NHS
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Research Governance Policy

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Staff Summary

This policy supports the YAS Research Strategy
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 who this policy applies to
It specifies and governs the duties of all parties with responsibilities for research in YAS
The policy describes how YAS will ensure compliance with good 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 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): and meeting research-specific requirements within the Care Act 2014.

1.3 YAS values demonstrate our organisation's commitment to innovation, placing the need to develop evidence, and use evidence, at the heart of clinical practice.

1.4 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 implement the YAS Research strategic objectives, namely:

- To support the promotion and conduct of research in pre-hospital urgent and emergency care;
- To support the national ambition to increase the number of patients taking part in clinical trials
- To participate in, and influence the development of high quality pre hospital research activity to the benefit of YAS patients and clinical practice;
- To enhance the organisation's reputation for research and development

[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 develop research leadership, skills and expertise in paramedics and other staff to contribute to the development of their professional practice
- To develop a team of skilled research staff with postgraduate and doctoral research qualifications led by a Consultant Paramedic (Research).

2.2 The YAS research strategy contains details of the initiatives that will be undertaken to realise the above strategic objectives.

2.3 The key objectives of this 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 or YAS data;
- To provide a source of advice, guidance and support for YAS staff relating to research activity to support their participation in research where 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.

2.4 This policy applies to any activity within YAS 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] 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

2.5 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.

2.6 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.

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

2.8 YAS will work within the systems and processes put in place by the Local Clinical Research Network: Yorkshire and Humber in line with national research strategy, and as agreed in the network membership agreements.

2.9 The YAS Intellectual Property Policy also supports the Research Strategy.

3.0 Process

3.1 Each research study within YAS will start only when study has been assessed by the Research & Development team using a standard proportionate process that identifies whether the study has the required approvals, YAS is willing to participate, has the capacity to participate, and has the 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 to the study.
- 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 place that sets out who is to meet the costs. Where Excess Treatment Costs[4] are identified, national 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 intellectual property.

[4] Excess Treatment Costs are the difference between the total treatment costs and the cost of standard treatment.

- Approval is in place covering ethical and legislative requirements, usually from 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.

3.2 A register of all research activity will be maintained by the R&D team.

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

3.4 Project start dates may need to be negotiated where additional staff or resources must be put in place for a specific project.

3.5 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 the study to take place quickly and efficiently, following national guidance.

3.6 YAS will monitor the conduct of studies, or will co-operate with external monitoring. Research incidents will be reported through YAS processes in addition to protocol-mandated reporting to trial centres. Investigations and learning from incidents will follow usual YAS processes. Incidents and learning will be included in reports to Clinical Governance Group.

3.7 Research income and expenditure will be managed via usual YAS processes to ensure financial transparency and probity, and accurate calculation of research costs.

3.8 Where research fraud or misconduct is suspected, appropriate, effective action is taken and supported by the R&D team. See Appendix B for further details.

3.9 The processes described above are supported by a suite of Standard Operating Procedures specific to the R&D team.

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[5] 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.

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

4.4 The R&D team will support and advise YAS staff regarding required training for each research study, and provide details of available training.

4.5 The R&D team will maintain records of GCP training, and alert staff when refresher training is required.

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.

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 YAS Research Department 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 References

7.1 Legislation

- Care Act 2014 Section 111(7)
- The Equality Act 2010 (Statutory Duties) Regulations 2011

[5] 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.

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 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

7.3 Fraud and Misconduct

- Code of Practice for Research: Promoting good practice and preventing misconduct (UK Research Integrity Office, September 2009)

8.0 Appendices

Appendix A: Roles and responsibilities

Appendix B: Fraud and misconduct in research

Appendix C: Research incidents and complaints

Appendix A: 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 or sponsor[6] the research.

Where YAS employs the researcher, 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;

[6] 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 main funder.

- 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.
- Ensure effective financial management

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 observational research;
- Take on responsibility for putting in place and keeping in place arrangements to initiate, manage and fund the study;
- Satisfy him/her self 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[7], seek a clinical trial authorisation and making arrangements for investigational medicinal products. The sponsor should meet their legal duties for these studies[8].
- Satisfy him/her self 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.

Additionally, 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, 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;

[7] 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.
[8] 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.

- 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 research site[9] the Executive Medical Director will put systems in place to ensure:

- Approval bodies can be confident that the location is suitable for the research;
- 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 CRN 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 CRN 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 & Development 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 & Development, 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[10];

[9] 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.

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

- 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;
- Having the authority to approve YAS sponsorship of interventional 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;
- 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 eg sponsors, employers, ethics committees, the HRA, the 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 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 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 Business Intelligence (BI) and Clinical Information Analyst, in consultation with BI, all research for feasibility of access to YAS data.

- Assess all research for patient experience components. Where these are identified, notify the Patient Relations Manager and take advice regarding compliance with YAS policy;
- 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[11], 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;
- 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 against the 70 day benchmark as contractually obliged by the NIHR.
- Reporting recruitment data for studies included in the NIHR CRN 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.

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[12] 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.

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

Investigations and any necessary further actions will be conducted according to the YAS Disciplinary Policy & Procedure, the YAS Anti-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, the Research and Development Department 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 (Whistle-blowing), 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 Anti-Fraud, Bribery and Corruption Policy;
- YAS Freedom to Speak Up Policy;
- YAS Code of Conduct;
- YAS Disciplinary Procedure

Appendix C: Research incidents and complaints

Incidents related to research will be captured in Datix and reviewed by the Head of Research. 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. 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[13] YAS will immediately comply with this decision.

[13] 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.