Trust-wide Policy
For
Research Governance

A document recommended for use

In: All departments involved with research

By: All staff involved with research

For: Undertaking research

Key Words: Research Governance

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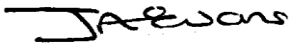
Trust Ratification: 

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Version	Date	Comment
1	February 2006	New Policy
2	September 2008	Scheduled Review
3	October 2011	Scheduled Review
4	March 2016	Revised to reflect creation of new Division for Research and Development and to incorporate the principles of the UK Policy Framework for Health and Social Care Research.
5	May 2018	Revised to include a) the UK Policy Framework for Health and Social Care Research b) the general data Protection Regulation 2018 and c) the Research Team Structure.

Equality Impact Assessment

This document has been reviewed in line with the Trust's Equality Impact Assessment guidance and no detriment was identified. This policy applies to all regardless of protected characteristic - age, sex, disability, gender-re-assignment, race, religion/belief, sexual orientation, marriage/civil partnership and pregnancy and maternity.

Dissemination and Access

This document can only be considered valid when viewed via the East & North Hertfordshire NHS Trust Knowledge Centre. If this document is printed in hard copy, or saved at another location, you must check that it matches the version on the Knowledge Centre.

Associated Documentation

Trust Policy on Intellectual Property

Review

This document will be reviewed within three years of issue, or sooner in light of new evidence.

Key Messages

This policy supports the national ambition to make the UK a great place to do research where more people have the opportunity to participate in health and social care research and continue to feel safe when they do. The Policy enhances the ability of the Trust to deliver its vision '*to be amongst the best'* because:

a) Patient care is enhanced by the Trust being research-active,
b) Research supports the strategic and operational needs of the organisation, and
c) The Trust and its staff are recognised as being an exemplar for the conduct of research.

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1. Introduction

1.1 This policy supports the national ambition to make the UK a great place to do research where more people have the opportunity to participate in health and social care research and continue to feel safe when they do.

1.2 The Policy enhances the ability of the Trust to deliver its vision '*to be amongst the best'* because:

a) Patient care is enhanced by the Trust being research-active,
b) Research supports the strategic and operational needs of the organisation, and
c) The Trust and it's staff are recognised as being an exemplar for the conduct of research.

1.3 The Trust is committed, and has put in place a structure (Figure 1) and processes, to develop and support an environment where:

