NHS
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Research Governance Policy

Author: Head of Research & Development

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Staff Summary

This policy supports the YAS Research Strategy 2024-27
Its purpose is to provide assurance that YAS is compliant with the UK policy framework for health and social care research, and compliant with guidance issued by the National Institute for Health Research and the Health Research Authority
It outlines the remit and responsibilities of YAS as a sponsor of research
It outlines to the duties and responsibilities for YAS staff in the delivery of research
The policy describes how YAS will ensure compliance with good clinical (research) practice
The policy describes how compliance with the policy will be monitored
The process for managing fraud and misconduct in research is described
The process for identifying and resolving research incidents is described

1.0 Introduction

1.1 Research and Development is central to the vision of the Yorkshire Ambulance Service NHS Trust (YAS), which is to be trusted as the best urgent and emergency care provider, with the best people and partnerships, delivering the best outcomes for patients.

1.2 YAS has implemented this Research Governance Policy to support the organisation's Clinical Governance Group, Research Institute Steering Group and Executive Medical Director in maintaining and further developing clinical excellence. It provides the Trust Board with assurance that the organisation is maintaining compliance with the principles and responsibilities within the UK policy framework for health and social care research[1], is acting in compliance with national operational policies and guidance from the National Institute for Health Research (NIHR) and the Health Research Authority (HRA); acts in compliance with General Data Protection Regulation (GDPR); and meeting research-specific requirements within the Care Act 2014.

1.3 YAS supports the NHS Constitution statement that the NHS is committed to the promotion and conduct of research.

2.0 Purpose/Scope

2.1 The purpose of this policy is to support the YAS vision and ambitions for research: Vision for 2027: Increasing opportunities for our ambulance service staff, patients and communities to participate in high quality research that improves the out-of-hospital emergency, urgent and non-emergency care we provide.

2.2 Ambitions:

- Setting the direction
- Being a trusted institute
- Creating impact

2.3 The YAS research strategy outlines the key objectives to lead and deliver impactful high-quality research.

2.4 The key objectives of this research governance policy are:

- To provide proportionate yet robust risk management and governance of research activity taking place within YAS, conducted by YAS staff, or involving YAS patients and their data.

[1] Maintained online by the Health Research Authority at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

- To provide a source of advice, guidance and support for YAS staff relating to research activity to support their participation in research were agreed by their managers and following applicable YAS policies and processes.
- To ensure that all research activity (including amendments to current research), is assessed, arranged and confirmed by the delegated individual(s) or groups within YAS; and that local or national approvals are in place prior to initiation of each study according to the responsibilities designated in the UK policy framework for health and social care research.
- To describe the infrastructure and process by which YAS receives assurance to declare full compliance with the principles of good research management described in the UK policy framework for health and social care research.
- To ensure that research activity is carried out in line with the principles of good practice in research management and conduct by providing a risk-based programme of routine and random monitoring and audit.
- To ensure income and expenditure related to research is appropriately managed in compliance with YAS financial policy and process.
- To ensure that the conduct, management and financial planning of any particular study which is sponsored by YAS is robustly assessed for risk

2.5 This policy applies to any activity within the YAS health care system meeting the definition of 'research' as described in the UK policy framework for health and social care research. Research is defined as:
'The attempt to derive generalisable or transferable[2] new[3] knowledge to answer or refine relevant questions with scientifically sound methods. 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 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.'

2.6 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 within the scope of this policy.

2.7 This research may involve:

- Patients and service users of YAS. This includes all potential research participants recruited by virtue of the patient or user's past or present treatment by, or use of, YAS. It includes YAS patients treated under contracts with private sector institutions.
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the YAS, as defined above.
- Access to data or human tissue material of YAS patients.
- The use of, or potential access to, YAS premises or facilities.
- YAS staff, recruited as research participants by virtue of their professional role.

[2] 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.
[3] Including new knowledge about existing treatments or care

2.8 Where YAS participates in research which is included in the National Institute for Health Research (NIHR) Research Delivery Network (RDN) portfolio of high quality research, YAS will be supported by the NIHR Regional RDN for Yorkshire and Humber and the NIHR who will put in place arrangements for the management and governance of NIHR portfolio research.

2.9 YAS will work within the systems and processes put in place by the NIHR RRDN for Yorkshire and Humber in line with national research strategy, and as agreed in the network partnership agreements.

2.10 YAS will comply with the wishes of patients who have opted-out from having their healthcare data used for research or planning purposes (national data opt-out, https://digital.nhs.uk/services/national-data-opt-out).

2.11 The YAS Intellectual Property Policy also supports the Research Strategy, and Research Governance Policy.

2.12 A centralised register of all research activity and performance data will be maintained by the Research Institute.

2.13 Records will be held by YASRI in compliance with the YAS Records Management Policy. All YASRI documents that form part of a trial master file or site file will be considered essential documents[4], and stored, managed and retained as such (see Appendix A).

2.14 YASRI will ensure that the assessment and management of research is proportional. This policy, its supporting SOPs and working instructions form the Quality Management System for research. Roles and responsibilities for research are described in Appendix B.

