Policy Group: Type
Version no.: 1.0
Date of issue: December 2019
Approved by: CEC

Research & Innovation Policy

1. **Policy Summary / Statement**
PURPOSE AND SCOPE

1 Introduction

1.1. Supporting research and innovation (R&I) is one of St Andrew's Healthcare's (STAH) strategic aims, as it plays a vital role in improving health outcomes and the quality of care. Research studies enable clinicians and researchers to develop new treatments and resolve uncertainty about existing treatments.

1.2. Health research is highly regulated. Clinical trials, medical device studies, use of patient data, professional qualifications, access to and treatment of NHS patients and other aspects of research studies are regulated by EU directives, UK legislation and professional standards of good practice (DH, 2006). The UK Policy Framework for Health and Social Care Research (2017) sets out principles of good practice in the management and conduct of health and social care research that take account of legal requirements and other standards. These principles protect and promote the interests of patients, service users and the public in health and social care research.

1.3. Non-NHS providers (commissioned to provide services to the NHS) are legally responsible for the research activity conducted at their sites, including the safety of their staff and patients, and using data from patients in their care.

1.4. STAH is open to collaborations on research projects with a variety of partners, including academic institutions, NHS Trusts and commercial companies. Establishing a common set of principles provides a sound basis for collaboration in research and innovation across non-NHS/NHS providers, academic boundaries and the private sector, ensuring that researchers who are active in other organisations can work to a largely consistent set of rules and regulations.

1.5 While there are important distinctions between a research project, service evaluation or audit, there are also similarities between these three activities; the most important being that they all require the rigorous and systematic application of methodology, data collection and analysis. This policy covers research, innovation and service evaluation projects that are managed via the Research Centre.

2 Purpose

2.1 This policy and associated procedures set out the Charity's Research Policy.

2.2. As a research active organisation, STAH is required to demonstrate that it has in place effective systems to manage and administer that activity. STAH is committed to a high standard of practice in the administration of its research activity and this policy is designed to ensure that those engaged in research and, therefore, charged with achieving these standards have available to them a suitable operational framework.

2.3. This policy and associated procedures are designed to ensure there is clear guidance across the Charity and for research active staff, in relation to requirements issued in the following main documents:

- Medicines for Human Use (Clinical Trials) Regulations 2004
- UK Policy Framework for Health and Social Care Research (2017)

2.4. This policy outlines the principles that must be followed by all staff and external researchers conducting research at STAH, and the responsibilities at each stage of a research project's lifecycle, from initiation to completion.

3 Definition of Terms

3.1 Research – the attempt to derive new knowledge by addressing clearly defined questions with systematic and rigorous methods.

3.2 Service evaluation – a performance review to establish what standard a service currently achieves, and to identify potential changes/service improvements.

3.3 Service development – In NHS terms, this relates to the decision-making about which treatments and interventions to routinely commission. In a St Andrew's context, this relates to the decision-making about which (new) treatments and interventions to deliver as part of routine care. It includes the piloting and evaluation of a service/therapy that has been proven within a context relevant to St Andrew's.

3.4 Innovation – a new/novel product, process and/or approach that offers a 'step-change' improvement[1]. Innovation projects must demonstrate value and have a plan for impact from the start; they are an effective vehicle for translating research into practice.

3.5 Research Principles – these principles serve as a benchmark for good practice that the management and conduct of all research projects in STAH are expected to meet.

3.6 Researchers – those conducting the research, service evaluation or innovation/development project.

3.7 Chief Investigator (CI) – the person designated as taking overall responsibility within the team of researchers for the design, conduct and reporting of a multi-site study. This can be a person inside or outside of STAH. In the case of a single-site study, the CI and Principle Investigator will normally be the same person.

3.8 Principal Investigator (PI) – the person designated within STAH to take overall responsibility for the conduct of a study at a research site, where the CI is based elsewhere. In the case of a single-site study, the Chief Investigator and PI will normally be the same person.

3.7 Sponsor – the organisation that takes on responsibility for confirming there are proper arrangements to initiate, manage and monitor, and finance a study. For any research that takes place in the context of the NHS or social care services in England, there must be a sponsor.

[1] https://improvement.nhs.uk/documents/3434/NHS_Mental_Health_Improvement_Chpter_9_1.pdf

3.9 Integrated Practice Unit (IPU) – a dedicated team, made up of both clinical and non-clinical personnel, which provides the care appropriate for the patient's condition. Care delivery in the IPU model is organised around the medical condition or around groups of related conditions.