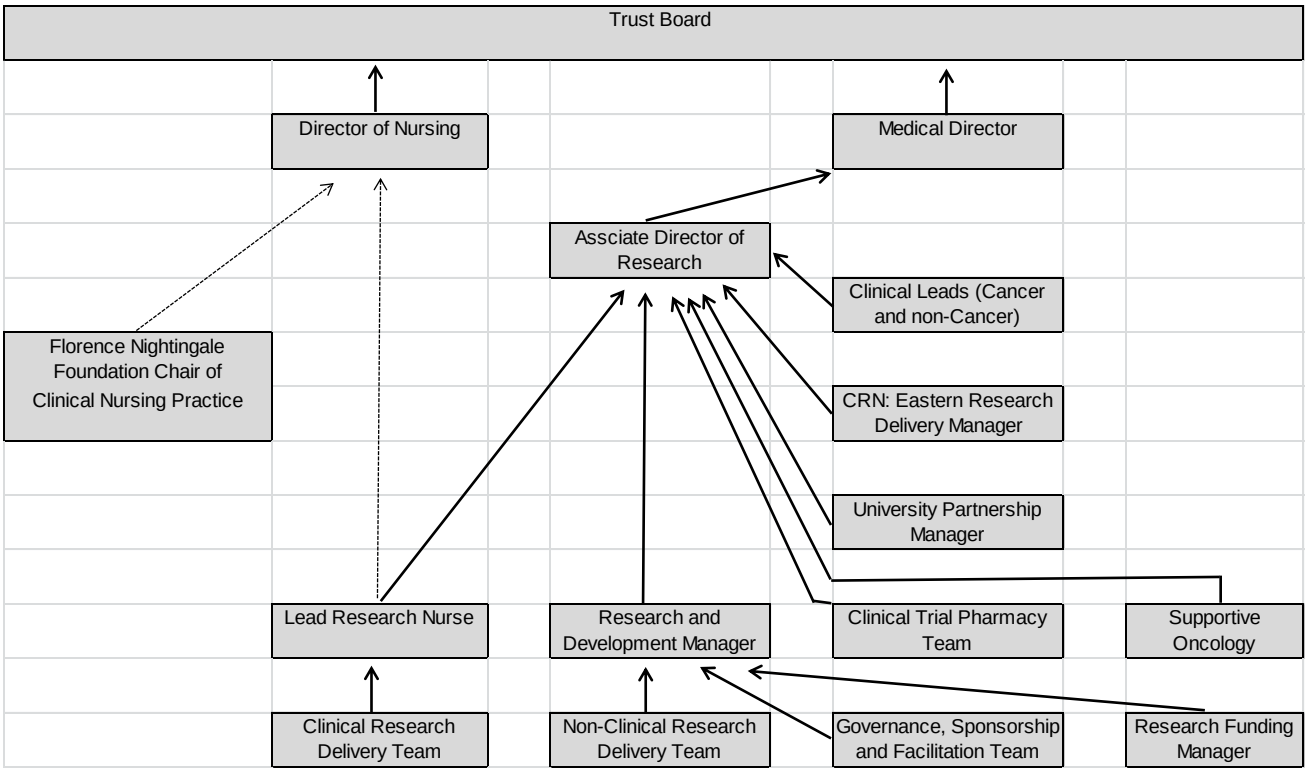
a) patients, service users and the public are given, and take, the opportunity to participate in health and social care research, and are confident about doing so; new treatments, care and other services are developed through ethical and scientifically sound research for the benefit of patients, service users and the public;
b) applying to do research is simple and getting a decision is quick and predictable;
c) researchers find it straightforward to do high-quality, ethical research; commissioners and providers of health and social care appreciate how health and social care research benefits patients, service users, staff and the public;
d) industry sees the UK as a great place to do health and social care research;
e) money from charities and other research funders goes into carrying out research, not into navigating needless bureaucracy or duplicating previous work; and

f) research projects get registered, the data and tissue they collect can be made available for future analysis, where appropriate and with adequate consent and safeguards, and research findings get published and summarised for those who took part in them.

1.4 The aim of this policy is to provide guidance and support for those undertaking research and to promote high standards of quality and ethics in all areas of research activity in line with the requirements of the UK Policy Framework for Health and Social Care Research[1].

1.5 This policy is required reading in Induction Training for new staff and is available on the Trust's public internet site.

Figure 1 Trust Research and Development Senior Management and Reporting Structure



[1] https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

2. Legal requirements and definitions

2.1 This policy provides a framework for research which complies with good practice in research without restricting the freedom of individual researchers to develop ideas which can improve clinical care.

2.2 The policy is relevant to all staff who undertake, support or manage clinical research including chief and principal investigators, care professionals, researchers, research nurses, managers and support staff.

2.3 The policy applies to all research activity involving the Trust including:

- Research where the Trust is a lead organisation
- Research where the Trust is a participating site in research
- Research where participants are patients, carers, volunteers and members of Trust staff
- Research using patient tissue, organs or data
- Research taking place on Trust premises
- Research involving Trust resources
- Research that is non-clinical or laboratory based
- Research being undertaken as part of an educational qualification

2.4 Research is defined by UK Policy Framework for Health and Social Care Research and a summary is given in Box 1.

2.5 Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. Examples of non-research activity include:

- **Audit** - Designed and conducted to produce information to inform delivery of best care.
- **Service Evaluation** - Designed and conducted solely to define or judge current care.
- **Public Health Surveillance** - Designed to manage outbreak and help the public by identifying and understanding risks associated.
- **Public Health** - Designed to investigate outbreak or incident to help in disease control and prevention.
- **Audit** - Designed and conducted to produce information to inform delivery of best care.
- **Service Evaluation** - Designed and conducted solely to define or judge current care.
- **Public Health Surveillance** - Designed to manage outbreak and help the public by identifying and understanding risks associated.
- **Public Health** - Designed to investigate outbreak or incident to help in disease control and prevention.