3.0 Process

3.1 These processes apply where YAS is a participating site in research (including where YAS staff are grant co-applicants, or where YAS is the sponsor but the only participating site)

3.1.1 Each research study within YAS will start only when study has been assessed by the Research Institute using a standardised, proportionate process that identifies whether the study has the required approvals and, YAS is willing to participate and, has the capacity and capability to participate. The assessment ensures:

- The Managers within YAS whose staff or service are involved in the study have received an assessment of the potential impact of the study and have agreed that participating will not be detrimental to the staff or service affected by study participation.
- Staff involved as researchers have received training appropriate to their role in the research.
- The costs of participation in the research have been identified, and an agreement is in

[4] Essential records are defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use as “the documents and data (and relevant metadata), in any format, associated with a clinical trial that facilitate the ongoing management of the trial and collectively allow the evaluation of the methods used, the factors affecting a trial and the actions taken during the trial conduct to determine the reliability of the trial results produced and the verification that the trial was conducted in accordance with Good Clinical Practice and applicable regulatory requirement.”

place that sets out who is to meet these costs. Where Excess Treatment Costs[5] are identified, Department for Health and Social Care and NIHR guidance is followed and agreement regarding who will bear this cost is in place.

- Roles and responsibilities of individuals involved in the study are agreed and documented, including arrangements for protecting intellectual property.

- Approval is in place covering ethical and legislative requirements, usually from the HRA but may be University ethical approval for single site studies involving staff only. Clinical Trial authorisation will be required for trials involving medicines or devices.

- The study has a 'Sponsor' who has overall responsibility for proportionate, effective arrangements being in place to set up, run and report the study.

- Where researchers require access to YAS premises or patients, letters of access or honorary contracts as appropriate are arranged following good HR practice.

- Confirmation that YAS will participate in the study (previously known as NHS permission) is documented and authorised by the Executive Medical Director or the Head of Research & Development, except where HRA approval confirms this is not required.

3.1.2 YAS will maintain an infrastructure to enable prompt, efficient and proportionate assessment of research capacity and capability.

3.1.3 All research conducted in YAS will have a formal agreement in place between YAS and the sponsor. This may take the form of an Organisation Information Document, a standard modified non-commercial agreement (mNCA) or other mutually agreed contract. Project start dates and targets may need to be negotiated where additional staff or resources must be put in place for a specific project.

3.1.4 The Medicines for Human Use (Clinical Trials) Regulations set out the requirements for the management and storage of any investigational medicinal products (IMPs) within a trial. All IMPs within the Trust must be managed in line with the YAS Medicines Management Policy, and includes accountability, storage, temperature management, monitoring, labelling and compliance with any trial-specific procedures.

3.1.5 Where there is an urgent need for research or a small window of opportunity such as public health emergencies, YAS will co-operate with other relevant parties to enable a study to take place quickly and efficiently, following national guidance.

3.1.6 YAS will monitor the conduct of studies and will co-operate with external monitoring. Research incidents, near misses and incidental findings will be reported through YAS processes in addition to protocol-mandated reporting to trial sponsors. Investigations and learning from incidents will follow usual YAS processes. Incidents and learning will be included in reports to the Research Institute Steering Group and Clinical Governance Group. See appendix D for further details.

3.1.7 Research income and expenditure will be managed via usual YAS processes to ensure financial transparency and probity, and accurate calculation of research costs. NIHR and Department of Health and Social Care income and related activity will be reported as required.

[5] Treatment Costs are the care costs that would continue to be incurred if the patient care service in question continued to be provided following the end of the research study. The difference between the Treatment Costs and the costs of the existing standard treatment is referred to as the Excess Treatment Cost (ETC).

3.1.8 Where a member of YAS staff is the recipient of research funding, but there is no research activity as defined in section 2.7 taking place within YAS, the YASRI will manage and administrate the research funding.

3.1.9 Where research fraud or misconduct is suspected, appropriate, effective action is taken and supported by the Research Institute. See Appendix C for further details.

3.2 These processes apply where YAS is sponsor of research

3.2.1 A research Sponsor is defined as: “An individual, company, institution, organisation or group of organisations that takes on responsibility for initiation, management and financing (or arranging the financing) of the research” (Health Research Authority, 2018). A formal research Sponsor must be assigned for any research under the remit of the Secretary of State for Health and Social Care. This policy applies for all research activity included in section 2.6.

3.2.2 YAS will not act as sponsor for any project that seeks to alter the treatment, care pathway or other services for a patient including Clinical Trials of Investigational Medicinal Products, medical device trials, research using or collecting patient tissue or organs.

3.2.3 YAS may consider entering into co-sponsorship or joint sponsorship arrangements which will be identified on a study-by-study basis with consultation with the Research Institute Steering Group.

3.2.4 YASRI will ensure that YAS has in place adequate insurance and indemnity to cover liabilities which may arise in relation to the design, management and conduct for the duration of the research project.

