Policy Group: Clinical
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Approved by: Policy Oversight Group

Code of Practice for Conducting Research at St Andrew's Healthcare

Contents

TARGET AUDIENCE (including temporary staff)	
People who need to know this document in detail	Research Centre staff
People who need to have a broad understanding of this document	Executive Medical Director, Clinical Directors, research-active clinicians, centre directors, all Directors, Associate Directors and Heads of
People who need to know that this document exists	Wider Executive and all other staff who may be involved in research in any capacity; external researchers

1. Preface – Permissions Flowchart

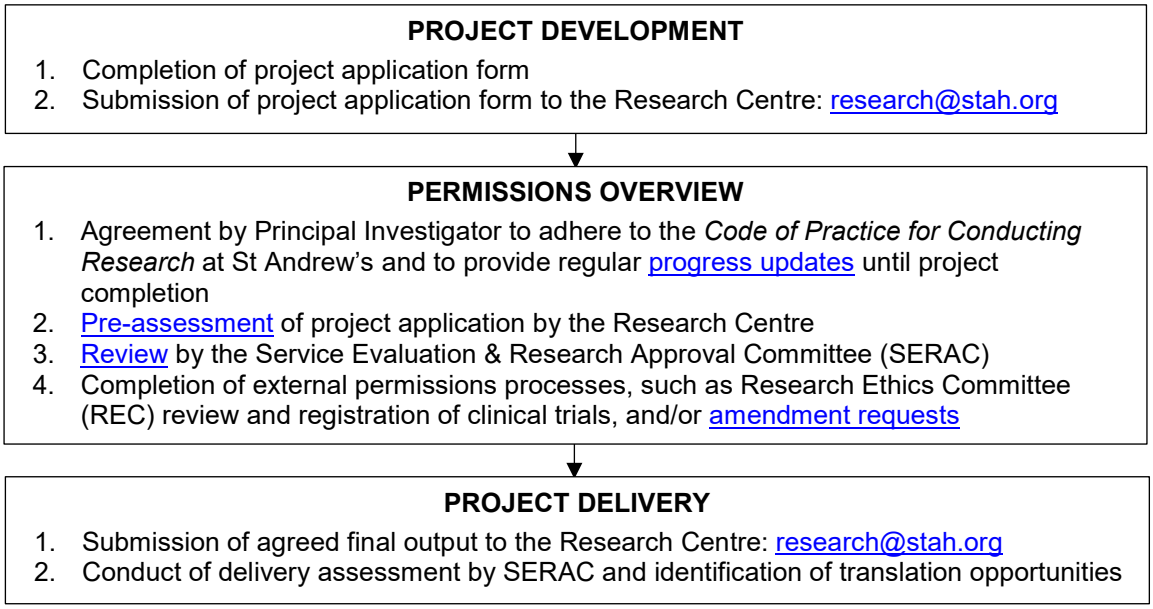


Figure 1: St Andrew's permissions and project delivery process

2. Policy Summary / Statement

St Andrew's Healthcare is committed to supporting research initiatives and data driven approaches to improving its services and outcomes for patients, service users and staff. This includes conducting research and non-research projects, such as service development/improvement, evaluation and service evaluation projects, in accordance with the highest standards of integrity, ethics, and compliance. We actively encourage and support clinicians to participate in projects that align with our organisational values, thereby enriching the impactful work of the Charity.

Our approach to research reflects our commitment to:

- Enacting procedures and practices that prioritise the safety and wellbeing of service users, patients and staff involved in research activities
- Following ethical and regulatory advice from the Health Research Authority (HRA) to maintain the quality of health and social care research and non-research activities
- Enacting procedures and practices that promote engagement in research by its employees, across the Charity, and from different professions
- Ensuring that research processes and training opportunities are clear, accessible and facilitate research engagement and practices

This code of practice is underpinned by the principles set out in the UK Policy Framework for Health and Social Care Research. We prioritise honesty, integrity transparency, and accountability in our work, and consult UK Research Integrity Office (UKRIO) guidance when adjusting the HRA's approach for our needs (for example, where we are unable to apply for NHS Research Ethics Committee approval, as a non-NHS provider). We partner with academics to help postgraduate researchers align with our guidelines and nurture future professionals. We are committed to updating research policies and practices in line with lessons learned from our research experiences and changes in national guidance.

3. Links to Policies and Procedures

Data Protection Policy
Information and Data Governance Policy (including Information Sharing and Transfer Procedure)
Financial and Contractual Authorisations Policy (includes Authority Matrix)
Disciplinary Policy
Risk Management Policy
Procurement Policy
Case Study for Academic Use Procedure
Patient Safety Incident Response Framework (PSRIF) Policy

Policies and procedures available via the Policy A-Z.
Policies - Policies - A-Z (sharepoint.com)

4. Scope

This code of practice for conducting research at St Andrew's covers all activities and governance processes related to both research and non-research activities, including those undertaken by the Research Centre. For ease of reference, all in scope activities (whether research or non-research) will be referred to as 'research', unless specified otherwise. This code of practice applies to individuals engaged in research at St Andrew's, regardless of their employment status, including paid, voluntary, student, patient/service user and honorary staff (including those with honorary contracts, alternative HR arrangements or other site access agreements in place). Additionally, it applies to all collaborative projects jointly sponsored (collaboration), those initiated internally and sponsored by St Andrew's (internal) and those generated independently of St Andrew's with sponsorship from another organisation (external).

Out of scope of this policy
St Andrew's has separate teams responsible for the conduct of clinical audit and continuing quality improvement (CQI) projects; such activities fall outside of the scope of this policy. See Appendix 7: Identification of Project Type. Activities using pre-existing published data (i.e. data already in the public domain), such as literature reviews, ethnographies, meta-synthases, and meta-analysis.

5. Background

National Frameworks
The UK Policy Framework for Health and Social Care Research lays out key principles and guidelines for research conduct, covering ethics, consent, governance, transparency, and accountability. The Health Research Authority (HRA) ensures UK research follows these guidelines, supporting researchers, sponsors, ethics committees, and others. Non-NHS providers must ensure research at their sites meets safety standards and respects patient/service user data.

The UK Research Integrity Office (UKRIO) offers independent guidance to promote good research practice, focusing on ethical standards and compliance with regulations.

6. Definitions

See Appendix 1: Definitions

7. Key Requirements

7.1. St Andrew's as a Research Site

St Andrew's sites primarily function as clinical settings; as such, the clinical priorities of the sites take precedence over all research activities.

7.2. Permissions Overview

All research activities undertaken at St Andrew's require organisational permissions before taking place. The process for acquiring these and overview of the expected delivery process, are outlined in *Preface 1*. This applies to all internal, external, and collaborative research initiatives.

7.3. Specialist Research Support

The activities relating to project development and management is the responsibility of the Principal Investigator and what is required will vary on a project-by-project basis. In addition to conducting its own research, the Research Centre can provide support to internal Principal Investigators, subject to capacity and/or funding – see Appendix 11 Research Centre.

Internal Principal Investigators should discuss requirements with the Head of R&D at the earliest opportunity – see Financing Research. External Principal Investigators requiring support beyond the basic approval process may be required to provide finances to cover the additional resources required by the Charity.

7.4. Legal Agreements

Any legal or binding agreements used to support the research process need to be authorised by the Legal Team before they are signed. See – Appendix 5: Common Legal Agreements.

The Research Centre is available to support Principal Investigators with the process of putting a legal agreement in place. If Principal Investigators do not request support from the Research Centre, the expectation is that they will liaise with the Legal Team directly.

Honorary contracts and other access arrangements relating to research are organised by the Research Centre.

7.5. Financing Research

St Andrew's has prioritised research at St Andrew's and actively seeks external funding, both independently or in collaboration with university, NHS and industry partners, to support the delivery of its research. In addition, St Andrew's allocates an annual budget to cover research administration and support costs.