Box 1

The attempt to derive generalisable or transferable[a] new[b] knowledge to answer or refine relevant questions with scientifically sound methods[c]. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part[d] of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research.

Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework.

Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at www.hra-decisiontools.org.uk/research

The activity of involving patients, service users or the public in the design, management, conduct or dissemination of research **should not be managed as though it is research** in its own right. Information on arrangements and controls relating to public involvement is available from INVOLVE at www.invo.org.uk

[a] NB This definition involves an *attempt* at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The *actual* generalisability or transferability of some research findings may only become apparent once the project has been completed.
[b] Including new knowledge about existing treatments or care.
[c] Projects that are not designed well enough to meet this definition are not exempt from this policy framework.
[d] This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey.

2.6 The Trust has no objection to acting as a Participant Identification Centre (PIC) providing that the Research Office is notified in advance and that the local team is satisfied that the activity does not affect local service delivery. PIC activity may only commence once NHS permission is granted by the research site. In this context the Health Research Authority definition of a PIC site is used i.e.

"*an organization that identifies participants, largely (but not exclusively) through patient records for possible participation in studies, provides information about / or informs patients directly about a study, e.g. a clinician speaks directly to a patient or advertises the opportunities to participate in a specific study, e.g. via posters in waiting rooms. An organisation is not acting as*

a PIC when it is responsible for any protocol-specified assessment to determine participant eligibility for a study, e.g. a screening blood test or x-ray, the recruitment (informed consent) of participants into a research study or the delivery of research procedures specified in the research protocol". In this context is a requirement of the research site to ensure that the use of the Trust as a PIC has satisfied all relevant ethical and legal authorisations.

http://www.hra.nhs.uk/resources/after-you-apply/participant-identification-centres/

2.7 All staff are contractually obligated to follow this Policy as well as any authorised and relevant Trust Standard Operating Procedures. Non-compliance with this Policy will be managed in accordance with other Trust Policies.

2.8 Guidance notes are to be issued by the Research Office, from time to time, to support the implementation of this Policy.

2.9 This policy adopts the definitions and responsibilities as laid out in the UK Policy Framework for Health and Social Care Research. A Glossary can be found in Appendix 2.

3. Registration and confirmation of capability and capacity for research projects

3.1 All research taking place within the Trust must have approval before any research activity begins. The Trust will only extend NHS Indemnity cover (for negligent harm) to its employees taking part in research studies that have been registered and approved. **The Trust will not accept liability for research that has not been registered and confirmation of capacity and capability has been issued from the Trust's Research office.**

3.2 All research requires a nominated 'Research Sponsor'. All research must have an identified sponsor. The sponsor is the institution that takes overall responsibility for the initiation, financing, management and monitoring of a study.

3.3 For commercially initiated research, the commercial company would be expected to act as research sponsor. Evidence of research sponsorship will be required before Trust approval is granted.

3.4 The Trust may act as Sponsor but this will need to be agreed by the Trust's Research and Development Steering Group. The funding for this activity needs to be identified and agreed in advance of any decision by the Trust to act as Research Sponsor.

3.5 To Trust will ensure that when considering whether or not to support a particular research study at a site there is a detailed consideration of the following:

a) **Strategy**: Determine study contribution to the Trust Strategic objectives.
b) **Assess**: Assessing whether or not the NHS organisation has the capacity and capability to participate in the study.
c) **Review**: Identify studies that are considered to be a significant risk to the Trust (in particular studies that are not 'cost neutral' or have special requirements that necessitate senior management team review) and be satisfied that the measures taken to mitigate the risk are acceptable and are included in the final confirmation from the Trust.
d) **Arrange**: Assessing that practical arrangements can be put in place to provide the capacity and capability to deliver the study.
e) **Confirm:** Confirming that the Trust has the capacity and capability in place to deliver the study and that it will deliver the study to time and target.