3.2.5 The employing organisation of a Chief Investigator (CI) is usually the research sponsor, except in the case of research being undertaken as part of an educational qualification but cannot be assumed. Where YAS is approached to be the research sponsor a robust assessment of the risks for sponsorship for each study will be undertaken. A preliminary assessment will be carried out prior to research funding application, with a final assessment of risks and controls completed once funding has been secured which will include:

- Rigour and quality in the design of the project and associated materials including favorable peer review
- Requirements to have in place ethical and research approvals
- Patients experience aspects
- Arrangements for the appropriate attribution and management of intellectual property
- The capacity of YAS to manage any finance, governance and monitoring responsibilities.
- Whether the study is single or multi-site, and the plans for the recruitment of participants
- Skill and resources of the research team, including provision for the collection, management, analysis and storage of research data.
- Conflicts of interest
- Overall study feasibility

3.2.6 Based on the risk assessment, the Research Institute Steering Group (RISG) will review the recommendation of the Head of Research or R&D Manager. RISG will provide a recommendation to Clinical Governance Group and Executive Medical Director to make the final decision on the sponsorship of the project.

3.2.7 Once a project has been approved for YAS sponsorship, the Head of Research will act as the sponsor representative. The Head of Research is responsible for oversight of the quality of all study documentation and applying for appropriate approvals. Research cannot begin in YAS or at any other site until all approvals are in place and the sponsor representative has provided the 'green light' to start.

3.2.8 The CI will agree to their responsibilities in the design, conduct and management of the study. YASRI will assign any sponsored study a performance management plan to monitor the study against planned outputs, where applicable, participant recruitment and compliance with the agreed protocol. Where studies are multi-site YASRI will put in place arrangements for the monitoring of site performance. This will include monitoring the integrity of research data and quality assurance of research outputs.

3.2.9 YASRI will have in place arrangements for the management of any research finances where YAS are the host of the grant

3.2.10 YASRI will have in place arrangements for the management of contracts with other sites or parties involved with research delivery.

3.2.11 YASRI will work with the CI to implement effective processes for incident reporting and corrective and preventive actions (CAPA) at all sites.

3.2.12 YASRI will have in place processes to manage close down activities for all sponsored studies including research data management, dissemination of results and publications, archiving and data destruction.

3.2.13 The Trust retains the right to terminate sponsorship for any of the following reasons:

- Where the CI or other key personnel are no longer employed by YAS
- Patient or public safety
- It is deemed that the study is no longer feasible to deliver
- Data integrity is significantly compromised
- Research fraud, or misconduct
- Lack of equipoise.

4.0 Training expectations for staff

4.1 Staff responsible for research management and governance within YAS will have specific knowledge and training as prescribed in their job descriptions. They will be supported to maintain current knowledge of national and regional policies and guidance to enable YAS to meet its responsibilities.

4.2 Staff acting as researchers within clinical trials[6] must complete trial-specific training as required by the study Chief Investigator or Sponsor. For staff with specific responsibilities over and above duties that are considered normal within their role, this may include 'Good Clinical Practice' (GCP) training which is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. This applies to staff who may be acting as Principal investigator or a co-investigator on any research project. The sponsor has overall

[6] A clinical trial is a set of medical research procedures conducted on human participants to allow safety and adverse effects of interventions, their efficacy, or their effectiveness to be established often by comparison with alternative or placebo/sham interventions. Interventions may be drugs, diagnostics, prophylactics, surgery, devices, non-invasive therapies, screening or other healthcare procedures or technologies.

responsibility for ensuring that PIs and/or co-investigators have suitable training or experience to undertake their role for the trial or study.

4.3 Staff acting as Chief Investigators (in overall charge of a study) must ensure that everyone involved in conducting clinical research is qualified by education, training, and experience to perform their respective tasks.

4.4 YASRI will support and advise YAS staff regarding required training for each research study and provide details of available training.

4.5 YASRI will maintain records of GCP training, and alert staff when refresher training is required, which is set at a minimum of every two years.

4.6 YAS staff should be made aware of the requirement to seek guidance from those with responsibility for the governance of research before any research can be carried out within the Trust.

5.0 Implementation Plan

5.1 The implementation of this policy may require training, familiarisation or change of practice dependent upon the needs of those individuals or groups to which it bears relevance. Such requirements will be provided accordingly and will be implemented by a mutually agreed schedule with all parties concerned according to the available resources that the Trust has at its disposal. Any further amendment to this policy that may effect change will be addressed in the same manner.

5.2 The latest approved version of this Policy will be posted on the Trust Intranet site for all members of staff to view. New members of staff will be signposted to how to find and access this guidance during Trust Induction.

5.3 A suite of Standard Operating Procedures and working instructions for individual research studies are available that enable the implementation of this policy. This policy together with SOPs and working instructions form the Quality Management System for Research.

6.0 Monitoring compliance with this Policy

6.1 Monitoring of this policy will be the responsibility of the Clinical Governance Group, who will receive reports and audits from the YASRI to inform and assure the Trust. Reports and audits will be produced at least annually and will cover key elements of this policy.

7.0 Reference

7.1 Legislation

- Care Act 2014 Section 111(7)
- The Equality Act 2010 (Statutory Duties) Regulations 2011
- The Public Records Act 1958
- Medicines for Human Use (Clinical Trials) Regulations 2004

The Equality and Human Rights Commission website provides further guidance, updates and resources in relation to equality impact assessments and the effect of the Equality Act 2010: www.equalityhumanrights.com

7.2 Guidance from Other Organisations

- UK policy framework for health and social care research is maintained online by the Health Research Authority at https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- NHS Constitution
- International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use. Good Clinical Practice E6(R3). 2023.
- NHS England. Records Management Code of Practice. NHS Transformation Directorate. 2023. https://transform.england.nhs.uk/information-governance/guidance/records-management-code/records-management-code-of-practice/. Accessed 23 May 2024.