St Andrew's is keen that staff become involved in research, whilst acknowledging that this carries a cost for St Andrew's. Staff wishing to undertake research must discuss and agree workload allocation with their line managers, prior to embarking upon a project.

Some research activities require funding that is in addition to what has been allocated within existing organisational budgets. In this instance, Principal Investigators are responsible for making a case for funding to the budget holder or applying for an external grant.

7.5.1. Collaborative or internal projects seeking St Andrew's funding

Principal Investigators seeking additional funding of ≥£5,000 from St Andrew's for research activities (i.e. those that are not being undertaken within agreed existing resources) are required to provide a justification of resources and have an external project peer review conducted. St Andrew's does not have a standard template for providing a costed plan; however, guidance is available here: Research Toolkit | Knowledge and Library Services (hee.nhs.uk). The review can be arranged by the Principal Investigator or via the Research Centre.

Both the costing and review should be submitted as part of the project application. Funding is not guaranteed, and requests will be scrutinised by budget holders.

7.5.2. Collaborative or internal projects seeking external funding

Principal Investigators planning to apply for external funding are first required to:

1) Submit the draft research protocol to SERAC for their support
2) Secure 'approval to contract' in line with St Andrew's Authority Matrix; the Research Centre can support with this process

When submitting a bid with an external collaborator, Principal Investigators are responsible for liaising with the collaborator to ensure their organisational processes have been followed. More information about pre- and post-award grant management can be found at Appendix 10: Pre- and Post-Award Grant Management.

7.6. Insurance

Insurance is required to provide cover against events which could potentially cause harm to a person participating in research. For projects where St Andrew's is not the Sponsor of the research, proof of insurance is required from the Sponsor. This is checked as part of the pre-assessment.

St Andrew's does not have a standalone policy to cover research; however, the majority of our research activities fall under the general insurance. This does not include clinical drugs trials or novel operations of medical equipment.

Where there are significant risks for participants or where the project involves unusual activity, such as a clinical drug trial, the Principal Investigator should contact the Research Centre for advice. The Research Centre will work with the Legal Team to obtain a quote for cover through their brokers (AON) where necessary. When additional insurance is required for a project, the Principal Investigator must consider and plan for the budgetary implications.

7.7. Research Placements

Postgraduate research and projects, often short-term with minimal requirement for Charity resources, are assessed based on their quality and potential benefit to patients/service users versus burden on staff and participants. Scientific merit review and research ethics review is the responsibility of the Sponsor (usually a higher education institution (HEI)).

St Andrew's does not allow undergraduate research projects to be conducted at the Charity but may support research-based placements; for example, a year's placement as part of a mental health-related sandwich course.

St Andrew's collaborates with academic partners through MOUs, facilitating postgraduate research placements that may be co-ordinated by the Research Centre.

Clinicians, serving as Principal Investigators and/or placement supervisors, are responsible for the final decision on student selection, project delivery, paperwork completion, and other responsibilities outlined in the university's placement supervisor agreement.

Projects undertaken during a research placement must adhere to St Andrew's standards, mirroring the requirements of other projects. Additionally, university-specific requirements may be applicable.

7.8. Research Roles and Responsibilities

Each project must have clearly defined and agreed roles and responsibilities – see Appendix 1: Definitions. Every project must have a:

- Principal Investigator (PI) who is a registered professional responsible for the project's overall conduct and integrity. Large multi-site projects are likely to have a Chief Investigator (CI). For projects led by students or non-registered professionals, a Project Supervisor must be assigned to provide necessary oversight and mentorship. The Lead Researcher, who may be a student, assistant psychologist, or other non-registered professional, will execute the project under the supervision of the PI or Project Supervisor.
- Sponsor – this usually an organisation, such as St Andrew's or a university
- Data controller – this is usually the Sponsor

See Appendix 3: Principal Investigator responsibilities for more detailed information.

7.9. Project Development

Researchers are expected to follow good research practice when developing research projects. They are directed to the HRA's resources: Planning and improving research - Health Research Authority (hra.nhs.uk).

See Specialist Research Support and Research Ethics, plus the appendices cover the following in more detail:

- Determining project type
- Roles & responsibilities
- Patient and Public Involvement (PPI)
- Participant information and informed consent
- Patients as active participants (new data collection)
- Patients as data only participants (secondary data analysis)
- Delays between consent and data collection

7.10. Risk Assessment

Safety is paramount in research, requiring strict adherence to health and safety laws and best practices; this is especially critical in sensitive settings like secure mental healthcare. Researchers must ensure compliance with:

- Regulations concerning hazardous materials and environmental
- Appropriate health and safety legislation
- Insurance and indemnity requirements for the project
- St Andrew's policies, including those that protect data

The St Andrew's research project application form has a dedicated risk assessment section, which requires researchers to outline risks and document their mitigation and contingency planning. This section enables SERAC to evaluate the risks within the unique context of secure mental healthcare. SERAC will also offer context-specific

guidance to applicants to ensure their planned activities are designed to minimise any potential harm or risk to staff, participants, researchers, and others. This may involve recommending or requiring the involvement of a Clinical Research Advisor (CRA).

7.11. Data Management

Research data management sits at project level and is the responsibility of the Principal Investigator. Proposed DMPs will be considered by SERAC as part of the application review process. The Research Centre can support internal Principal Investigators with the development of a Data Management Plan (DMP), as well as with data storage and scheduled data destruction.

7.11.1. Research data storage

The Research Centre stores documentation related to the administration and approval of individual projects on the Charity's secure S:\ drive, with each project having its own separate folder.

Principal Investigators are responsible for securely storing documentation relating to the conduct of their research. The Research Centre uses SharePoint 365 (SP365) for this purpose and can set up and manage project folders on SP365 on behalf of internal Principal Investigators.

7.11.2. Recording patient participation in health records

The researcher is responsible for advising the Clinical Care Team about a patient or service user's participation in research. The member of staff should be asked to update the electronic care record, which is kept in RiO at St Andrew's. Also see Patient participants.

7.11.3. Researcher access to patient health records

Where researchers are required to have access to electronic health records (EHR), as part of the approved protocol, they are expected to undertake the necessary RiO training, as organised by the Research Centre, and to update the EHR in accordance with the protocol and as advised by the Clinical Care Team.

7.11.4. Special category personal data

At St Andrew's, the data collected by researchers frequently pertains to our patients' mental illness, placing it within the special category of personal data under GDPR.

7.11.5. Protecting patient identity

We prioritise the protection of patient identity and recognise that there is a lack of clarity about when deidentified patient-level data can reasonably be considered anonymous and outside of GDPR. To enable the use of this data for the enhancement of patient care and treatment, we have developed a RAG tool. This tool assists researchers involved in St Andrew's sponsored projects in assessing the status of patient-level information – see patient_data_RAG_v0.2.xlsx.

7.11.6. Data retention and destruction

The Principal Investigator is responsible for determining the data retention period, ensuring alignment with GDPR guidelines to prevent excessive storage. It is best practice to detail the approach in the protocol, at the start of a project.

Typically, retention periods range from 3 to 10 years, based on project significance, future plans and funder stipulations. Advice is available from the Research Centre and the Information Governance Team.

The Research Centre keeps a data destruction log and carries out scheduled data destruction for projects, where they have been engaged to do so by the Principal Investigator. Further guidance available from the HRA: GDPR: technical guidance - Health Research Authority (hra.nhs.uk).

7.11.7. Data sharing

All data sharing plans should be considered during project development and outlined in your project application. Prior to sharing any research data, internally or externally, please read the relevant St Andrew's policy and procedure: Refer to Section 3 Links to Policies and Procedures. If you are unsure, please consult the Data Protection Officer (DPO) in the Information Governance Team, or the Research Centre.

While we understand that plans may change, any alterations require updating and resubmitting the original form before implementation.

7.11.8. Internal data sharing for research purposes

Caution is also needed when sharing patient data internally. Identifiable patient data should not be shared outside of the care team without due consideration, good reason, and approval. Deidentified data is obviously lower risk but must still only be shared where there is a legitimate reason.