3.6 Detailed Guidance notes are available from the Research Office and also via the Trust's internet.

4. Ethical Practice

4.1 The dignity, rights, safety and wellbeing of participants must be the primary consideration in any research study. Research involving patients, service users, care professionals or volunteers, or their organs, tissue or data must be reviewed independently to ensure it meets ethical standards.

4.2 For all research which falls within the remit of the Governance Arrangements for Research Ethics Committees (GafREC) review from a recognised NHS Research Ethics Committee (REC) is required[2].

4.3 All research at the Trust must be submitted for regulatory review via the Integrated Research Application System (IRAS) https://www.myresearchproject.org.uk/ This is a single system for applying for the permissions and approvals for health and social care / community care research in the UK.

4.4 IRAS captures the information needed for the relevant approvals from the following review bodies:

- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Health Research Authority (HRA) for projects seeking HRA Approval
- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS / HSC Research Offices
- NHS / HSC Research Ethics Committees
- National Offender Management Service
- Social Care Research Ethics Committee

4.5 For many studies informed consent from participants is essential and consent must be sought in the way agreed during ethical review.

4.6 All clinical trials, given a favourable opinion by a Research Ethics Committee (REC) within the Health Departments' Research Ethics Service and currently in active recruitment in the UK, have been registered on a publically accessible register in compliance with existing duties of sponsors and the Health Research Authority (HRA) requirements and extended compliance checks.

5. Grant Applications, Financial management and Costing of Research

5.1 All Research Accounts have to be used in accordance with the Trust's Standing Orders and Standing Financial Instructions. Systems to ensure financial probity are a legal requirement for all projects. Researchers are required to liaise with R&D management to agree costing, budgetary management and workforce requirements of projects prior to commencement. There must be transparency and accountability of all research income and expenditure.

5.2 The Attributing the Costs of Health and Social Care Research and Development[3] provides a framework for the NHS and its partners to identify, attribute and recover the various costs associated with research in the NHS in a transparent, robust and consistent manner.

5.3 The Trust will implement the principles of the NIHR guidance relating to "Income Distribution from NIHR CRN Industry Portfolio Studies[4]".

[2] http://www.hra.nhs.uk/resources/research-legislation-and-governance/governance-arrangements-for-research-ethics-committees/

[3] https://www.gov.uk/government/news/attributing-the-costs-of-health-social-care-research-development-acord

5.4 The research costs of all projects funded via external grant applications, commercial agreements or the internal funding system will be calculated according to a standardised and robust model by the Research Office. This is to ensure that the financial risks to R&D and the Trust can be anticipated and managed.
5.5 Research accounts should always maintain sufficient balance to fund at least six months' worth of expenditure. Accounts that do not meet this requirement will be reported to the R&D Board, accounts that fall into deficit are at risk of closure. Regular meetings with Finance can assist with forward planning and other support. In particular, prompt and accurate collection of agreed income is fundamental to achieving this: it is the Research teams' responsibility to request necessary invoices are raised via Finance.
5.6 Where a Research Account becomes inactive and has not conducted research for two consecutive years, the balance on the account will revert back to R&D to use for ongoing research activity.
5.7 Before a Research team can increase its workforce, a costing from Finance and approval from R&D Management is required.

6. Data Protection

6.1 The Data Protection Act requires that confidential patient data is only accessed by researchers who have obtained ethical and R&D approval for their study and who understand their responsibilities with regard to data protection regulations, particularly ensuring patient anonymity and confidentiality. In some circumstances this may not be possible and within the legal frameworks there are mechanisms to provide exemption to this where consent is not practicable or would be inappropriate, both in relation to confidential patient information and human tissue samples in research. Expert advice is to be sought if legal exemption is required.
6.2 The Trust Data Protection Policy is available for researchers. Researchers are required to have read the guidance and made arrangements for appropriate storage of research documentation. Data will be managed in accordance with the General Data Protection Regulation (GDPR) 2018 previously The Data Protection Act (1998) (See Appendix 2).
6.3 The Trust will ensure that appropriate arrangements are in place to archive data when the research has finished and to make it accessible.