7.3 Fraud and Misconduct

- Code of Practice for Research: Promoting good practice and preventing misconduct (UK Research Integrity Office, June 2023).

8.0 Appendices

8.1 This Policy includes the following appendices:

Appendix A: Retention of research records.
Appendix B: Roles and responsibilities
Appendix C: Fraud and Misconduct in Research
Appendix D: Research incidents and complaints

Appendix A: Retention of research records.

Records will be held by YASRI in compliance with the YAS Records Management Policy. There are additional minimum retention periods that are required for certain records, which are outlined below. Unless specifically identified in these tables, the standard minimum retention period will be 2 years from the 31st December of the year that the record was created or ceases to be considered active.

Table 1: Retention periods for records and data directly relating to the Research Institute management, or where the Research Institute is the Sponsor of the research study

Note: Unless otherwise specified in the notes section, the 'clock start' time, i.e. the time at which the minimum retention period duration commences, coincides with the study end date or publication of the final report, whichever occurs last.

Record type	**Minimum Retention period**	**Archive Date**	**Disposal**	**Notes**
Trial master file of advanced therapy	20 years	2 years	Review and consider transfer to PoD. Destroy if no longer required.	
Clinical trial master files where clinical trial data are used to support a marketing authorisation	15 years or 2 years after the granting of the last marketing authorisation in the European Union	2 years	Review and consider transfer to PoD. Destroy if no longer required.	
Trial master file for CTIMP (adults)	15 years	2 years	Review and consider transfer to PoD. Destroy if no longer required.	
Trial master file for CTIMP (children)	15 years or 3 years after the youngest participant reaches 18 years of age, whichever is longer	2 years	Review and consider transfer to PoD. Destroy if no longer required.	
Trial master file for IIT	Follow retention periods for CTIMP, non-CTIMP studies unless longer time-period specified in commercial partner contract.	2 years	Review and consider transfer to PoD. Destroy if no longer required	
Trial master file for Non-CTIMP interventional studies requiring ethical approval	10 years	2 years after closure of study or published date of final report or publication, whichever is longer	Review and consider transfer to PoD. Destroy if no longer required	This includes post-graduate research receiving university ethical approval.
Trial master file for Non-CTIMP **non-interventional** studies which may or may not require ethical approval	5 years	2 years after closure of study or published date of final report or publication, whichever is longer	Review and consider transfer to PoD. Destroy if no longer required	
Data for a research study or clinical audit that can be re-produced using	2 years	N/A	Review and destroy if no longer required	Clock start: Date data supplied to research team

existing code and data warehouse access				
Data that cannot be re-produced using existing code and data warehouse access	Retention period same as for study itself	2 years after closure of study or published date of final report or publication, whichever is longer	Review and destroy if no longer required	This would typically relate to data that required manual case review for example.
Research data used to screen or derive final datasets	2 years		Review and destroy if no longer required	
Linkage identifiers for existing research databases	Lifetime of the research database + 5 years	2 years	Review and destroy if no longer required	The retention of linkage identifiers should be reviewed every 3 to 5 years, coinciding with renewal of ethical approvals for the research database.
Research Enquiries that do not result in research activity	2 years	N/A	Review and destroy if no longer required	
Anonymised routine data for scoping queries/clinical audits/ service evaluations that cannot be re-produced using existing code and data warehouse access	5 years	2 years	Review and destroy if no longer required	Clock start: Publication date of associated final report
YASRI quality assurance records	12 years	2 years	Review and consider transfer to PoD.	Clock start: 31st December of the year the record relates to.
Research specific SOPs and policies not held centrally by the Trust	Life of organisation + 6 years	On date superseded	Review and consider transfer to PoD.	Clock start: Document approval date until superseded. If the retention period reaches 20 years from the date of approval, then consider transfer to PoD.
All other documents including copies of emails that do not fall within other categories or are held centrally by the Trust e.g. FOI requests, policies, strategies	2 years	N/A	Review and destroy if no longer required	Clock start: 31st December of the year document relates to or when document ceases to be considered active e.g. is superseded.
Unsuccessful grant applications	3 years	2 years	Review and destroy if no longer required	Unsuccessful applications may be reworked for future applications and/or provide useful feedback for unrelated applications to the same funder.

Table 2: Retention periods for research where the Research Institute is **not** the Sponsor

Note: Unless otherwise specified in the notes section, the 'clock start' time, i.e. the time at which the minimum retention period duration commences, coincides with the closure of the study or publication of the final report, whichever occurs last.