7.11.9. Sharing St Andrew's data externally

If existing St Andrew's data is requested by a research team as part of an approved project that has an external Sponsor, a data sharing agreement is necessary. This may take the form of a Data Sharing Agreement (DSA) or similar or be part of a separate data processing contract. A DPIA may also be required. For guidance, contact the DPO or the Research Centre before proceeding. A data sharing agreement is not required when data is being collected by an external researcher as part of an approved project.

7.11.10. Secure transfer

Zivver (soon to be replaced by Egress) is the platform used for secure data transfer at St Andrew's. Refer to the Charity's Information Sharing and Transfer procedure.

7.12. Research Ethics

The Principal Investigator is responsible for determining the ethics approval requirements for their research activities. Some external project applications are submitted with Research Ethics Committee (REC) approval in place; however, REC approval is not a prerequisite for applying to St Andrew's. Where REC approval is a project requirement, it must be in place before project commencement.

The HRA decision tool will assist Principal Investigators in making and capturing their decision about REC approval: Do I need NHS Ethics approval? (hra-decisiontools.org.uk). Project applicants are required to submit the outcome from this tool with their application.

Internal Principal Investigators are recommended to secure SERAC's conditional approval before submitting a project for ethical review.

7.12.1. NHS REC review

If a research project requires NHS REC approval, the Principal Investigator must apply via Integrated Research Application System (myresearchproject.org.uk). Internal Principal Investigators can seek support from the Research Centre.

7.12.2. Independent REC review

If a research project does not need NHS REC approval, but would have done, were the research taking place within the NHS, then St Andrew's requires the Principal Investigator to arrange an alternative REC review.

In this instance, there are two potential routes for seeking the required ethical approval:

1) University REC or
2) Independent REC – see Research Ethics Committee Review in Appendix 1: Definitions for more information)

7.12.3. REC review not required

For projects that do not require REC review, typically those involving non-research activities, Principal Investigators are required to complete the ethics screening questions developed by the Research Centre. These questions are part of the application form – see Appendix 6: Ethic Screening Questions.

7.12.4. Ethics and permissions relating to the use of secondary data

Ethics and permissions relating to the use of secondary data require careful consideration due to the diverse nuances involved. Researchers are expected to seek permission from the designated data controller, which may vary depending on the dataset's management. The application process outlined in this document guides researchers through obtaining this permission for the use of existing clinical data from St Andrew's, specifying required documentation and approval procedures. While there is no universal rule for ethical approval or data sharing agreements, each use case must undergo individual assessment, considering factors such as data provenance and intended analysis. The Research Centre is available to provide advice and guidance to internal Principal Investigators. Regardless of the specifics, researchers must prioritise confidentiality and adhere to stringent data security measures to safeguard sensitive information.

7.13. Health Research Authority (HRA)

If a project is taking place within the NHS (in England or Wales) HRA approval will be required, regardless of whether NHS REC approval is needed. The Principal Investigator is responsible for applying for HRA approval. Further information can be found on the HRA website: HRA Approval - Health Research Authority HRA approval is not currently required for non-NHS research projects: Non-NHS research projects - Health Research Authority (hra.nhs.uk).

7.14. Application Forms

All research conducted within St Andrew's requires the completion of a project application form, which can be found here: Research Centre - templates - All Documents (sharepoint.com). This asks for project details including, but not limited to, information about the intended informed consent process, risk assessment, data management and project timelines.

7.14.1. Site recruitment only

For externally funded projects with a comprehensive protocol, study documentation and Research Ethics Committee (REC) approval secured, the recruitment-only application should be used. This streamlined form is designed to avoid repetitive input of information already captured within the ethically approved protocol.

7.14.2. Application submission

Completed applications must be submitted to the Research Centre, via research@stah.org

7.15. Pre-assessment

Before review by the Service Evaluation & Research Approval Committee (SERAC), all applications undergo pre-assessment by the Research Centre. This preliminary evaluation ensures preparedness for SERAC's formal assessment and confirms that external applications originate from individuals affiliated with organisations adhering to appropriate research conduct standards – see Appendix 2: Research Code of Conduct

Pre-assessment is conducted under a standing agenda item on the Research Centre's weekly Management Team agenda – see Appendix 4: Research Centre Management Team Agenda Template. Notes and actions are recorded on the shared drive.

The Research Centre may propose rejecting an application if the research topic is deemed irrelevant to St Andrew's. Recommendations for rejection will be shared with the Chair of SERAC, who will need to respond only if they disagree with the recommendation.

7.16. Review

The Service Evaluation & Research Approval Committee (SERAC) is responsible for reviewing applications to conduct research at St Andrew's. All project applications are reviewed by SERAC, following the principles of proportionate review recommended by the HRA. The level of review is determined based on factors such as project objectives, methodology, risks and potential impact – see: Appendix 9: Project Application Review Form.

For full details about SERAC, including information on exceptions, retrospective approval and communicating outcomes, please see – Appendix 8: SERAC Terms of Reference.

7.17. Induction

External researchers are required to attend a one-day St Andrew's induction, if they are going to be working at a St Andrew's site. The induction day is held at St Andrew's Northampton and attendance by the researcher is co-ordinated by the Research Administrator.

Prior to booking an external researcher onto an induction, their project must have been approved and the Research Administrator must have received a current DBS and Good Clinical Practice (GCP) certificate.

7.18. Notification of Approval

7.18.1. Final approval letter

The Principal Investigator must be in receipt of a final approval letter from the Research Centre before commencing a project. the final approval letter will only be issued once all requirements are in place.

7.18.2. Amendment to approval

If adjustments are required to the established protocol, the Principal Investigator must submit a revised application to research@stah.org. Following review and approval, the Research Centre will issue a formal letter of approval amendment. No modifications to

the protocol must be initiated, unless there is immediate danger, prior to receiving this amendment.

7.18.3. Delays to project start

Projects experiencing uncommunicated delays may require reapproval. Principal Investigators are advised to inform the Research Centre of any delays exceeding three months.

7.19. Site Access

The Research Centre is responsible for contacting external researchers to make the necessary arrangements for site access, including the issue of a St Andrew's ID badge, following completion of Induction and issue of Final approval letter.

7.20. Key Access

It is the responsibility of the host team at St Andrew's (e.g. a specific ward in a division) to determine whether an external researcher can be given key access. When this is deemed appropriate, the Ward Manager or nominated member of staff is responsible for arranging appropriate key training or asking the Research Centre to co-ordinate.

7.21. Project Progress Reporting

The Principal Investigator defines project completion criteria, such as submitting a final report, and submits regular progress reports to the Research Centre via the Project Progress Form (PPF). Any project member must promptly inform the Research Centre of significant delays or risks.

Reporting frequency and completion indicators are determined on a project-by-project basis in consultation with the Principal Investigator at project outset. Progress reporting will be recorded in the Project Master List, which is maintained by the Research Centre, and regularly reported to SERAC.

7.22. Protocol Deviations and Violations

7.22.1. Clinical trials

Where a protocol deviation or violation has occurred, the SOP for that project must be followed. Where St Andrew's is the research Sponsor, a Datix report must also be logged.

7.22.2. All projects

As soon as a protocol deviation or violation has occurred, the Principal Investigator must stop all activity on the project (including data collection, where applicable), unless dangerous to do so. The Research Centre must be informed immediately via research@stah.org and the Principal Investigator must work with them to manage any impact of the incident.

Following review via the standard Datix process, outcomes will be agreed with SERAC and reported to the Principal Investigator. In the case of significant violations or deviations, permissions for the project may be withdrawn and the project will be terminated at St Andrew's.

All protocol deviations and violations will be recorded in the Project Master List, which is maintained by the Research Centre, and regularly reported to SERAC.

