities for non-negligent harm. In exceptional circumstances, the researcher's employing organisation may consider whether an ex-gratia payment could be offered.

3.1.8.6 Should a claim for compensation arise from unauthorised research – i.e. research that has not had formal approval from the Trust – then the researcher may be personally liable for (a) meeting the legal and administrative costs of defending any claim for negligent or non-negligent harm or of reaching a settlement, (b) the plaintiff's costs, and (c) any damages awarded.

3.1.9 Commercial Trials

3.1.9.1 A Commercial Study is defined as a study initiated and funded by a commercial company. The commercial company is therefore responsible for the design of the protocol, sponsorship, indemnity arrangements and financial management for each commissioned commercial study.

3.1.9.2 Each commercial trial shall have a Clinical Trials Agreement which delineates each party's responsibilities in the commercial trial including financial arrangements for the study. The Trust has adopted the use of the model Clinical Trial Agreement, developed by the Department of Health and Association of British Pharmaceutical Industry, as its core template and will only undertake research with pharmaceutical companies who use this template. Only the Research & Development Department is authorised to sign this agreement on behalf of the Trust.

3.1.9.3 The Trust will be responsible for making arrangements for the scoping, set-up, costing, negotiation of per patient fee, clinical trial agreement, invoicing and monitoring of research with the pharmaceutical company. The Trust Research & Development Department will work closely with the Principal Investigator to ensure the process runs smoothly. Appropriate administrative and clinical support will be provided.

[4] NHS Executive, NHS Indemnity: Arrangements for Clinical Negligence Claims in the NHS. 1996, NHS Executive: Leeds

3.1.9.4 The Trust R&D department will assess feasibility for the conduct of clinical trials and capacity within the Trust's clinical trial centre to deliver the protocol. If it is considered unfeasible to conduct the clinical trial ensuring it is delivered safely and meets its recruitment targets, the R&D department reserves the right to decline the trial and cease set up.

3.1.9.5 All clinical trials in the Trust must be conducted either at or in partnership with the Trust's Research Unit (DRU) in Crowborough. The unit has the available R&D infrastructure, facilities and support in order to safely carry out commercial research.

3.1.9.6 Surplus Income from commercial clinical trials (and any other research funding) will not be used for service development or patient care. Detailed procedures and responsibilities regarding commercial research and its financial managements are set out in a separate Trust procedure. See "Financial Management of Commercial Surplus" for further information.

3.1.10 Management and finance: sponsorship

3.1.10.1 For any research that takes place in the context of the NHS or social care services in England there must be a sponsor. The sponsor is the individual, or organisation (or group of individuals or organisations) that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study. Normally, the sponsor will be one of the organisations taking the lead for particular aspects of the arrangements for the study, typically the Chief Investigator's employing organisation.

3.1.10.2 For research in which the Chief Investigator is a substantive employee of Sussex Partnership NHS Foundation Trust, the researcher can request that the Trust acts as Sponsor. The request is made within the Research approval application (via the Integrated Research Application System). Sponsorship is awarded at the discretion of the Trust following a risk assessment of the proposed study and the study management arrangements.

3.1.10.3 Research undertaken in part or whole fulfilment of a qualification from a higher education institute should ordinarily be sponsored by that institute.

3.1.10.4 For clinical trials involving medicines, the sponsor is defined as the person (e.g. individual, institution, company or organisation) who takes responsibility for the initiation, management and financing (or arranging the financing) of that trial. Such sponsors have specific legal duties under the Medicines for Human Use (Clinical Trials) Regulations 2004 and Amendment Regulations 2006. Regulation 3 defines options for sponsorship, including single sponsorship, joint sponsorship and allocation of sponsorship responsibilities within a group.

3.1.10.5 The Trust will only sponsor clinical trials involving medicines if funding is available to cover the management costs incurred by the Trust in discharging Sponsor responsibilities.

3.1.11 Management and finance: research approval and monitoring

3.1.11.1 The UK Policy Framework for Health & Social Care Research requires that researchers obtain the green light before the research starts from each NHS organisation whose patients, staff, premises, data or resources will be involved in the research. It is the responsibility of the researcher to gain Confirmation of Capacity & Capability for the research. It is also the responsibility of the researcher to ensure that approvals are in place from an NHS Research Ethics committee, the Health Research Authority and other external authorities, as required, before the research starts.