Record type	**Minimum Retention period**	**Archive Date**	**Disposal**	**Notes**
Site file of advanced therapy	As specified by study protocol	2 years after closure of study	Review and destroy if no longer required.	
Site files where clinical trial data are used to support a marketing authorisation	As specified by study protocol	2 years after closure of study	Review and destroy if no longer required.	
Site file for CTIMP (adults)	As specified by study protocol	2 years after closure of study	Review and destroy if no longer required.	
Trial master file for CTIMP (children)	As specified by study protocol	2 years after closure of study	Review and destroy if no longer required.	
Site file for IIT	As specified by study protocol	2 years after closure of study	Review and destroy if no longer required.	
Site file for Non-CTIMP interventional studies requiring ethical approval	As specified by study protocol	2 years after closure of study		This includes post-graduate research receiving university ethical approval.
Site file for Non-CTIMP **non-interventional** studies which may or may not require ethical approval	As specified by study protocol	2 years after closure of study		
Data for a research study or clinical audit that can be re-produced using existing code and data warehouse access	2 years	N/A	Review and destroy if no longer required	Clock start: Date data supplied to research team
Data that cannot be re-produced using existing code and data warehouse access	As specified by study protocol or 5 years, whichever longer	2 years		Clock start: Closure of study This would typically relate to data that required manual case review for example.
Research data used to screen or derive final datasets	2 years			Clock start: Closure of study
Site file for Undergraduate research studies	2 years		Review and destroy if no longer required	Clock start: Graduation date

Local YASRI copies of records that are held centrally by the Trust e.g. data protection impact assessments, policies, and are therefore retained in compliance with the Trust's Records Management Policy [1], will only be kept for 2 years unless identified in the table above as requiring a longer minimum retention period.

The Public Records Act 1958 requires organisations to select records for permanent preservation. However, it is designed to permanently preserve only a small proportion (2–5%) of key records. While this may include research-related records (for example research relating to rare conditions), records should not be transferred for the sole reason that they relate to research activity [2]. If research conducted by YASRI is thought to be eligible for permanent preservation and therefore transferred to a place of deposit (PoD), this will be undertaken by a process that has been agreed by the information governance lead for the Trust.

Essential records are defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use as “the documents and data (and relevant metadata), in any format, associated with a clinical trial that facilitate the ongoing management of the trial and collectively allow the evaluation of the methods used, the factors affecting a trial and the actions taken during the trial conduct to determine the reliability of the trial results produced and the verification that the trial was conducted in accordance with Good Clinical Practice and applicable regulatory requirement.” To operationalise this definition, all YASRI documents that form part of a trial master file or site file will be considered essential documents (whether the research study relates to pharmaceuticals or not) and the minimum retention times outlined above will apply.

Before any records are destroyed, a check should be made to ensure that they are not likely to be required for a public or statutory inquiry. If there is any doubt regarding records that may or may not be of use for an inquiry, they must be retained until there is clear instruction from the inquiry.

Once records are believed to be ready for destruction, the process of records disposal laid out in the Trust records management policy should be followed. In summary, an Authorisation for Destruction of YAS Records form should be requested from the Information Governance (IG) team. This form needs to be authorised by the Executive Medical Director or Associate Medical Director for YASRI records. If the records are physical and held off-site by a Trust-appointed storage contractor, IG will co-ordinate with the contractor to arrange destruction of the records. For clinical research that is not sponsored by YASRI, the data retention timeframes should be specified by the sponsor and/or clinical trial team in the study protocol. Where a specific retention date has not been specified, this should be clarified with the sponsor or clinical trial team.

Appendix B: Roles and responsibilities

Trust Board and Chief Executive

The Trust Board and Chief Executive will encourage a high-quality research culture, and ensure researchers understand and discharge their responsibilities. They should promote opportunities to take part in health care research, retain responsibility for the care of patients and service users as research participants, and have regard to the UK policy framework for health and social care research according to their legal duty under section 111(7) of the Care Act 2014.

The Trust Board and Chief Executive will assure themselves that national laws and guidance relating to research within YAS are appropriately applied; and that research activity is appropriately assessed, agreed and managed in a way that reduces risk to patients, participants and to YAS, while enabling high quality research to take place.

The Trust Board will receive annual reports from the Executive Medical Director via the Clinical Governance Group providing assurance regarding research conduct, sufficient to declare compliance with applicable external assessment regimes.

Duties and responsibilities of organisations that provide care, employ researchers or sponsor research are set out in the UK policy framework for health and social care, and reflected in this policy.

Executive Medical Director

The Chief Executive has delegated responsibility for research activity within YAS to the Executive Medical Director.

The Executive Medical Director will put in place and maintain the infrastructure required to deliver this responsibility to the standards required, including where YAS agrees to fund and/or sponsor[7] the research.

The Executive Medical Director will put systems in place to ensure:

- Promotion of a high- quality research culture.
- Researchers understand and discharge their responsibilities.
- Individual researchers have appropriate knowledge and competence.
- Studies are properly designed and have been or are submitted for independent, expert peer review commensurate with the size and complexity of the study; have taken account of patient, service user and public involvement.
- Studies are managed, monitored and reported as agreed, according to the research protocol.
- Good HR practice is followed, including that written procedures, training and supervision are provided.
- Action is taken if misconduct or fraud is suspected or in the event of errors and breaches.
- Effective financial management.
- Appropriate research data management including storage, archiving and destruction.

[7] A sponsor is the organisation (or individual) taking responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study. The sponsor is often, but does not have to be, the employer of the Chief Investigator.