7.23. Reporting Incidents

In addition to any project-specific SOPs, adverse events, incidents and near misses must be reported in Datix, in line with the Charity's Patient Safety Incident Response Framework (PSIRF) Policy.

For ease of reporting, all project-related reports will be recorded in the Project Master List, which is maintained by the Research Centre, and regularly reported to SERAC.

7.24. Project Completion

Upon completion of project, the agreed final output must be shared with the Research Centre. See – Data retention and destruction. A final report is generally expected as a minimum output. A delivery assessment will be conducted by SERAC.

7.25. Dissemination and publication

Dissemination is covered in more detail in Appendix 3. However, researchers should note St Andrew's position on good authorship practice and collaboration with our Comms Team, as follows:

7.25.3. Good authorship practice

All authors should observe good practice relating to authorship of publications. Ideally, all the expected roles, contribution and responsibilities, including authorship of all collaborators (https://casrai.org/credit/) should be agreed at the start of the project. Any change in agreed authorship needs to be approved by the Charity ahead of publication.

Affiliation
External researchers (with an Honorary Contract) must include their affiliation to St Andrew's in their authorship – for example:

Dr A N Other, University of Somewhere; Honorary Researcher at St Andrew's Healthcare

St Andrew's acknowledgement
Publications involving research conducted at St Andrew's must include this acknowledgement:

We would like to acknowledge the assistance of St Andrew's Healthcare in conducting this study.

7.25.4. Service evaluation/evaluation disclaimer

It is advisable to include the following disclaimer when publishing evaluation and service evaluation projects:

> ***Disclaimer:*** *This service evaluation was conducted to assess and improve specific services within St Andrew's. The findings are based on data and practices unique to our organisation and are intended to inform internal improvements. While other organisations may find these results informative, they should consider their own contexts before applying these findings to their practices.*

See Appendix 7b: Determining Generalisability and Transferability for more background.

7.25.5. Press releases and other comms activities

All researchers and research organisations should advise the Research Centre of planned press releases and comms activity, in order to facilitate joint press releases.

The Research Centre will facilitate collaboration between the comms teams from St Andrew's and the research organisation. Each organisation should acknowledge the other on publicity material, documentation or online information relating to the project using the appropriate logos, as respectively approved and provided. Draft press releases should be sent to each other's Comms teams for approval, ahead of publication.

7.26. Research Equipment and Software

The Research Centre can purchase and store a limited amount of research equipment and software, subject to budget and cost-benefit, as assessed by the team.

7.26.1. Equipment loan

The Research Administrator and Senior R&D Project Manager are responsible for conducting visual checks of the equipment before loaning it out to research personnel. Equipment is rechecked and when it is returned. The equipment log is updated at each end of this process.

7.26.2. Taking equipment on wards

Researchers are responsible for familiarising themselves with the ward contraband list. If they wish to take research equipment onto wards, for example, a Dictaphone for recording an interview with a patient or member staff, they must speak to the Ward Manager before doing so.

7.27. Managing Misconduct

All research projects are required to be conducted within the parameters of the permissions given and in accordance with this code of conduct. Deviations from the standards of good practice provided in *Conduct of Research at St Andrew's Healthcare*, while not necessarily amounting to misconduct, may ultimately have similarly serious health, moral or legal consequences and undermine public and patient trust in St Andrew's, and, more generally, in research.

We maintain a zero-tolerance policy towards research misconduct, and researchers at St Andrew's are expected to act in good faith, report misconduct promptly, and manage conflicts of interest transparently – see Appendix 13 Misconduct.

7.28. NHS OpenAthens

NHS OpenAthens is an access management service that provides secure and seamless access to quality, trusted, evidence-based digital resources for health and care staff throughout their career, including community pharmacists and pharmacy technicians. The Research Centre's Research Administrator is the main point of contact for managing St Andrew's access to OpenAthens accounts.

7.29. St Andrew's Organisational Reporting

Researchers are required to provide information, as needed by the Research Centre for their reporting duties. For more information about the role of the Research Centre – see Appendix 11: Research Centre.

8. Roles and Responsibilities

Board of Directors

The board sets strategic direction, approves and reviews the research integrity policy, allocates resources, and monitors compliance. It ensures senior management upholds integrity standards, receives reports on research activities, and addresses misconduct.

Research Committee
The Research Committee provides strategic leadership and direction to the research activity that takes place at the Charity in support of St Andrew's research strategy. The Committee's role is to provide the interface between research and the Board.

Chief Executive Officer (CEO)
The CEO implements and communicates the policy, establishes supporting procedures, and fosters a culture of integrity. They monitor policy effectiveness, collaborate with the board on challenges, and liaise with external stakeholders on integrity matters. This role is delegated to the Director of Education, Research & Training.

Executive Medical Director (EMD)
The EMD holds overall responsibility for overseeing research, service evaluation and other similar activities within St Andrew's. The role involves strategically allocating resources to support compliance efforts, setting strategic research goals and fostering collaboration with external partners. The EMD plays a pivotal role in promoting research and development, and continuous improvement within the Charity, while ensuring alignment with institutional objectives. The implementation of this policy and day-to-day compliance procedures are delegated to the Research Centre and Service Evaluation & Research Approval Committee (SERAC) under the direction of the EMD. The Research Centre reports to the EMD.

Research Centre
The Research Centre plays a critical role in maintaining St Andrew's values and ensuring high-quality, safe research. It oversees various aspects of research management, including project databases, reporting, staff publications, project progress tracking, pre-assessment of applications, conducting research, supporting project development, administrative assistance to SERAC, report production, communication development, and incident reporting to SERAC on a quarterly basis. See Appendix 11: The Research Centre.

Service Evaluation and Research Approval Committee
SERAC's role is integral to upholding the Charity's core values and ensuring project alignment with organisational objectives, through the:

- Conduct of the St Andrew's review and approval process for research taking place at St Andrew's
- Conduct of post-project completion delivery assessments: an evaluation of how well a project has met its aims. This process also provides an opportunity to identify ways to translate findings into meaningful change and share with relevant stakeholders

Conduct of research
Responsibilities relating to the conduct of research are embedded within the key requirements – see Research Roles and Responsibilities.

9. Monitoring and Oversight

9.1. Governance Overview

Figure 2, over, shows the governance and quality assurance framework that applies to the conduct of research at St Andrew's.

A table detailing assurance and monitoring is provided at Appendix 12: Table of assurance processes.

Figure 2: Governance and Quality Assurance Framework

10. Training & Guidance

10.1. External researchers

External researchers engaging in research with or at St Andrew's are expected to arrive fully trained in research integrity principles and research good practice; as well as adequately trained for their role on the specific project. However, St Andrew's recognises the importance of facilitating their understanding of our policies and procedures – this is done by providing them with the *Code of Practice for Conducting Research*. It is expected that external researchers familiarise themselves with this information prior to commencing their research activities to ensure alignment with our standards and expectations.

10.2. Staff

Staff conducting research at St Andrew's are provided with access to a repository of training resources on research integrity and good practice, available through the *Code of Practice for Conducting Research*: For Researchers. These resources, sourced from reputable organisations, institutions, and platforms, cover various aspects of ethical conduct, responsible research practices, and direction to other relevant Charity policies and procedures. In addition, the Research Centre offers specialist support and the CDCT offer research skills workshops.

Staff are encouraged to use these resources regularly to enhance their understanding of research integrity and to stay informed about best research practices. St Andrew's periodically reviews and updates the repository to ensure the availability of the most current and relevant training materials.

By providing access to existing resources, St Andrew's aims to empower its staff to uphold the highest standards of research integrity and contribute to a culture of responsible research conduct within the organisation and the broader research community.

The Research Centre provides links to training and education programs to ensure that staff understand their obligations under this policy and have access to best practice guidance.

10.3. Patients and service users

If a patient or service user has an idea for a research project, they are encouraged to contact the Research Centre who will support them to conduct a project.