7. Good Clinical Practice (GCP)

7.1 Everyone involved in the conduct of clinical research must have training to ensure they are best prepared to carry out their duties. It is the responsibility of the Principal Investigator to be satisfied that the local research team are trained to deliver the study.
7.2 The principles of GCP state that "*Each individual involved in conducting a trial should be qualified by education, training and experience to perform his or her respective task(s*)".
7.3 The Medicines for Human Use (Clinical Trials) (2004) regulations[5] require that all staff are trained to carry out their duties on each study they are working on. All staff involved in clinical trials of medicinal products (CTIMPS) must complete GCP training, every two years. A refresher course is available for those who have already attended a full introduction to GCP course. GCP training can be accessed as either a taught course or online through e-learning. This training is recommended for all staff completing research though for non-interventional studies that have little risk to patients the requirement for GCP training is recommended but not mandatory with a decision being made by the Principal Investigator.

[4] https://www.crn.nihr.ac.uk/wp-content/uploads/Industry/LCRN%20Guidance%20S12%20-%20Income%20Distirbution%20Model%20Guidance%20v2.0.pdf
[5] http://www.legislation.gov.uk/uksi/2004/1031/pdfs/uksi_20041031_en.pdf

8. Indemnity

8.1 The Trust participates in the NHS risk pooling scheme administered by the NHS Litigation Authority "Clinical Negligence Scheme for NHS Trusts" for medical professional and/or medical malpractice liability, and general liability
8.2 NHS indemnity for negligent harm is extended to researchers with an employment contract (substantive or honorary) with the Trust. The Trust only accepts liability for research activity that has been managerially approved by the Trust.
8.3 For commercial Clinical Trials of Investigative Medicinal Product (CTIMP) studies, commercial companies will be expected to provide cover for negligent and non-negligent harm under the standard Clinical Trial Compensation Guidelines recommended by the Association of the British Pharmaceutical Industry. This should be clearly outlined in the Clinical Trial Agreement.

9. Commercial and Non-Commercial Partner organisations and the use of model contracts / agreements

9.1 For commercial CTIMPs or commercial studies involving medical devices the Trust expects that commercial companies will use the national model Clinical Trial Agreements[6] for pharmaceutical companies working with the NHS.
9.2 When the Trust conducts research with involving non-commercial partner organisations the allocation of responsibilities should be clearly documented.
9.3 For non-commercial studies and where agreements are required, the Trust expects that other non-commercial partners will use the national model Non-Commercial Agreement[7] which will be superceded by a revised version to be issued by the Health Research Authority.

10. Research Personnel

10.1 The safety of research participants and research staff must be given priority at all times.
10.2 The Health and Safety Regulations and Trust policies or employing organisation's Health and Safety policies must be strictly observed during the course of the research. This is particularly important if the research involves the use of potentially dangerous or harmful equipment, substances or organisms.
10.3 It is the responsibility of the Chief Investigator or Principal Investigator at each site, to ensure staff have the necessary contracts or letters of access in place before staff begin research work within the Trust. Researchers not employed by any NHS organisation who interact with research participants in a way that has a direct bearing on the quality of their care should hold an NHS Honorary Research Contract or Letter of Access[8]. Other arrangements will be made for non-NHS staff where their research does not have a bearing on the quality of patient care.
10.4 All research support staff, including those funded by Trust Departments, are to be managed as a single coherent team working to support the strategic and operational objectives of the Trust.
10.5 Staff employed to support research may need to be flexible and provide support where appropriate, and as needed, across the Trust or site or department.
10.6 For research undertaken by a student(s) in fulfilment of educational qualifications below doctoral level, the academic supervisor will take on the role of Chief Investigator.
10.7 It is normally expected that a doctoral student undertaking a project will be named as the Chief Investigator rather than the academic supervisor. However, in some cases it may be more appropriate for a clinical supervisor to take on the role of Chief Investigator for a project undertaken by a doctoral student.

[6] http://www.nihr.ac.uk/industry/industry-tools.htm
[7] http://www.ukcrc.org/regulation-governance/model-agreements/
[8] http://www.nihr.ac.uk/policy-and-standards/research-passports.htm

Decisions relating to the suitability of the student to act as Chief Investigator can be made by the Associate Director Research and Development or R&D Clinical Lead.