Additionally, where YAS agrees to sponsor the research, the Executive Medical Director will put systems in place to:

Confirm that regulatory and practical arrangements are in place ready for the research to begin:

- Having the authority to approve YAS sponsorship of research.
- Take on responsibility for putting in place and keeping in place arrangements to initiate, manage and fund the study.
- Satisfy themselves that the investigators, research team and research sites are suitable; Ensure appropriate arrangements for registration, accessibility and dissemination of research; Ensure the study has research ethics committee approval, or Health Research Authority approval where required, and any other relevant approval, before it begins.
    - For clinical trials involving medicines[8], seek a clinical trial authorisation and making arrangements for investigational medicinal products. The sponsor should meet their legal duties for these studies[9].
- Satisfy themselves arrangements are kept in place for good practice in conducting the study, and for monitoring and reporting, including prompt reporting of suspected unexpected serious adverse events or reaction.
- Ensure adequate arrangements for finance and managements of the project.
- Ensure that the research does not discriminate against participants or staff on account of any protected characteristics described under The Equality Act (2010). Ensure that the research does not impact on the safety or wellbeing of staff.
- Ensure adequate provision for insurance or indemnity.
- Ensure roles and responsibilities are agreed and documented.

Where YAS agrees to fund the research, the Executive Medical Director will put systems in place to:

- Assess the scientific quality of the research as proposed, including obtaining independent, expert and proportionate peer review.
- Establish the value for money of the research as proposed.
- Involving patients, service users and the public where appropriate in funding decisions.
- Consider the suitability of the research environment in which the research will be undertaken, particularly the experience and expertise of the chief investigator, principal investigator(s) and other key researchers involved.
- Ensure that attribution of costs have been described and agreed and that funding is conditional on a sponsor and relevant approvals being in place before research commences.

Where YAS is a participating research site[10] the Executive Medical Director will put systems in place to ensure:

- Approval bodies can be confident that the location and/or setting is suitable for the research;

[8] The Medicines for Human Use (Clinical Trials) Regulations 2004 specify the responsibilities that have to be undertaken by or on behalf of sponsors of trials involving medicines.
[9] Sponsors of clinical trials of investigational medicinal products have particular legal duties – see www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/ for details.
[10] Research sites are the organisations with day-to-day responsibility for the locations where a research project is carried out. In health and social care research, they are often providers of health or social care and/or the employer of members of the research team.

- There is no duplication of checks or assessments made by the HRA, and that YAS can promptly, efficiently and proportionately assess their ability to take part in a project;
- Participation in student research, which is not assessed by the HRA, can be assessed and confirmed by the Executive Medical Director or Head of Research;
- Information about capacity and capability to support different types of research is available;

For research, which is part of the NIHR RDN portfolio, and has been assessed as of high quality, peer reviewed, and with appropriate financial support in place, the Executive Medical Director will assure him/her self that systems put in place by NIHR RDN and the Health Research Authority have appropriately assessed risks, to YAS to participate in the research. Once satisfied, the Executive Medical Director or the Head of Research will formally confirm participation in the research within the timescale agreed with NIHR and Health Research Authority.

Authority to confirm YAS participation in research is reserved to the Executive Medical Director or Head of Research, subject to assurance having been provided of robust risk assessment according to standard procedures.

Clinical Governance Group
The Clinical Governance Group (CGG) will support the Executive Medical Director in the governance of research activity, specifically:

- Ensure that research activity in YAS is managed and monitored according to applicable laws, policy, and guidance.
- Oversee strategies developed by the YAS Research Department to support research activity in YAS, contributing to the continued development of YAS.
- Approve and provide annual reports to the Quality Committee including information on staff qualified to work on CTIMPs[11];
- Approve plans for the distribution of any commercial income related to research or innovation, which are underpinned by the NIHR CRN: Yorkshire and Humber commercial income policy.
- Ratify and oversee the implementation of the work programme of the YAS Research Department in relation to the research strategy.
- Having the authority to approve YAS sponsorship or co-sponsorship of research.
- Monitoring and assuring the work of the YAS Research Department.
- Receiving regular reports of research activity and governance from the YAS Research Department.

Head of Research/ Research & Development Manager
The responsibilities of the Head of Research and the Research & Development Manager are:

- Promoting and facilitating the delivery of high quality R&D activity across the Trust.
- The implementation of national R&D strategy.
- The maintenance of Research Governance standards and compliance with other statutory obligations.

[11] Clinical Trial of an Investigational Medicinal Product in Human Subjects (Clinical Trials Regulations 2006) more commonly known as ‘drug trial’ or ‘clinical trial’.