10.4. For Researchers

10.4.1. NIHR Learn

NIHR Learn - Health Research Authority (hra.nhs.uk) brings together the learning from the HRA and the NIHR. NIHR Learn is fully mobile-optimised and is free to use by anyone, on any device. Learning includes:

- PI Essentials – virtual session run on a regular basis
- Research Practice in Clinical Settings – e-learning module
- Good Clinical Practice (GCP): i) introduction to GCP; ii) GCP; iii) GCP refresher – e-learning modules
- Informed Consent with Children – e-learning module
- Remote Consent – e-learning module

10.4.2. Research Skills Workshops

The Centre for Developmental and Complex Trauma (CDCT) offers a series of ten Research Skills Workshops, available to clinicians and those with an interest in research at St Andrew's. The workshops cover a wide range of research methodologies and skills relevant to conducting service development and evaluation projects, as well as research, in clinical settings. For the latest brochure, or to book onto a workshop, please visit: Conference Events and Workshops » St Andrew's Healthcare (stah.org).

10.4.3. Research Planning Tools

Recommended guidance is available from: Research planning - Health Research Authority (hra.nhs.uk) Topics covered include:

- systematic review
- funding
- research methodology
- roles and responsibilities
- student research
- identifying participants
- publishing research findings
- preparing study documentation – including protocol preparation and link to detailed consent and participant information sheet development: Home - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk) participation information quality and design

10.4.4. Research Toolkit

The Research Toolkit is a useful resource that was originally developed for librarians in the health sector wanting to undertake a research project, from a small-scale local study to larger more formal projects: Research Toolkit | Knowledge and Library Services (hee.nhs.uk).

10.5. For Reviewers

REC member learning resources - Health Research Authority (hra.nhs.uk)

10.6. Educational Resources at St Andrew's Healthcare

CPD events and divisional training sessions can provide additional expertise to advance research skills and knowledge.

11. References to Legislation and Best Practice

Topic	Link
Code of Practice for Research	Code of Practice for Research (ukrio.org)
Research Integrity	• Research Integrity - UK Research Integrity Office (ukrio.org) • https://ukrio.org/wp-content/uploads/UKRIO-Recommended-Checklist-for-Researchers.pdf

12. 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 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@stah.org.

13. Exception Process

Please refer to the exception process Policy and Procedure Exception Application Link.

14. Key Changes

Version Number	Date	Revisions from previous issue
1.0	Dec 2019	New policy
1.1	Feb 2023	Minor changes during scheduled review include: Update to new template Amendment of Research Centre to R&I Removal of Director of Research Centre and replacement with Executive Medical Director Replacement of IPU with Division Addition of link to R&I wiki for procedures
2.0	Jun 2024	Major changes: Replace Research and Innovation with Research Centre Update and combine previous policy with procedure (dated Mar 2021) and addition of guidance/best practice Alignment with Health Research Authority approach, addition of principles, code of conduct, research misconduct procedure, the Service Evaluation and Research Approval Committee (SERAC) and other elements of governance

Appendix 1: Definitions

Term	About
Clinical Research Advisor (CRA)	A term coined by St Andrew's, this role may or may not be required, as recommended by SERAC as part of the project review process. Where appropriate, the CRA may be a member of SERAC or individual identified by the division in which the research is taking place. The CRA is anticipated to be a clinician; but may be another member of the MDT, if deemed more appropriate or relevant to the research project in question.
Chief Investigator (CI)	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#chief
Clinical Research Fellow	Similar to a Research Associate role but open to St Andrew's clinical staff on secondment. Leads research programs, collaborates independently, and contributes to ethical applications and co-production activities.
Collaborations	Collaboration-based research carried out at St Andrew's can be completed within several different contractual based frameworks. Where collaborative processes are undertaken, such approaches need to be underpinned by one of the frameworks below. Principal Investigators also need to be cognisant about data management, data sharing and disseminations in the process of these projects. See Appendix 5: Common Legal Agreements.
Consent Form	A consent form is a document used in research studies to formalise and document a participant's voluntary agreement to take part in the study. It is used, along with a participant information sheet, as part of an informed consent process. Content: Consent Form - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)
Data controller	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#data
Delivery assessment	This assessment, conducted by SERAC on completed projects, evaluates how well the project met its aims and identifies opportunities for translating findings into practice. Feedback will be given to the Principal Investigator by the Research Administrator. Projects outcomes that are assessed to be relevant to other teams will be referred, as appropriate; for example, Clinical Effectiveness Group, Therapies Advisory Group (TAG), Medicines Management Operational Group (MMOG), Health Records Group (HRG).
Evaluation	Evaluation refers to a systematic process of assessing a specific program, initiative, or intervention to determine its effectiveness, impact, and value. Unlike service evaluations, which specifically focus on the assessment of healthcare services, evaluations can be broader in scope and may include various types of projects such as educational programs, clinical interventions, or organisational initiatives. Evaluations aim to provide insights and inform decision-making by systematically collecting and analysing relevant data. At St Andrew's, we often combine evaluations with clinical service developments as part of a quality assurance process to assess the effectiveness of newly implemented service developments or pilots. To ensure best practice, we treat evaluations with the same rigour as

	research projects, recommending that researchers follow an informed consent process to protect participants and ensure ethical standards are met.
Funder	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#funders
Lead researcher	The individual primarily responsible for executing the research, often handling the majority of the research work and co-ordination. This may be the PI. In the context of a St Andrew's-sponsored project this might be a student, assistant psychologist, or junior researcher.
National Data Opt-Out	The National Data Opt-Out is a service that allows patients to opt out of their confidential patient information used for research and planning. The records of patients who have registered to 'opt out' must not be included in any research and planning activity; this includes the requirement to exclude these records from data anonymisation processing. Also see the official website: National Data Opt-Out - NHS England Digital
Non-research	In this context, encompasses activities related to developing and evaluating services rather than conducting traditional research studies.
Participant Information Sheet	A participant information sheet is a document provided to individuals who are invited to participate in a research study. Its purpose is to inform potential participants about the study's purpose, procedures, risks, benefits, confidentiality measures, and their rights as participants. It is used, along with a consent form, as part of an informed consent process. Examples - Consent and Participant information sheet preparation guidance. (hra-decisiontools.org.uk)
Patient	Person receiving care in our secure care services.
Principal Investigator (PI)	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#pi In the context of a St Andrew's-sponsored project this might be a registered psychologist, a medical doctor, or another registered healthcare professional.
Project Supervisor	An individual who oversees the work of students or non-registered professionals, ensuring the project is conducted according to standards and providing necessary guidance. This may also be the PI. In the context of a St Andrew's-sponsored project this might be a senior researcher or registered psychologist supervising an assistant psychologist.
Protocol	A full description of the research study and will act as a 'manual' for members of the research team to ensure everyone adheres to the methods outlined. The length and content will vary depending on the type of research and the level of complexity. Protocol - Health Research Authority (hra.nhs.uk)
Research	https://www.hra.nhs.uk/approvals-amendments/glossary/?search=research
Researcher	Any person authorised to undertake research including a postgraduate student, a member of staff and persons not employed by St Andrew's, but who is carrying out research under the auspices of the Charity or on Charity premises.