3.10 Project costing terminology

3.10.1 Directly incurred (DI) – project costs that directly cost STAH money (aka cash spend); for example, the purchase/hire of a piece of equipment or recruitment of a project researcher

3.10.2 Directly allocated (DA) – the share of the cost of a resource used by a project, where the same resource is also used by other activities; for example, the costs associated with a member of staff working on a project

3.10.3 Indirect – costs that are not directly attributable to a project, for example, estates and overheads (personnel, security, lighting etc.)

3.11 Clinical Research Advisor (CRA) – a senior member of STAH, from a relevant multi-disciplinary team (MDT) involved in the project, who acts as champion for the project within their IPU.

3.12 Data controller – is the organisation responsible for the management and oversight of the data. More information on the role of data controllers and personal data in health and care research can be found on the HRA website.

3.13 Good Clinical Practice (GCP) – an international quality standard for conducting clinical trials in accordance with ethical principles, sound scientific evidence and clear detailed protocols.

3.14 Patient & Public Involvement (PPI) – in a research context, is defined as research being carried out ‘with’ or ‘by’ patients and members of the public, rather than ‘to’, ‘about’ or ‘for’ them. The term ‘public’ includes potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use care services.

4 Duties, Accountability and Responsibilities

4.1. Research Committee

4.1.1 The Board of St Andrew’s Health has established a Research Committee that reports directly to the Board. The principal purpose of the Research Committee is to provide strategic leadership and direction to the Research Centre in support of STAH’s research strategy. The Committee’s role is to provide the interface between research undertaken by the Research Centre and the Board (see Appendix 1 for Terms of Reference), and to provide assurance to the Board that research activity in STAH meets the standards defined in this policy.

4.1.2 The Terms of Reference for the Research Committee include having oversight both of STAH’s performance on research metrics and of the processes for approvals.

4.2 Research Centre

4.2.1 STAH has established a Research Centre, whose Director reports via the Executive Medical Director to the Chief Executive. The principal purpose of the Research Centre is to:

- Develop and implement a research strategy that identifies and addresses the obstacles preventing people detained in secure hospital settings from moving to the most appropriate, least restrictive setting, in a safe and sustainable way
- Manage the research process according to the principles in the Policy Framework for Health and Social Care Research (2017)

4.2.2 Coordination and administration of the Research Policy will take place through the Research Centre, working with other internal and external departments and personnel to achieve the objectives set out in it.

4.2.3 The Research Centre will ensure that research undertaken at STAH meets accepted standards of quality and is always conducted in line with GCP.

4.3 Researchers

4.3.1 It is the responsibility of STAH's researchers, or persons granted access to this organisation for the purposes of undertaking research, to ensure that the quality of the research they carry out in the Charity is done to an acceptable standard. It is also the responsibility of any person with a delegated role in the study to ensure that the quality of the research is done to an acceptable standard.

Responsibilities of individuals
There should be clear designation of responsibility and accountability with clear lines of communication between all those involved in research, service evaluation and innovation. These should be clear in terms of what, how, who, when and why, with documented roles and responsibilities.

4.4 Clinical Research Advisor (CRA)

4.4.1 All projects that have research participants from STAH are required to have a CRA; for some larger projects, it is necessary to have a CRA for each IPU involved in the research.

4.4.2 The role holder should be a senior member of staff from one of the MDT involved in the research, service evaluation or innovation.

4.4.3 The role of the CRA is to:

- Read the protocol and raise any concerns with the Research Centre
- Act as a champion for the project within their IPU
- Facilitate the introduction of the researcher to the MDT for each ward
- Be a point of contact for clinical advice and queries from the Research Centre and the researcher
- Alert the Research Centre to any concerns relating to changes in protocol or research staff

5 Health Research Principles

5.1 The Policy Framework for Health and Social Care Research (2017) outlines a set of principles that are considered essential in the conduct of all research within the NHS and can be found at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

5.2 These principles protect and promote the interests of service users, staff and members of the public taking part in health research. This is to support and facilitate high quality research, in the UK, that has the confidence of our service users, staff and the public.

5.3 STAH's policy is to align research, service evaluation and innovation management with this framework.

6 Research Conducted at St Andrew's Healthcare

6.1 The Research Centre will promote the development of a multidisciplinary research-oriented workforce. Those with experience of good practice in the management and conduct of research are encouraged to share their knowledge with those new to the area.