- To maintain a record of all research being undertaken within or through YAS (including research that students undertake as part of their training). This also includes studies approved by HRA where YAS is not required to confirm participation.
- To maintain a database of YAS staff qualified to work on CTIMPs.
- Assess enquiries and applications to determine whether they fit the scope of this policy (fit the definition of 'research'), and where appropriate, forward enquiries to the Patient Relations Manager, Clinical Effectiveness Manager or others as appropriate.
- Provide consistent standard recommendations to the Executive Medical Director or Head of Research to approve or reject participation in research based on proportionate assessment processes, accepting reliable assurance from others e.g. sponsors, employers, ethics committees, the HRA, the Medicines and Healthcare products Regulatory Agency (MHRA).
- Provide consistent standard recommendations to the Executive Medical Director or Head of Research to confirm continued participation in (previously approved) research where the study has been amended or timescales have been extended.
- Provide expedited confirmation of participation in urgent public health studies, where HRA has confirmed that the study has approval and should be exempt from usual NHS Trust processes.
- Assess, with the Research Institute Steering Group, all research where the researcher is requesting YAS to accept sponsor responsibilities, for compliance with standards of research design and conduct, and provide consistent standard recommendations to the Research Institute Steering Group and Clinical Governance Group or the Executive Medical Director to approve or reject sponsorship of the research.
- Assess all research for resource and capacity implications. Where identified, ensure all such implications are fully funded and can be delivered without adversely impacting trust performance or patient care, and receive the explicit support of the relevant manager or budget holder. Budget holders may support research where the resource implications are minimal and the potential benefit to patients or staff outweigh this.
- Assess, with the YAS research data analysts and if appropriate the YAS Business Intelligence (BI) and Clinical Information Analytics teams, all research for feasibility of access to YAS data, including patient data.
- Work closely with the YAS Information Governance team to ensure that software licencing agreements support the use of YAS data for research, and that data is appropriately and adequately protected during processing and transfer.
- Assess all research for patient experience components. Where these are identified, notify the Patient Relations team and take advice regarding compliance with YAS policy.
- Work with local collaborators, principal investigators, chief investigators (where projects are sponsored by YAS) to robustly assess and manage risk.
- The delivery of the Trust's R&D reporting requirements to external bodies as required and including Quality Accounts.
- Take action regarding allegations of research fraud or misconduct[12], in accordance with relevant YAS policies and procedures.
- Maintain a risk based programme of monitoring and audit of research conducted within YAS. Audits will include checking key principles within the UK policy framework for health and social care, and utilising findings from MHRA GCP inspections where applicable.

[12] See appendix C: Fraud and misconduct in research.

- Maintain a system to ensure intellectual property arising from research is identified, protected and exploited appropriately.
- Reporting against and publishing performance in initiating and delivering clinical research any performance measures as contractually obliged by the NIHR or DHSC.
- Reporting recruitment and performance data for studies included in the NIHR RDN portfolio.
- Plan for the distribution of commercial income related to research or innovation.
- Support the dissemination of research findings at the conclusion of projects, in compliance with any applicable regulatory standards, using the HRA summary if applicable.

Research Institute Steering Group
The members of the Research Institute Steering Group are responsible for the oversight of all research and development activity. Responsibilities are outlined in the Terms of Reference. These are:

- To develop and monitor the implementation of the Research Strategy and its supporting implementation plans relating to research governance, research training and research communications and engagement, implementation plans for the creation of an Academic Research Unit, including regular monitoring of key performance indicators.

- To monitor and review individual research projects that are underway to assist in performance management. This will include NIHR portfolio and non-portfolio e.g. student projects. To maintain oversight of all research projects in development and in-set up phase.

- To regularly review links with local and national NHS and Department of Health and Social Care systems and ensure adequate YAS involvement in research collaborations e.g. Yorkshire and Humber Applied Research Collaborative.

- To oversee the development and management of local Memorandum of Understanding agreements with partners.

- To promote developments which improve the equity of access for research participation for YAS patients and the public, with consideration of Black, and Minority Ethnic (BAME) participants and those in under-represented groups.

- To support the development and clarification of research priority topics.

- To develop plans for decision making processes and procedures for the allocation of Research Capability Funding support and monitor the use of Research Capability Funding within the Trust and any partners.

- To have oversight of research budgets

- To support the development of research staff capacity and capability to undertake and lead research

- To support the planning for the implementation of research findings from YAS-lead projects

YAS Staff
The responsibilities of all staff are:

- To be aware that all research activity is subject to national and local laws, policies and guidance; in particular that all research in YAS or involving YAS staff or patients requires prior approval from a Research Ethics Committee and confirmation from the trust.
- To seek guidance from those with responsibility for the governance of research (as listed above) where appropriate, and
- To ensure that any research activity in which they are researchers and/or participants has the required prior authorisations as above and also has the knowledge and support of their immediate manager(s).

YAS staff who are Chief Investigators / Principal Investigators / Researchers
YAS staff who are Chief Investigators / Principal Investigators / Local Collaborators / Researchers[13] have specific duties and responsibilities under the UK policy framework for health and social care research. The R&D team will provide advice to support YAS researchers.

[13] For details of the roles and responsibilities of Chief Investigators and Principal Investigators see here: https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/ and https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

Appendix C: Fraud and Misconduct in Research

This process supports existing YAS policies relating to countering fraud and misconduct and:

- Defines research fraud and misconduct.
- Indicates how to avoid unintentional research fraud or misconduct.
- Advises on additional actions specific to research fraud or misconduct.
- Advises staff what to do if they suspect research fraud or misconduct.
- Lists sources of advice and guidance, and
- Lists YAS policies and processes which apply to alleged or actual research fraud or misconduct.

What is research fraud or misconduct?

Research fraud or misconduct includes, but is not limited to:

- Fabrication.
- Falsification.
- Misrepresentation of data and/or interests and/or involvement.
- Plagiarism.
- Failure to obtain approvals as necessary.
- Failure to follow accepted procedures or to exercise due care in avoiding unreasonable risk or harm to humans, the environment, or animals used in research.
- Failure in proper handling of privileged or private information on individuals collected during the research.

YAS recognises that research fraud and misconduct may be deliberate and possibly malicious, or unintentional and not malicious, possibly as a result of carelessness, ignorance or lack of critical awareness.