3.1.11.2 Prior to proceeding with a research study, the researcher must have written confirmation from the R&D Office that either the green light or Confirmation of Capacity & Capability for this study at each study site is in place. The researcher must comply with all conditions of approval throughout the lifetime of the project for the approval to remain valid.

3.1.11.3 The carrying out of research without Trust Confirmation of Capacity & Capability constitutes professional misconduct and is grounds for disciplinary action and/or reporting to the appropriate professional bodies. Researchers should note that NHS indemnity cover for clinical negligence might not be in place if the incident has occurred in unauthorised research.

3.1.12 Management and finance: honorary employment contracts

3.1.12.1 Non-Trust employees who wish to engage in research which is likely to have a 'direct bearing on the quality of care' of NHS patients or service users (meaning that the actions of researchers could foreseeably directly affect the type, quality or extent of prevention, diagnosis or treatment of illness or foreseeably cause injury or loss to an individual to whom the organisation has a duty of care)[5] must hold the appropriate Research Passport with the Trust.

3.1.12.2 It is the responsibility of the Lead Researcher to ensure that these contracts are in place.

3.1.12.3 The Trust issues Research Passports in line with national guidance[6] and Health Research Authority recommendation.

3.1.12.4 Detailed procedures and responsibilities regarding Research Passports are set out in a separate Trust procedure (SOP 04) ‘Research Passports’.

3.1.13 Management and finance: research agreements

3.1.13.1 Almost without exception, a research activity is conducted under the terms of one or more contracts or agreements, such as commercial research contracts, confidentiality agreements, Sponsorship agreements, research grant awards, statement of activity and Forms of Indemnity. The researcher and Trust R&D Office, jointly, must ensure that all relevant

[5] NHS R&D Forum, Honorary research contracts and the Research Passport system. 2006, NHS R&D Forum, Birmingham.

agreements are satisfactory and have been properly authorised prior to commencement of research.

3.1.13.2 External funding applications, research contracts and corporate research agreements should be signed by the Authorised Signatory for the Trust. Researchers are authorised to sign the 'investigator agreement' and other project-level documents only, in their capacity as the lead local researcher and not as the delegated authority of the Trust.

3.1.14 Management and finance: financial management

3.1.14.1 The Trust and individual researchers collectively have a responsibility to ensure the good financial management of research projects. Good financial management is essential to the successful conduct and completion of research studies, and good collective financial management is essential to the Trust's standing as a secure and competent host organisation.

3.1.14.2 All research funding must be managed in full compliance with the Trust's Standing Financial Instructions and other relevant policies.

3.1.14.3 It is Trust policy that in all cases the financial arrangements for a study must be scrutinised and approved by the Trust prior to commencement of the study. For research undertaken within the Trust, this scrutiny and approval is carried out by the Trust R&D Governance Office.

3.1.14.4 It is the responsibility of the researcher to ensure that applications for approval of new projects demonstrate:

- That all additional NHS costs associated with the project have been identified;
- That funding from an appropriate non patient care funding source has been identified to meet in full the additional NHS costs;
- That satisfactory arrangements are in place for the management of income and expenditure.

3.1.14.5 Where possible the Trust shall ensure overhead costsare recovered. Examples are office space and equipment, general upkeep of building, general running of building and organisation including heating, lighting, HR, finance, R&D, estates etc.

3.1.14.6 The Trust shall levy a charge on commercial research income for capacity building, calculated as a percentage of procedure costs and staff and services where this does not already include a charge for capacity building (eg. BMA rates). This percentage shall be agreed on a study-by-study basis between the company, the researcher and the R&D Department.

3.1.14.7 Under no circumstances may a Trust employee retain any research monies as a payment outside the employee's NHS salary, e.g. as a personal gift from the company, nor may any monies be paid into an external account, e.g. a building society account.

3.1.14.8 For all commercial research studies scheduled over 24 months in length; on the second anniversary of the final signature on the Clinical Trials Agreement, all clinical trials subject visits payment will be increased by

2%. On the third and every subsequent anniversary, clinical trial subject visit payments will be increased by an additional 2%

3.1.15 Quality Research Culture

3.1.15.1 This organisation supports and promotes high quality research as part of a service culture receptive to the development and implementation of best practice in the delivery of care.