6.2 The Research Centre will encourage and help researchers to engage with patients, carers and other stakeholders in the development and co-production of research, through PPI activities.

6.3 The Research Centre will encourage externally-funded research, and will strengthen its links with external collaborators through programmes that are complementary to the objectives of all organisations and STAH's Research Strategy.

6.4 The Research Centre will protect STAH's Intellectual Property Rights, and, where appropriate, exploit the product of its research in collaboration with industry and commerce, in return for a fair and reasonable share in the proceeds of such exploitation.

6.5 The Research Centre will develop standard agreements for contracting research projects with external organisations. Such agreements will be used as a basis for protecting the Charity's financial position and as a means of minimising the Charity's risks and legal liabilities.

6.6 The Research Centre will ensure that research projects are approved by a properly constituted ethics committee and have appropriate insurance arrangements, as applicable.

6.7 All research undertaken by STAH employees, or persons granted access to this organisation for the purpose of undertaking research, service evaluation or innovation, will be overseen and administered by the Research Centre.

6.8 All research undertaken at STAH or using our patients' data is expected to deliver defined outputs (e.g. development of policy guidance, publication in a peer-reviewed journal and/or development of a toolkit for clinicians) within a specified timeframe.

7 Other Prerequisites for Research in St Andrew's Healthcare

7.1 Use of Patient Information for Research

7.1.1 The Data Protection Act, the GDPR, the Caldicott Report, the UK Policy Framework for Health and Social Care Research, the EU, and funding and professional bodies all provide guidance on how patient information should be gathered, handled, stored and disclosed, for the purposes of research. The purpose of these guidelines is to ensure that staff undertaking research are aware of their responsibilities with regard to use of participant data and existing medical records, as well as the creation of new patient records for research and informed consent process.

7.1.2 Research projects that make use of identifiable and de-identified patient data can take several different forms. This policy and supporting procedures recognises the importance of involving key stakeholders (e.g. clinicians, system owners) in the approval and conduct of such projects.

7.2 Agreements with External Organisations

7.2.1 All external collaborations will be covered by an appropriate agreement. The final responsibility for wording of agreements is with the Research Centre and ultimately the Research Centre Director, in consultation with the Charity's legal department.

7.2.2 Subject to the Scheme of Delegation, the Research Centre Director and/or Head of Research and Development will be STAH's legal signatory for such agreements.

7.3 STAH Review of Research

7.3.1 All research at STAH will be reviewed by the Research Centre. It is crucial that the review takes into consideration the impact on routine clinical work and related services such as Pharmacy, etc. Failure to address these issues at the outset may lead to problems when the research is underway.

7.3.2 The Research Centre will seek input and feedback from:

- Clinicians, in relation to the suitability of a project for the IPU (e.g. number of eligible patients, suitability of the patient information sheet etc.); and
- Clinical and Operational Leads, who should assess the staff requirements to support the project, highlight any potential, IPU-specific risks and arrangements for their mitigation, and identify a Clinical Research Advisor;
- Patients, carers and other stakeholders, as appropriate.

7.3.3 The Research Centre wishes to ensure that all research, including that which is internally resourced, is subject to a thorough review process. This to help STAH demonstrate that all its research meets standards of quality and strategic fit.

7.3.4 Postgraduate student research – the Research Centre is committed to supporting the development of researchers and clinicians of the future, so postgraduate student research and other projects which are short term and have minimal resource implications should be treated proportionately, with the emphasis on general appropriateness and the impact the research would have on the service and on patients. Review of the scientific merit of the studies will be undertaken by the HEI (higher education institution) and the STAH Research Centre. The Research Ethics Committee review will be undertaken by the HEI.

7.3.5 Externally-funded research – research that requires external funding normally has peer review built into the process. However, this will consider the scientific value of the research and not the departmental resources required to conduct the research. While STAH will not re-examine the scientific value of the proposal, whether a department can sustain the research from its available resources should be part of the STAH review, alongside the consideration of capacity and capability.

7.3.6 STAH-funded projects will be subject to an external peer review, which is proportionate to the amount of funding and the level of review that has taken place across the Charity and externally to the Research Centre.

7.3.7 STAH-funded research (e.g. joint-funded PhD projects) will either be developed by or co-developed with the Research Centre. To ensure the peer review is objective, such proposals must be put out to external peer review by at least one subject expert.

8 Research Approvals Process

8.1 All research projects conducted at STAH will be subject to a fair and proportionate approval process that involves the appropriate stakeholders.