Allegations of possible research fraud and misconduct may arise from audit and monitoring of research activity, concerns raised by YAS staff, or concerns raised by external partners (e.g. research networks, Higher Educational Institutions, ethics committees, or manufacturers of drugs or devices).

Allegations of possible research fraud or misconduct should be reported to the Head of Research or the Executive Medical Director, who will advise managers regarding immediate safety measures, and requirements for reporting to external organisations. This may include professional bodies, research ethics committees, Higher Education Institutions, and research sponsor organisations. Where YAS is the sponsor organisation, allegations must be raised against the Executive Medical Director who may refer to any appropriate other Trust Director if any potential conflicts of interest are raised.

Investigations and any necessary further actions will be conducted according to the YAS Disciplinary Policy & Procedure, the Local Counter Fraud, Bribery and Corruption Policy, or professional misconduct policies as appropriate.

Actions specific to research fraud or misconduct

The Head of Research or the Executive Medical Director should be advised of allegations of research fraud or misconduct.

The Head of Research or the Executive Medical Director will advise the investigating manager where there is a need to take immediate steps to protect patient or staff safety, including the welfare, rights and dignity of the participants.

The Head of Research or the Executive Medical Director will advise the investigating manager of the need to inform research partners, research ethics committees, or an appropriate regulatory authority.

How to avoid unintentional research fraud or misconduct

The most successful way to prevent unintentional fraud or misconduct is to:

- Ensure research is planned and carried out to high standards.
- Ensure researchers have the necessary training, skills and knowledge, and
- Obtain formal approval to conduct research from YAS.

Research approved and monitored under the terms of the YAS Research Governance Policy is systematically risk assessed, and any unintentional failure to comply with standards is addressed constructively. YAS research managers can provide advice on legal, policy or conduct matters, and can identify training opportunities for less experienced researchers. Researchers are encouraged to take advice at an early stage in the planning of projects. Conflict of interests by any YAS parties, this includes individual researchers or at an organisation level, involved in the research must be declared. In practice these would be declared in an IRAS application. In cases where no IRAS application has been made or is not required the Research and Development Manager must undertake to confirm in writing (or by email) with the researcher(s) that there is no conflict of interest. Where a conflict of interest is declared, YASRI will work with the discloser to address this and disclose to other external organisations as required.

What should I do if I suspect research fraud or misconduct?

You should follow the YAS Freedom to Speak Up policy (Whistleblowing) or bring your concerns to the Executive Medical Director or Head of Research or to the line manager of the person you have a concern about.

Sources of advice and guidance

- YAS pulse pages.
- YAS Research Governance Policy.
- UK Policy Framework for Health and Social Care Research https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
- Medical Research Council 'Good Research Practice: principles and guidelines' (2012) https://www.mrc.ac.uk/publications/browse/good-research-practice-principles-and-guidelines/
- YAS Research & Development Manager – see YAS pulse for contact details.

YAS policies relevant to research fraud and misconduct

- YAS Research Governance Policy.
- YAS Local Counter Fraud, Bribery and Corruption Policy.
- YAS Freedom to Speak Up Policy.
- YAS Code of Conduct Policy.
- YAS Disciplinary Policy. Procedure & Guidance

Appendix D: Research incidents and complaints

Incidents related to research will be captured in Datix and reviewed by the Head of Research. Incidents may be highlighted using the specific 'research' tab in Datix, or these may be highlighted by another member of the Clinical Directorate where research was part of a clinical incident. All incidents, complaints and near misses will be reported and discussed with the YAS Principal Investigator. The PI assess all incidents for causality and seriousness in line with the protocols plan for adverse event monitoring and reporting. The PI will sign off any action plans and reporting to the trial team.

Where YAS is the sponsor of research, the Chief Investigator will plan the procedures for reporting, assessing, attributing, correcting and preventing future incidents, complaints and near misses. This will be included in the study protocol, or any local working instructions. Where the study is multi-site, the CI will liaise with local collaborators or PIs at other sites to compile all incidents in the study where YAS is the sponsor.

A compilation of incidents will be included in reports to CGG. This will also cover any complaints that have been made to YAS in relation to research. These will be collected by contacting Patient Services.

Where the rights, welfare, dignity or safety of participants or staff are deemed to be at risk, either through the identification of a new risk or the reporting of a research incident, the Head of Research will escalate this directly with the study team for resolution. Where the risk has not been resolved sufficiently to assure the Head of Research, they will consult with the Executive Medical Director and decide if recruitment of participants to a study may have to be suspended within YAS until the risks have been mitigated against to the satisfaction of the Head of Research and Executive Medical Director. Where a risk has not been able to be resolved then it may be appropriate to end the participation of YAS in the study, or to close the study where YAS is the sponsor. This decision will be taken by the Executive Medical Director, with expert input from the Head of Research, and reported to the Clinical Governance Group.

Where a research team, research sponsor or external regulatory body has requested that a study be suspended YAS will immediately comply with this decision. Where a research team, research sponsor or external regulatory body has taken the decision to close a study early to recruitment[14] YAS will immediately comply with this decision.

[14] Reasons for this may include but are not limited to; poor recruitment rates that indicate the required sample size may not be met; global competitive recruitment target met; lack of equipoise; safety issues.