3.1.15.2 The Trust commission's research themes within the Trust and all research must be adopted by a theme and approved by theme leaders as part of the Trusts Confirmation of Capacity & Capability process. For more information on current themes see the Trust R&D web pages (http://www.sussexpartnership.nhs.uk/r-and-d/themes).

3.1.15.3 Good research practice can only be achieved if research staff at all levels are trained and supervised properly in a research culture that encourages open discussion and debate. Those supervising research:

- are responsible for engendering a research ethic of openness, honesty, and constructive and co-operative working;
- must ensure staff have the appropriate training, experience, support and resources to carry out their duties effectively;
- must ensure that students and new researchers have adequate supervision, support and training.

3.1.15.4 The Trust has a duty to ensure that patients or users and carers are provided with information on research that may affect their care. This will be made available in an accessible and appropriate format which may include non-English language, audio etc. If a patient's care will be affected by a piece of research then staff have a responsibility to make the patient aware of that fact – assuming that they are not actually a participant in a study that requires individual consent. An example might be a health services research project that pilots a new type of service delivery, e.g. a minor injuries triage unit.

3.1.15.5 The Trust strongly supports the principle that NHS patients should be involved in decision-making regarding research strategy, policy and activity. Wherever possible, researchers should aim to involve service users and carers in the design, conduct, analysis and reporting of individual projects.

3.1.15.6 Researchers are required to set out their plans for user involvement, and these plans are assessed as part of the R&D office's assessment of capacity and capability for any given research project.

3.1.16 Service User and Carer Involvement

3.1.16.1 Researchers are actively encouraged to apply for external funding designated for PPI for individual studies to support involvement at design stage. Where this is not possible and no other external budget is available, eligible researchers can table their PPI plans with one of the themed PPI design groups.

3.1.16.2 LEAF (Lived Experience Advisory Forum) members are invited to participate in all R&D reporting structures, e.g design and delivery fora. The chairs of these groups will report the PPI activities to the RAC which will also be attended by LEAF members. A separate LEAF report on activities not covered by Design and Delivery will be given to the RAC.

3.1.16.3 Researchers should seek to involve service users and carers in the design, conduct, analysis and reporting of individual projects. Where this is not possible Expert Organisations, e.g. the Alzheimer's Society may be consulted. Research that does not seek to involve service users, carers or Expert Organisations in the design, conduct, analysis and reporting is less likely be supported.

3.1.16.4 Wherever possible, LEAF will be consulted on plans which may impact positively or negatively on the quality of service user and carer experience of taking part in research and on broader engagement of existing and potential research participants. When this is not possible a reason will be supplied.

3.1.16.5 Wherever possible, LEAF will be consulted on plans to evaluate service user and carer experience in research. Where both relevant and practical, LEAF expertise will be sought in the design, conduct and translation of evaluation of participant experience into improved research quality and practice. When this is not possible a reason will be supplied.

3.1.16.6 All Service Users and Carers involved in the design, conduct, analysis and reporting of individual funded projects must be offered payment in line with Trust Policy on the Payment of Service Users and Carers. Service Users and Carers that wish to volunteer will still be able to do so. Wherever possible, expenses for Service User and Carer involvement will be paid on the day.

3.1.16.7 Service Users and Carers will be offered appropriate training and support to participation in the design, conduct, analysis and reporting of individual projects and to participate in LEAF.

3.2 Additional Provisions

3.2.1 Clinical Trials of Investigational Medicinal Products (CTIMPs)

3.2.1.1 The statutory provisions for clinical trials of an investigational medicinal product are set out in The Medicines for Human Use (Clinical Trials) Regulations 2004, The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, and The Medicines for Human Use (Clinical Trials) Amendment (No.2) Regulations 2006. Anyone carrying out research to which these Regulations apply has a duty to act in accordance with the principles and provisions of the Regulations.

3.2.1.2 These Regulations help to ensure that the rights, safety and well-being of clinical trial subjects are protected by requiring sponsors of trials to be responsible for designing, conducting, recording and reporting clinical trials according to internationally recognised principles of Good Clinical Practice (GCP).