9 Sponsorship

9.1 All research studies conducted within STAH must have a research sponsor. The sponsor takes responsibility for ensuring that the research is financed, initiated, managed and monitored appropriately. In general, the substantive employer of the Chief Investigator (CI) usually takes on the role of research sponsor.

10 Budgets and Funding

10.1 STAH will award an annual budget to the Research Centre.

10.2 The Research Director will be responsible for allocating budgets (which may include an element of funding for DI and DA project costs) in line with the priorities set by the Research Committee.

10.3 The Research Director will seek external funding to develop research and innovation.

10.4 Where external funding is to be received to carry out research, documentation that clarifies the funding arrangements is required; where appropriate, this should detail the allocation across DI, DA and/or Indirect costs. In addition, it must be clear that the funding belongs to STAH and not the individual researcher, and all expenditure must be in line with standing STAH procedures for pay/non-pay expenditure.

10.5 All commercial funding received must be declared in line with STAH's business conduct policies.

11 Monitoring

11.1 The Research Centre will require regular progress reports for all projects taking place at or in collaboration with STAH. It is recognised that the frequency of this reporting is best decided on a project-by-project basis.

12 Honorary Research Contracts

12.1 The underlying principles for issuing an honorary research contract are to ensure that:

- External researchers are contractually bound to take proper account of the STAH's duty of care and to follow research principles and other research regulations at every stage of their research process
- Research participants, researchers, services users and host organisations are protected
- There is a clarity in a legal situation should adverse incidents occur with respect to research activity

13 Study Documentation and Archiving

13.1 The conduct of a drug or invasive intervention trial must be able to be reconstructed both during the study and for some time after its completion from the documentation, which is filed and retained within the project/investigator site file (or Trial Master File for clinical trials).

13.2 Maintenance of the correct and appropriate documentation in a manner suitable for managing the conduct of the study and enabling evaluation by audit or inspection is essential for GCP compliance.

14 Reporting Adverse Events / Protocol Deviations

14.1 The requirements for CIs and PIs to report adverse events and protocol deviations should be detailed in the protocol for each project.

14.2 Reporting requirements will take full account of other STAH policies and procedures.

15 Identification of Stakeholders

15.1 This policy has been circulated within the Research Centre, as well as a STAH-wide consultation period of 4 weeks to the following:

- Executive Medical Director
- Clinical Directors
- Clinical Leads
- Chair of MAC
- Head of Profession for Psychology
- Operational Lead for New Leaf
- Academic Department
- Legal Department (including Data Protection Officer)
- Quality & Audit Team
- Patient Engagement & Patient Advice and Liaison Service (PALS)
- Finance Department
- HR Department
- Patient/Carer Engagement

16 Training

16.1 In order to ensure that research staff follow health research principles, STAH require any research staff consenting participants, or delivering an intervention as

part of a research study, to complete Good Clinical Practice Training, every three years or as appropriate.

17 Research Culture

17.1 STAH is committed to developing an open and supportive research culture. It has endorsed the view that we should enable people to develop and learn together through research and experiences without unnecessary reproach or recrimination.

2. **Links to Procedures** (if applicable)
3. **Monitoring and Oversight** – the Research Centre Director is accountable; responsibility for adherence to the relevant policies sits with the Head of Research & Development; it is the role of the Research Committee to give assurance for the delivery of strategic research programmes.
4. **Diversity and Inclusion**
   St Andrew's Healthcare is committed to *Inclusive Healthcare*. This means providing patient outcomes and employment opportunities that embrace diversity and promote equality of opportunity, and not tolerating discrimination for any reason.
   Our goal is to ensure that *Inclusive Healthcare* is reinforced by our values, and is embedded in our day-to-day working practices. All of our policies and procedures are analysed in line with these principles to ensure fairness and consistency for all those who use them. If you have any questions on inclusion and diversity please email the inclusion team at DiversityAndInclusion@standrew.co.uk
5. **Training** – please see individual procedures, for details.
6. **References to legislation and best practice**
   - https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/
   - https://www.universitiesuk.ac.uk/policy-and-analysis/reports/Pages/research-concordat.aspx
   - Individual procedures
7. **How to request a change or exception to this policy**
   Please refer to either the Policy and Procedure Update Application Link, or the exception process Policy and Procedure Exception Application Link.
8. **Key changes** – please state key changes from the previous version of the policy.

Version Number	Date	Revisions from previous issue
v1.0	18/12/19	