Research Assistant	Supports high-quality research through literature reviews, stakeholder engagement, and program preparation. Also involved in governance compliance, data management, and skill development. *Senior Research Assistant:* Oversees research projects, conducts data analysis, and collaborates with partners. Responsibilities also include contributing to publication and presentation, grant writing, and ensuring ethical compliance.
Research Associate	Leads research programs, develops innovative ideas, and ensures high-quality standards in studies. Responsibilities include supervising PhD programs, leading ethical applications, and delivering outputs.
Research Ethics Committee (REC) review	Identifying the need for (Do I need NHS Ethics approval? (hra-decisiontools.org.uk) and securing REC approval is the responsibility of the Principal Investigator. There are three routes for REC approval: i) NHS REC approval – this is often required for research taking place in the NHS; it is sought via IRAS. ii) University REC This route is available if: • A member of staff is working on a collaboration with an academic partner who is a joint Research Sponsor for the project (the university will need to be a signatory of The concordat to support research integrity (or equivalent) in order for their ethical approval to be accepted by the Research Centre); • A researcher employed by a university or a university student undertaking a qualification is conducting the project, i.e. where a university is the Research Sponsor. Note: This route is not available to you if the university is not the Research Sponsor, e.g. if a student is supporting a clinician with a project that is not considered as part of the student's qualification. iii) Independent REC This route must be used if a research project **would have required NHS REC were it taking place in the NHS** • The Reading Independent Ethics Committee (RIEC) is an experienced, NHS-recognised research ethics committee that St Andrew's has set up as an approved supplier. • Applications to RIEC cost around £650, so the Principal Investigator must consider funding for this as part of their project development. • The Research Centre is responsible for providing financial support for a limited number of submissions to an independent research ethics committee (IREC). Where there is competition for the available monies, requests will be prioritised by the Chair of SERAC and Head of R&I, in collaboration with other experts and stakeholders, as deemed appropriate by their judgement. As the budget holder, the Head of R&D has the final decision
Research Nurse	Ensures adherence to study protocols and SOPs for clinical studies, including participant recruitment and informed consent management. Responsibilities also include promoting the study and reviewing medical notes.

Research Team	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#researchteams
Research Site	https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#researchsites **St Andrew's as Research Site:** Day-to-day responsibility for the location where a research project is carried out. Practical elements of working at a specific are delegated to the Research Centre.
Secondary data	Secondary data refers to information that has been collected by someone else or for a purpose other than the current research or study being conducted. It is data that already exists and is available for analysis or interpretation. Secondary data can come from various sources and researchers often use it to supplement their own primary data collection efforts or to address research questions that can be answered using existing data. All projects that use existing clinical data for research are conducting secondary data analysis.
Service Development / service improvement	NHS England » Specialised Commissioning: Service development policy and methods Service development projects aim to enhance and improve existing healthcare services to better meet the needs of patients, clients, and communities. These projects involve the design, implementation, and evaluation of innovative approaches to service delivery, with the goal of optimising quality, efficiency, and effectiveness.
Service Evaluation	https://www.hra.nhs.uk/approvals-amendments/glossary/?search=service%20development At St Andrew's, we often combine a service evaluation with clinical service developments, as a quality assurance process to assess the effectiveness of a new implemented service development or pilot. In order to ensure best practice, we treat service evaluations as we do research; therefore, we recommend that researchers follow an informed consent process.
Service user	Person receiving care in our outpatient services.
Study documentation	This refers to all documents that support a project; this includes the protocol, participant information sheet (PIS) and the consent form. Guidance on producing appropriate and effective study documentation can be found on the HRA website: Prepare study documentation - Health Research Authority (hra.nhs.uk) St Andrew's advocates this good practice approach for all projects.
Sponsor	https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#sponsor **St Andrew's as Sponsor:** Practical elements of governance are delegated to the Research Centre.
Volunteer	Volunteers are engaged through Voluntary Services and are required to have qualification relevant to research, for example, a masters in a health-related subject, when they are volunteering as a researcher. Volunteers are matched to research needs and are, generally, supervised by the Head of R&D or the project-leading clinician/allied health professional.

Appendix 2: Principles for Health and Social Care Research

St Andrew's is signed up to the principles set out in the UK Policy Framework for Health and Social Care Research.[1]

The following table lists these principles and references the related St Andrew's requirements, processes and guidance as set out in the *Code of Practice for Conducting Research*.

UK Policy Framework for Health and Social Care Research	Cross reference to the *Code of Practice for Conducting Research*
Principle 1: Safety The safety and well-being of the individual prevail over the interests of science and society.	St Andrew's as a Research Site Safety and risk assessment Protecting patient identify Review Reporting Incidents
Principle 2: Competence All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.	Research Roles and Responsibilities Training and skills
Principle 3: Scientific and Ethical Conduct Research projects are scientifically sound and guided by ethical principles in all their aspects.	Good practice Special category personal data Review
Principle 4: Patient, Service User and Public Involvement Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.	Patient and Public Involvement (PPI) Review
Principle 5: Integrity, Quality and Transparency Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.	Review Project Progress Reporting Appendix 3 Misconduct
Principle 6: Protocol The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents – see Planning and improving research - Health Research Authority (hra.nhs.uk)	Good practice Review Protocol Deviations and Violations
Principle 7: Legality The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.	Review Protecting patient identify

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

Principle 8: Benefits and Risks Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated (A formal, structured risk assessment is only expected where identified as essential. The risk: benefit ratio will normally be sufficiently described and considered as part of review processes such as research ethics committee review.)	Good practice Patient and Public Involvement (PPI) Review
Principle 9: Approval A research project is started only if a research ethics committee and any other relevant approval body (i.e. the HRA, the Administration of Radioactive Substances Advisory Committee (ARSAC), the Human Fertilisation and Embryology Authority (HFEA) or the Medicines and Healthcare products Regulatory Agency (MHRA)) have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.	Review Research Ethics
Principle 10: Information about the Research In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).	Permissions Overview
Principle 11: Accessible Findings Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.	Permissions Overview
Principle 12: Choice Research participants (either directly, or indirectly through the involvement of data or tissue that could identify them) are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit	Specialist Research Support Study documentation Research participants

consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.	
Principle 13: Insurance and Indemnity Adequate (special provision is not expected unless existing arrangements (e.g. professional insurance, membership of NHS Litigation Authority schemes) provide inadequate cover) provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.	Insurance
Principle 14: Respect for Privacy All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.	Data Management Plan (DMP) Protecting patient identify
Principle 15: Compliance Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.	Legal Agreements Managing Misconduct

Principles that apply to interventional health and social care research
In addition to the 15 principles above, the addition four, below, apply to interventional research, i.e. where a change in treatment, care or other services is made for the purpose of research, which is highly relevant to St Andrew's:

UK Policy Framework for Health and Social Care Research	Cross reference to the *Code of Practice for Conducting Research*
Principle 16: Justified Intervention The intended deviation from normal treatment, care or other services is adequately supported by the available information (including evidence from previous research).	Review Research Ethics
Principle 17: Ongoing Provision of Treatment The research proposal or protocol and the participant information sheet explain the special arrangements, if any, after the research intervention period has ended (e.g. continuing or changing the treatment, care or other services that were introduced for the purposes of the research).	Review Research Ethics Study documentation
Principle 18: Integrity of the Care Record All information about treatment, care or other services	Care record

UK Policy Framework for Health and Social Care Research	Cross reference to the *Code of Practice for Conducting Research*
provided as part of the research project and their outcomes is recorded, handled and stored appropriately and in such a way and for such time that it can be understood, where relevant, by others involved in the participant's care and accurately reported, interpreted and verified, while the confidentiality of records of the participants remains protected.	
Principle 19: Duty of Care The duty of care owed by health and social care providers continues to apply when their patients and service users take part in research. A relevant health or social care professional (who may or (particularly where the research team is not local to the research site) may not be a member of the research team) retains responsibility for the treatment, care or other services given to patients and service users as research participants and for decisions about their treatment, care or other services. If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.	Review Research Ethics Protecting patient identify

Appendix 3: Project Development and Project Management

Every project must have a specified Principal Investigator (PI) who has overall responsibility for the conduct and delivery of the project at the site. The PI may delegate specific responsibilities to other members of the research team.