3.2.1.3 In addition, the Regulations further protect public health by helping to ensure that the results of clinical trials are collected, recorded and analysed in accordance with those principles so that they can be audited and verified before being used to impact on public health, for example through a publication that changes medical prescribing practice or as evidence to support applications to place medicines on the market.

3.2.1.4 The Regulations provide a statutory basis for:

- standardisation of procedures for ethical and competent authority consideration and authorisation
- GCP standards for commencing and conducting clinical trials
- Good Manufacturing Practice (GMP) standards for medicines used in clinical trials
- inspections against internationally accepted principles and standards of GCP and GMP, supported by enforcement powers.

3.2.1.5 Sponsors of clinical trials of investigational medicinal products are required to make an application for Clinical Trials Authorisation (CTA) to the Medicines and Healthcare Products Regulatory Agency (MHRA). A clinical trial of an investigational medicinal product may be undertaken in this Trust only when the Clinical Trials Authorisation is in place.

3.2.1.6 Good Clinical Practice

The Regulations, and in particular The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006, set out the principles of Good Clinical Practice in clinical trials of an investigational medicinal product.

Researchers conducting clinical trials of investigational medicinal products in the Trust must have undertaken Good Clinical Practice training prior to commencement of the trial.

3.2.2 Research involving ionising radiation

3.2.2.1 The statutory provisions for research involving ionising radiation are set out in The Ionising Radiation (Medical Exposure) Regulations 2000 (“IRMER”), The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2006, and The Medicines (Administration of Radioactive Substances) Regulations 1978 (“MARS”). Anyone carrying out research to which these Regulations apply has a duty to act in accordance with the principles and provisions of the Regulations.

3.2.2.2 The Ionising Radiation (Medical Exposure) Regulations 2000 (IRMER) govern the exposure to ionising radiation of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic research programmes.

3.2.2.3 Procedures involving ionising radiation include:

- Diagnostic X-rays, CT scans or DXA scans

- Radiotherapy (including brachytherapy and therapy using unsealed sources)

- Radionuclide imaging (including diagnostic imaging and in vitro measurements).

3.2.2.4 Magnetic Resonance Imaging (MRI) or ultrasound investigations do not involve ionising radiation.

3.2.2.5 The research provisions of IRMER apply to any research exposure involving ionising radiation, not only to exposures that are additional to routine care.

3.2.2.6 A research exposure is any exposure required by the research protocol following initial consent from the participant. It includes all exposures carried out on the participant as determined by the protocol, including those which would otherwise be part of routine clinical care for patients treated outside the research setting.

3.2.2.7 The local researcher / Principal Investigator (PI) is advised to notify the Trust's R&D Office and the Radiology, Radiotherapy and/or Nuclear Medicine Departments at an early stage of plans to conduct research (or participate in a multi-site study) involving radiation exposures. Early discussion will give departments more time to prepare for the research. Advice can be given on local procedures for research governance and compliance with IRMER and other statutory requirements.

3.2.2.8 The Trust has a legal requirement to demonstrate compliance with IRMER for research, in particular that:

- Dose constraints are established and adhered to in studies where there is no health benefit to be expected from the exposure

- Target dose levels are established where there is some expected health benefit for participants

- Exposures are individually justified by an "IRMER Practitioner"

- Individuals participate voluntarily

- Participants are informed of the risks of exposure.

3.2.2.9 The researcher/PI should contact the IRMER Practitioner for the site. The IRMER Practitioner should be a registered health professional with clinical expertise in the modality involved. Where more than one modality (or type of radiotherapy) is involved, it may be necessary to seek input from more than one IRMER Practitioner.

3.2.2.10 The IRMER Practitioner should review the protocol and main Health Research Authority (HRA) application and confirm in writing to the PI and the Trust's Lead R&D Officer that:

- The site can adhere to the protocol.

- Where local patients would receive additional exposure, this has been identified in the HRA application and has been ethically approved by the main REC and the HRA.

- Any additional exposure is justified having regard to IRMER.

3.2.2.11 Once the IRMER Practitioner's review is complete, the researcher/PI should contact the Radiology, Radiotherapy and/or Nuclear Medicine Departments as appropriate and provide a copy of the approved protocol, participant information sheet, supporting documentation from the IRMER Practitioner and the following information:

- examinations required

- number and frequency

- clinical conditions to be studied

- age ranges of subjects

- use of healthy volunteers

- any other relevant information.