11. Peer Review

11.1 All projects where the Trust is Sponsor will require appropriate peer review that is independent i.e. no conflicts of interest, expert, in terms of understanding of the clinical and research methodologies and outcomes and recorded.
11.2 All non-commercial research that is externally Sponsored and funded via grants from research councils or major charities will have already been subject to peer review.
11.3 For commercially sponsored projects, it is the responsibility of the commercial sponsor to arrange peer review.
11.4 For non-doctoral student projects, peer review by the individual's supervisor should normally be adequate.

12. Project Management

12.1 The Principal Investigator for each project is responsible for efficient and ethical management of all aspects of the project and is required to ensure all trial documentation is in order and available for internal and external audit and inspection.
12.2 It is the responsibility of the Principal Investigator to inform the Research Office when a study has ended. The definition of end of trial or study should be included in the study protocol.

13. Medical Devices

13.1 The use of Medical Devices in research is to be consistent with other Trust Policies. Further guidance available from the Research Office.

14. Fraud and Misconduct in Research

14.1 The Trust is committed to maintaining the integrity and probity of research undertaken in the Trust and will thoroughly investigate any allegations of misconduct in research made against employees of the Trust.

15. Involving Consumers in Research

15.1 The Consumers in NHS Research Group recommends that major advisory bodies in NHS R&D programmes should have at least two consumer representatives.
15.2 The R&D Office is actively encouraging researchers in the Trusts to involve consumers wherever it is appropriate.

16. Intellectual Property Rights

16.1 All projects are reviewed to consider the potential intellectual property rights before ethical approval is given.
16.2 The IP Policy outlines the principles of IP Management in the Trust and identifies an IP Lead.

17. Publication of Research

17.1 When established, findings (including negative findings) should be published in a way that allows critical review and dissemination through the accepted scientific and professional

channels. Findings must be made accessible to those participating in research and to those who could benefit from them.

17.2 The Trust will actively support and encourage dissemination of research findings at local, regional, national and international meetings.

18. Monitoring and Effectiveness

18.1 The effectiveness will be monitored through the following:

- Project review
- Annual R&D review
- Audit plans for Trust Sponsored projects
- Annual Report submitted to the Trust Board
- Involvement in external/internal audit/inspection.

Appendix 1: UK Policy Framework for Health and Social Care Glossary

The UK Policy framework for health and social care research sets out principles of good practice in the management and conduct of health and social care research that take appropriate account of legal requirements and other standards. These principles protect and promote the interests of patients, services users and the public in health and social care research, by describing ethical conduct and proportionate, assurance-based management of health and social care research, so as to support and facilitate high-quality research in the UK that has the confidence of patients, service users and the public.

The UK Policy Framework for Health and Social is available via the Health Research Authority website http://www.hra.nhs.uk/

Glossary

chief investigator	The overall lead researcher for a research project. Has responsibility for its overall conduct.
employer	The body or bodies that employ the investigators and research teams for a research project.
funder	The body or bodies that fund a research project.
health research	Any research into matters relating to people's physical or mental health. Excludes anything authorised under the Animals (Scientific Procedures) Act 1986).
interventional research	Research involving a change in treatment, care or other services made for the purpose of the research. Does not refer to research involving other methodological 'interventions', e.g. issuing a postal survey.
patients and service users	Recipients of health care, social care or other services or support provided by or on behalf of health or social care organisations, such as NHS patients and social care service users. Includes people receiving integrated health and social care, e.g. Health and Social Care (HSC) users in Northern Ireland. Excludes children's social care service users in England and Scotland.
principal investigator	The lead researcher for a research project at a particular site. Has responsibility for the conduct of the project at that site.
the public	The general public. Includes carers, relatives of patients and service users and healthy volunteers.
public involvement	Working in collaboration with patients, service users or the public in the design, management, conduct or dissemination of research.
research	The attempt to derive generalisable or transferable new knowledge
research site	The organisation with day-to-day responsibility for the location where a research project is carried out.
research team	The people involved in the conduct of a research project. There may be different research teams for the project at different sites.
should	We use 'should' for expectations we regard as minimum good practice, but for which there is no specific legal requirement.
social care research	Any research into matters relating to personal care or other practical assistance for individuals (in England and Scotland, specifically individuals aged 18 or over) who are in need of care or assistance because of age, physical or mental illness, disability, pregnancy, childbirth, dependence on alcohol or drugs or other similar circumstances.
sponsor	The organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