1. PI responsibilities: planning and application

The PI is responsible and accountable for the accurate completion of the project application form including:

- Determining whether their project activity is classified as research or non-research; the HRA decision tool will assist and evidence that decision: Is my study research? (hra-decisiontools.org.uk). More nuanced guidance is also available using the project type decision tree – see Appendix 7a: Identification of Project Type and Appendix 7b: Determining Generalisability and Transferability
- Determining the ethical review requirements – see Research Ethics
- Conducting a risk assessment
- Confirming on the application form that they, and individuals associated with the project have read and understood their responsibilities, as set out in Appendix 2: St Andrew's Research Code of Conduct
- Ensuring financing for the research is in place – see Financing Research
- Provision of a data management plan – see Data management plan (DMP)
- Completion of the project submission checklist on the application form
- Ensuring that all appropriate approvals and permissions are in place at the right time; for example, sign off from their organisation and/or research Sponsor, Research Ethics Committee and/or HRA approvals, as appropriate
- Ensuring receipt of a final letter of approval prior to commencing a project
- Submitting an amended application form, if a change to an approved protocol is required; please note, the most recent version of the application must be used

The above is the same for all projects; the following describes how the process continues and varies between internal and entirely external research:

1.1. Internal research and collaborations

The PI is responsible for:

- Discussing and agreeing workload allocation with their line managers, prior to embarking upon a project
- Establishing the support of the relevant Clinical Director, where projects require patient/service user participation or use of clinical data, prior to submission of the completed project application form

1.2. External projects

The Principal Investigator is responsible for:

- Following any processes that are required by the research Sponsor prior to applying to St Andrew's
- Liaising with the Research Centre to seek the support of the Clinical Director of the division/s involved in the project; this is more appropriately sought after SERAC has given a minimum of conditional approval

2. PI responsibilities: project live

The PI is responsible and accountable for project management and conduct of the project, including:

- Providing regular progress reports

- Reporting project deviations and violations
- Reporting incidents

3. PI responsibilities: project completion

The PI is responsible and accountable for delivering:

- The specified deliverables including a final report
- Updating the participants, where promised
- Dissemination and publication activities

4. Patient and Public Involvement (PPI)

St Andrew's is invested in meaningful PPI activities. Recognising that PPI is not always simple to instigate within a secure mental health setting, the Research Centre can help researchers develop their engagement activities at St Andrew's. This includes seeking feedback to proposed Participant Information Sheets (PIS) from staff and/or patients. The research team is also experienced in advising researchers about what to consider when planning and conducting research within a secure mental health setting – researchers should get in touch via research@stah.org.

5. Participant information and informed consent

It is important that people are informed about and understand what participating in a research project means. They must be told about how their data will be used, have time to consider their participation and have given informed consent. This information is provided in the Participant Information Sheet, and we require that participants in anything excepting an online questionnaire are given at least 24-hours to consider their participation before they are asked for their consent.

6. Patients as active participants (new data collection)

Prior to initiating contact with a patient participant, researchers are required to get in touch with the Responsible Clinician (RC) to obtain permission for approaching the patient. Additionally, confirmation of the patient's capacity to consent to participation must be secured from the RC. While it is recommended to obtain this confirmation in writing, researchers may also speak directly to the RC to expedite the process. In such cases, it is advisable to document the details of the verbal conversation in an email to the RC for clarity and record-keeping purposes. Only after obtaining these approvals should the researcher proceed to arrange a meeting with the patient.

A patient participant must be given a minimum of 24 hours to consider the information sheet and their participation. The researcher who has obtained consent, must scan and upload a copy of the signed informed consent to the document store for the relevant patient's electronic health record. If the researcher does not have access to do this, a request can be made to Health Records via the Research Centre, or a member of the Clinical Care Team can do this.

7. Patients as data only participants (secondary data analysis)

When identifiable clinical data is to be used for research, patient consent must be obtained (as above). However, if the data is anonymised or deidentified in a way that re-identification is very difficult (costs and technology involved), it falls outside the scope of GDPR and may be used without explicit consent. A member of a patient's or service user's care team may render confidential patient information anonymous without breaching the duty of confidentiality,[2] with one key exception: the data of patients who have opted out via the National Data Opt-Out service must not be used for research

[2] Guidance for using patient data - Health Research Authority (hra.nhs.uk)

purposes. This exception also applies to conducting database searches to identify potential participants; the opt-out must be applied before the results are provided to the researcher. Also see – Ethics and permissions relating to the use of secondary data.

8. Delays between consent and data collection

Due to the nature of mental health conditions among patients at St Andrew's, it's crucial to address any delays of more than three weeks between obtaining informed consent and collecting data directly from a patient participant. (NB/ Timeframes detailed in project-specific protocols will take precedence over this guide.) In such cases, researchers are required to reassess the appropriateness of contacting the patient with the RC. Additionally, it is standard good research practice to verbally confirm consent at each subsequent contact with the participant.

9. Dissemination, Publication and Other Comms Activity

9.1. Plain language summaries

Research findings should be made accessible and understandable for study participants, interested groups, communities, and the general public. Researchers are expected to include a plain language summary of their findings in their final report, which should be submitted to research@stah.org.

9.2. Information to participants at the end of the study

Wherever possible, researchers are expected to provide participants with a summary of the findings, as this acknowledges their contribution and respects their involvement. The Research Centre can support external researchers with this activity.

9.3. Publications

It is expected that publication will continue past the end of a project. Research sponsors are expected to encourage publication; this includes encouraging a student to publish, in the case of a postgraduate project. If publication is not forthcoming, research organisations should encourage the principal investigator/lead supervisor to publish any findings. If, within 2 years, there is no expression of intent to publish, research organisations should note that St Andrew's may decide to publish.

Staff must advise the Research Centre about any publications they have authored/co-authored. The Research Centre will add the details to the external website: https://www.stah.org/research-centre/our-research/

Also see: Good authorship practice and Press releases and other comms activities.

Appendix 4: Research Centre Management Team Agenda Template

[Internal use only]

Weekly Management Meeting
[insert date]

No.	Agenda (B/G bullets & question for team)	Meeting notes	Agreed actions
A. PREVIOUS MINUTES			
0	1) Notes agreed 2) Update on actions	Attendees:	
B. UPDATE ON PROJECT PROGRESS REPORTS			
1			
C. PROJECT MANAGEMENT (discuss problematic progress reports, reports of misconduct, reports of protocol deviations – decide whether referral to SERAC required)			
1			
D. PRE-PEER REVIEW ASSESSMENT (Proposed rejections of applications irrelevant to St Andrew's go to the SERAC Chair, who responds only if disagrees)			
1			
E. PROJECTS IDEAS			
1			
F. STRATEGY/STAFFING/ADMIN			
1			
G. AOB			
1			

Appendix 5: Common Legal Agreements

Collaboration Agreement

Collaboration agreements play a crucial role in establishing partnerships with other entities. These agreements outline the terms, responsibilities, and expectations between the Charity and external collaborators, such as other research institutions, industry partners, or community organisations. A well-defined collaboration agreement ensures clarity on data sharing, intellectual property rights, funding arrangements, and ethical considerations. It serves as a foundational document that governs the collaborative research process, promoting transparency, compliance, and effective teamwork within the Charity's research initiatives.

Honorary Research Contracts

The honorary research contract acknowledges the individual's contributions, expertise, or collaboration in a specific area of research. While not serving as a formal employment contract, the honorary position comes with certain privileges, such as access to St Andrew's facilities and involvement in research projects. Individuals holding honorary research contracts do not receive any payment. The duration of an honorary research contract can vary, ranging from a fixed term to an open-ended arrangement. They are typically used for external researchers who are conducting research at or with St Andrew's. the Research Centre are responsible for issuing honorary contracts and associated induction.

Information Sharing Agreement (ISA) aka Data Sharing Agreement (DSA)

An ISA or DSA is a crucial component when collaborating with external entities. This agreement outlines the terms and conditions governing the sharing of sensitive or confidential information between St Andrew's and collaborating partners. It addresses data protection, confidentiality, and the purpose for which the information will be shared. The ISA/DSA ensures compliance with relevant privacy laws and ethical standards, safeguarding the integrity and confidentiality of research data. Clear guidelines on information sharing contribute to transparency, trust, and the responsible conduct of research within the hospital setting.