3.2.2.12 The local Medical Physics Expert (MPE) should review the protocol and the HRA application form and confirm to the PI that the protocol can be performed at the site within the estimated range of dose made by the lead MPE for the research. A local dose constraint or target dose should be established: this should not exceed the maximum exposure estimated in the HRA application.

3.2.2.13 In cases where the protocol cannot be performed at the site within the estimated range of dose made by the lead MPE for the research (i.e. the range that has been approved by the main REC), then an amendment will need to be made to the protocol and/or the Patient Information Sheet, either generally or in relation to the local site, and submitted to the main REC for review. This amendment should only be submitted following discussions between, and with the agreement of, the local PI, the Chief Investigator, the lead MPE, and the local MPE.

3.2.2.14 Where research involves the administration of radioactive substances, an ARSAC certificate must be held at each research site where administrations take place. The certificate is site, procedure and holder specific. A "research ARSAC certificate" will only be required if the research exposure is additional to those carried out by the certificate holder as part of normal clinical care. The local MPE will advise if a research ARSAC certificate is needed.

3.2.3 Clinical investigations of medical devices

3.2.3.1 The statutory provisions for clinical trials of non CE marked medical devices are set out in The Medical Devices Regulations 2002 and The Medical Devices (Amendment) Regulations 2005. Anyone carrying out

research to which these Regulations apply has a duty to act in accordance with the principles and provisions of the Regulations.

3.2.3.2 These regulations establish systems under which a manufacturer must submit to the Medicines and Healthcare Products Regulatory Agency (MHRA) information about clinical investigations of medical devices to be carried out in the UK.

3.2.3.3 Researchers and manufacturers conducting clinical investigations involving non-CE marked medical devices are required make a notification of a clinical investigation to the MHRA. Researchers should be aware that there are significant fees associated with pre-clinical assessment of clinical investigation of a medical device notification by the MHRA; it is usual to submit such notifications in collaboration with a commercial manufacturer.

3.2.3.4 A clinical investigation involving non-CE marked medical devices may only begin in this Trust once the MHRA has issued a letter of no objection.

3.2.3.5 If a clinician uses a CE marked device for a new or off-label purpose which is unsupported by the manufacturer, then the clinician may take on liability in the event of an adverse incident.

3.2.3.6 If the clinician and Trust see or intend a commercial application for the device they may also take on the responsibilities of "the manufacturer" and must, therefore, fulfil the requirements for the manufacturer as set out in the Medical Devices Regulations 2002, including notification of a clinical investigation to the Medicines and Healthcare Products Regulatory Agency.

3.2.3.7 Manufacturers may not sponsor a clinician to evaluate a new or off-label purpose for a device outside of a formal clinical investigation.

3.2.3.8 Manufacturers may choose or may be obliged to carry out clinical studies in the post marketing phase on the CE Marked device. These post marketing studies do not require review or approval by MHRA but may need ethical approval.

3.2.3.9 The policy of this Trust is that permission for studies involving off-label use of a CE marked device will be considered by the organisation on a case-by-case basis.

3.2.4 Research involving the use of animals

3.2.4.1 The Trust is not a designated establishment under the Animals (Scientific Procedures) Act 1986 and therefore research involving the use of animals is not permitted.

3.2.5 Research on human material

3.2.5.1 Any research that involves activities relating to human tissue must be carried out in compliance with the Human Tissue Act (2004) and the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

3.2.5.2 The Human Tissue Authority is established as the regulatory body to license a number of activities set out in the Act. The licensing requirement applies to all establishments whether operating within the NHS, a university or the private or commercial sector. It is unlawful to carry out certain activities without a licence from the HTA.

3.2.5.3 Researchers are required to ensure that activities relating to human tissue carried out as part of research are appropriately licensed by the Human Tissue Authority.

3.2.6 Research involving people who lack mental capacity

3.2.6.1 The Mental Capacity Act 2005 sets out the statutory provisions for research involving adults lacking mental capacity. Anyone carrying out research to which the Act applies has a duty to act in accordance with the principles and provisions of the Act and to have regard to the guidance given in the Mental Capacity Act Code of Practice. This Act makes specific provisions for consent in research involving incapacitated adults.