APPENDIX 2: Implementing the General Data Protection Regulation (GDPR) 2018 previously The Data Protection Act (1998)

Requirements under the General Data Protection Regulation

East & North Hertfordshire NHS Trust expects staff to maintain strict confidentiality in respect of personal data held in paper or electronic format. Everyone is under a legal duty under the General Data Protection Regulation to keep personal information secure and confidential, and to ensure there are no inaccuracies in data held about an individual. It is therefore essential that records about employees comply with these standards. Staff are entitled to have access to their personal records, and these guidelines give information to line managers on how to respond to such a request.

Timescale for retention of employee records

Minor records of the sort that would normally be held in the departmental file should normally be retained for at least two years. Thereafter they may be destroyed under confidential conditions, unless the manager considers there is a particular reason why they should be retained for longer. The content of the personal file should be reviewed from time to time, and information that is no longer accurate (for example out-of-date personal contact details) should be destroyed under confidential conditions, so that inaccurate information is not retained on the file.

Inaccuracies in Health records

Credible records are an important aid in providing safe healthcare to patients. Records should reflect the observations, judgements and factual information collected by the contributing health professional. The GDPR requires that information should be accurate and kept up-to-date. This provides the legal basis for enforcing correction of factual inaccuracies. An opinion or judgement recorded by a health professional, whether accurate or not, should not be deleted. Retaining relevant information is essential for understanding the clinical decisions that were made and to audit the quality of care.

However, individuals are entitled to have personal data rectified if it is inaccurate or incomplete. If the personal data is disclosed in question to third parties, you must inform them of the rectification where possible. You must also inform eh individuals about the third party to whom the data has been disclosed where appropriate. The time scale for response to rectification is within one month. This can be expanded to two months where the request for rectification is complex.

Where both parties agree that information is factually inaccurate it should be amended to clearly display the correction whilst ensuring the original information is still legible. An explanation for the correction should also be added.

Where the health professional and patient disagree about the inaccuracy of the entry, the data controller should allow the patient to include a statement within their record to the effect that they disagree with the content.

If the patient is unhappy with the outcomes, there is the option of taking this more formally via the complaints department.

Individual Rights

- “The right to be informed”
- “The right to erasure”
- “The right of rectification”
- “The right to restrict processing”
- “The right to object”
- “The right not to be subject to automated decision-making including profiling”

"The right of rectification" individuals are entitled to have personal data rectified if it is inaccurate or incomplete. If the personal data is disclosed in question to third parties, you must inform them of the rectification where possible. You must also inform the individuals about the third party to whom the data has been disclosed where appropriate. The time scale for response to rectification is within one month. This can be expanded to two months where the request for rectification is complex. Where both parties agree that information is factually inaccurate it should be amended to clearly display the correction whilst ensuring the original information is still legible. An explanation for the correction should also be added.

"The right to be informed" The right to be informed encompasses your obligation to provide 'fair processing information', typically through a privacy notice.It emphasises the need for transparency over how you use personal data. The information you supply about the processing of personal data must be: concise, transparent, intelligible and easily accessible;•written in clear and plain language, particularly if addressed to a child; and free of charge.

'Right of access' Individuals have the right to access their personal data and supplementary information. The right of access allows individuals to be aware of and verify the lawfulness of the processing **(SAR).** The timetable to respond to subject access requests in any event is within one calendar month of receiving it, in either format by email or one sent in hard copy.