3.2.6.2 In the context of research, the following factors determine whether the provisions of the Act apply:

- The proposed research is defined as 'intrusive' i.e. it is of a kind that would otherwise require the consent of the potential participant in order to be lawful;

- The research includes participants who have an impairment of, or disturbance in, the functioning of the mind or brain that results in a lack of capacity to consent to participating in the research; and

- The research proposed is not a clinical trial covered under the Medicines for Human Use (Clinical Trials) Regulations 2004.

3.2.6.3 If the Act applies to the research, research cannot take place on or in relation to a person lacking capacity unless the approval of an independent Research Ethics Committee and Health Research Authority have been obtained. The Research Ethics Committee and Health Research Authority can only approve a research project if the following requirements are met:

- The research is connected with an impairing condition affecting the person lacking capacity or the treatment of that condition;

- There are reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project is confined to those who have capacity to consent to it;

- The research has a potential benefit to the person lacking capacity that is not disproportionate to the burden imposed on him/her by participating in the research; or

- The research is intended to provide knowledge of the cause or treatment of, or the care of persons with, the same or similar condition as the person lacking capacity - if research falls into this category only,

the risk to the person lacking capacity of taking part in the research must be negligible and anything done to or in relation to him/her must not interfere with his/her freedom of action or privacy in a significant way, or be unduly invasive or restrictive; and

- Reasonable arrangements are in place to ensure that the necessary consultation with carers (or other consultee) will take place and other safeguards implemented.

4. Development, consultation and ratification

4.1 Learning from Serious Incidents: All SIs are tabled at the Research Assurance Committee and any learning from them will contribute to the Research Policy and associated SOPs on an on-going basis.

4.2 The Research Assurance Committee was consulted about this policy on 01/09/2017. The ratifying forum is the Clinical Policy Forum.

4.3 This version of the ratified policy is updated to Trust format and layout, has undergone an Equality Impact Assessment.

5. Monitoring Compliance

5.1 It is a requirement of Care Quality Commission's quality and safety regulation that "The healthcare organisation complies with requirements of the UK Policy Framework for Health and Social Care Research". Compliance is reported on for the CQC Essential Standards.

5.2 The R&D Department review their systems and processes for undertaking governance checks on an ad-hoc basis in response to revised national guidelines and practice.

6. Document Control and Archiving

6.1 Following ratification this policy will be forwarded to the Governance Support Team to allocate an official document number and log the document on the central Trust database. The Governance Support Team will also store electronic copies of the Equality Impact Assessment, Dissemination Plan and Review & Approval Checklists, according to the Organisation-wide policy for the development and management of procedural documents.

6.2 Old copies of the policy will be archived in accordance with the Trust Policy for the Management of Corporate Administrative Records.

7. References

Department of Health, 'Research Governance Framework for Health & Social Care', 2nd edition, 2005, Department of Health, London

Department of Health, 'UK Policy Framework for Health and Social Care Research', 2018, Department of Health, London

International Committee of Medical Journal Editors, Uniform requirements of manuscripts submitted to biomedical journals. Medical Education, 1999. 33(1): p.66-78

National Institute of Clinical Excellence, 'Principles for Best Practice in Clinical Audit', 2002, National Institute for Clinical Excellence: London

NHS Executive, NHS Indemnity: Arrangements for Clinical Negligence Claims in the NHS. 1996, NHS Executive: Leeds

NHS R&D Forum, Honorary research contracts and the Research Passport system. 2006, NHS R&D Forum, Birmingham.

8. Policy cross references

The Medicines Code – (Chapter 26 - Clinical Trials Involving Pharmaceutical Products).

Policy on Clinical Audit

Policy on Equality and Diversity

Policy for the Governance of Commercial Clinical Trials

Policy for the Management of Corporate Administrative Records

Policy on the Payment of Service Users and Carers

Trust Procedure: Operational Capability Statement (SOP01)

Trust Procedure: R&D Approvals (SOP03)

Trust Procedure: Research Passports (SOP04)

Trust Procedure: Handling of Suspected Fraud and Misconduct (SOP06)

Trust Procedure: CTIMP Pharmacovigilance (SOP07)

Trust Procedure: Storage of research documents and data (Externally-sponsored CTIMPs) (SOP08)