"The right to restrict processing" Individuals have a right to 'block' or suppress processing of personal data. When processing is restricted, you are permitted to store the personal data, but not further process it. You can retain just enough information about the individual to ensure that the restriction is respected in future. You will be required to restrict the processing of personal data in the following circumstances: Where an individual contests the accuracy of the personal data, you should restrict the processing until you have verified the accuracy of the personal data. Where an individual has objected to the processing (where it was necessary for the performance of a public interest task or purpose of legitimate interests), and you are considering whether your organisation's legitimate grounds override those of the individual, When processing is unlawful and the individual opposes erasure and requests restriction instead. If you no longer need the personal data but the individual requires the data to establish, exercise or defend a legal claim. If you have disclosed the personal data in question to third parties, you must inform them about the restriction on the processing of the personal data, unless it is impossible or involves disproportionate effort to do so. You must inform individuals when you decide to lift a restriction on processing.

'The right to data portability' the right to data portability allows individuals to obtain and reuse their personal data for their own purposes across different services. It allows them to move copy or transfer personal data easily from one IT environment to another in a safe and secure way, without hindrance to usability.

"The right to object" Individuals have the right to object to processing based on legitimate interests or the performance of a task in the public interest/exercise of official authority (including profiling); direct marketing (including profiling); and processing for purposes of scientific/historical research You must inform individuals of their right to object "at the point of first communication" and in your privacy notice.

This must be "explicitly brought to the attention of the data subject and shall be presented clearly and separately from any other information and statistics. Individuals must have an objection on "grounds relating to his or her particular situation".

"The right not to be subject to automated decision-making including profiling" Individuals have the right not to be subject to a decision when it is based on automated processing; and it produces a legal effect or a similarly significant effect on the individual. You must ensure that individuals are able to obtain human intervention; express their point of view; and obtain an

explanation of the decision and challenge when processing personal data for profiling purposes, you must ensure that appropriate safeguards are in place.it.

"The right to erasure" The right to erasure is also known as 'the right to be forgotten'. The broad principle underpinning this right is to enable an individual to request the deletion or removal of personal data where there is no compelling reason for its continued processing. The right to erasure does not provide an absolute 'right to be forgotten'. Individuals have a right to have personal data erased and to prevent processing in specific circumstances.

- Where the personal data is no longer necessary in relation to the purpose for which it was originally collected/processed.
- When the individual withdraws consent.
- When the individual objects to the processing and there is no overriding legitimate interest for continuing the processing. The personal data was unlawfully processed (i.e. otherwise in breach of the GDPR).
- The personal data has to be erased in order to comply with a legal obligation. The personal data is processed in relation to the offer of information society services to a child.

Under the GDPR, this right is not limited to processing that causes unwarranted and substantial damage or distress. However, if the processing does cause damage or distress, this is likely to make the case for erasure stronger.

'Children' The GDPR contains new provisions intended to enhance the protection of children's personal data. Where services are offered directly to a child, you must ensure that your privacy notice is written in a clear, plain way that a child will understand. If you offer an 'information society service' (i.e. online service) to children, you may need to obtain consent from a parent or guardian to process the child's data. The GDPR states that, if consent is your basis for processing the child's personal data, a child under the age of 16 can't give that consent themselves and instead consent is required from a person holding 'parental responsibility' – but note that it does permit member states to provide for a lower age in law, as long as it is not below 13. 'Information society services' includes most internet services provided at the user's request, normally for remuneration.

The GDPR emphasises that protection is particularly significant where children's personal information is used for the purposes of marketing and creating online profiles.

'Consent' Consent means offering individuals genuine choice and control. Consent requires a positive opt-in.

- Don't use pre-ticked boxes or any other method of consent by default.
- Explicit consent requires a very clear and specific statement of consent.
- Keep your consent requests separate from other terms and conditions.
- Be specific and granular. Vague or blanket consent is not enough. Be clear and concise. Name any third party controllers who will rely on the consent.
- Make it easy for people to withdraw consent and tell them how. Keep evidence of consent – who, when, how, and what you told people.
- Keep consent under review, and refresh it if anything changes. Avoid making consent a precondition of a service. Public authorities and employers will find using consent difficult. Remember – you don't always need consent. If consent is too difficult, look at whether another lawful basis is more appropriate.