Memorandum of Understanding (MOU)

A Memorandum of Understanding (MOU) serves as a foundational or preliminary document outlining the broad terms and objectives of collaboration between partnering entities. Typically, a non-binding agreement, an MOU outlines the common goals, roles and general expectations of both parties. It provides a framework for collaboration without delving into specific contractual details. In St Andrew's setting, an MOU is used to formalise partnerships with other research institutions, potential collaborators, or organisations, setting the stage for more detailed agreements or collaborations as projects develop.

Research/Evaluation Contract or Grant Funding

This is a formal agreement that establishes the terms and conditions associated with the receipt and utilisation of funding. This contract outlines the specific project scope, objectives, budget, and reporting requirements as stipulated by the funder. It includes details on the project timeline, milestones, and any specific deliverables expected. The contract ensures compliance with the terms set forth by the funder and provides the project team with a framework for conducting the research. Clear delineation of responsibilities helps to manage expectations and facilitates a smooth collaboration between St Andrew's and the funder.

Appendix 6: Ethic Screening Questions

For use with service evaluation (including service improvement or development and project evaluations) and research projects that do not automatically require REC approval

Does the proposed project have any of the following ethical issues that need consideration before starting?[18]	
Infringe on any patient rights? ☐ Yes ☐ No Patients recruited without consent? ☐ Yes ☐ No Risk breaching any patient's confidentiality or privacy? ☐ Yes ☐ No Place a burden on a patient beyond those of his or her routine care? ☐ Yes ☐ No Involve any clinically significant departure from usual clinical care? ☐ Yes ☐ No	Involve a potential conflict of obligation to patients, for example, a trade-off between quality and cost? ☐ Yes ☐ No Involve the use of any untested clinical or systems interventions? ☐ Yes ☐ No Allocate any interventions differently among groups of patients or staff? ☐ Yes ☐ No Could the findings have implications for a specific patient's immediate care? ☐ Yes ☐ No
If the answer to any of the above questions is yes, the project should have ethical consideration	
We expect projects at St Andrew's to potential to provide direct benefit to patients or improve patient care – is that true for this project? ☐ Yes ☐ No	
If the answer to this question is no, the project should have further ethical/strategic consideration	

Infringing patient rights — Review any activity that limits or restricts patients' rights to make choices about their healthcare, such as restricting access to evidence-based practice.

Risk breaching confidentiality or privacy — Review any of the following situations: collecting or disclosing data that could be used to identify any patient; using such small sample sizes that individual patients can be identified; or having someone collect data who does not normally have access to patients' information or records.

Placing a burden on a patient beyond those of his or her routine care — Review the following types of activities: A patient is required to spend additional time for data collection, provide samples not essential for care or attend extra clinic or home visits; a vulnerable person is required to participate directly; or a patient is asked to answer more than a minimal number of factually based questions or to provide sensitive information.

Involving any clinically significant departure from usual clinical care — Review an activity that varies from accepted current clinical practice or that causes any disruption in the clinician-patient relationship.

Involving a potential conflict of obligation to patients — Review any activity that considers a trade-off between cost and quality for individual patients or a group of patients.

Involving the use of any untested clinical or systems intervention — Consider the risk patients could face if an activity involves implementing a new practice that is not already established.

Allocating any interventions differently among groups of patients or staff — Review if different groups of patients are to be assigned to interventions or treatments or patients are to be recruited to participate in an activity.

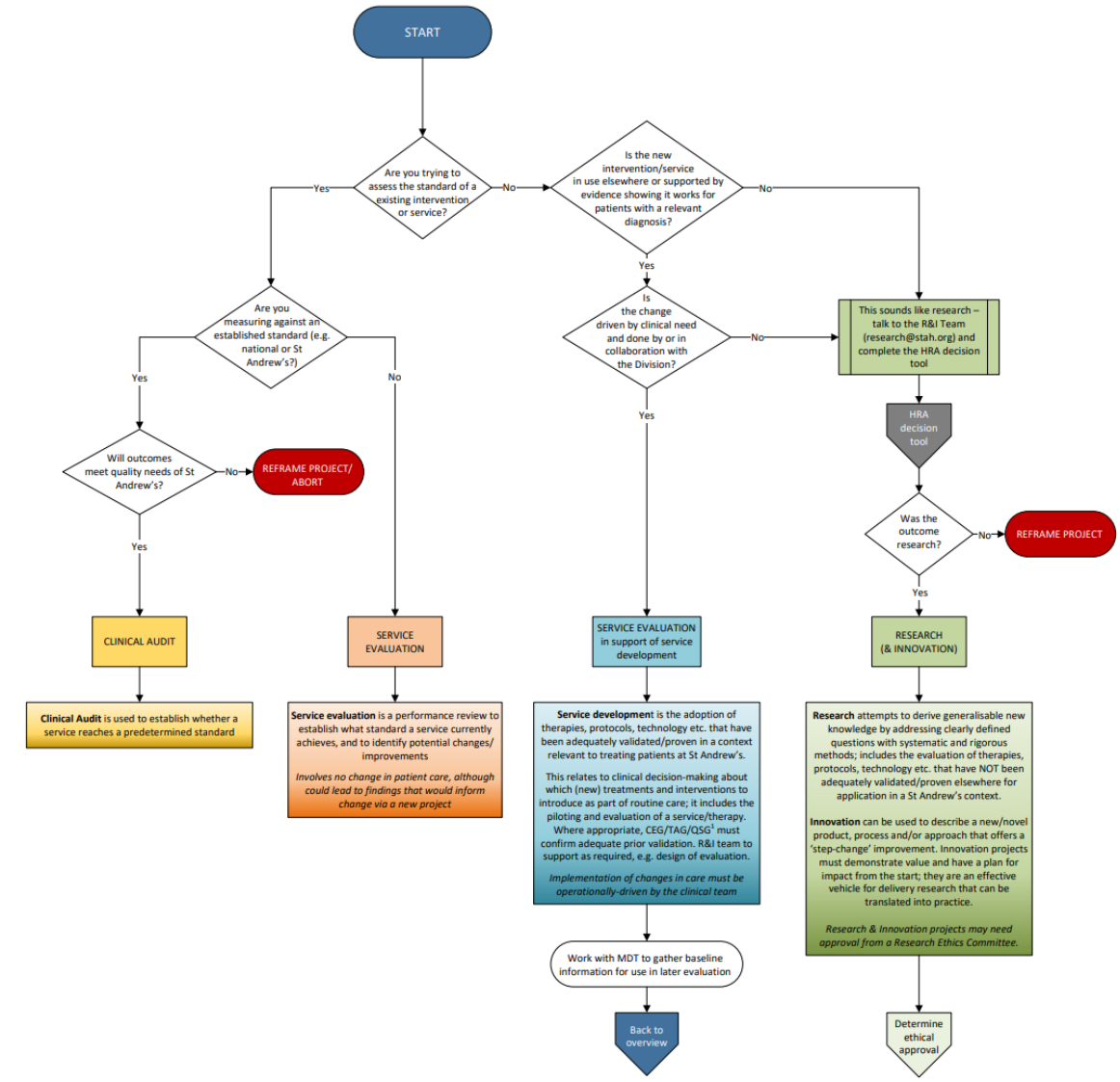
Providing no direct benefit to patients or patient care — Review any activity that does not directly benefit the patients participating to ensure that the risk to patients is acceptable.

Appendix 7a: Identification of Project Type

Also see Appendix 7b: Determining Generalisability and Transferability

Back to overview

Determining Project Type: Clinical Audit, Service Evaluation or Research



This process was developed in conjunction with the Clinical Audit Team

24 March 2022

NOTES
Seeking approval from an Ethics Committee
Any project/assessment/methodology that is likely to cause distress (e.g. discussing sensitive topics with either staff or patients, psychological stress, invasive physical measurements) should be considered for review by a Research Ethics Committee

Abbreviations
[1] CEG = Clinical Effectiveness Group; TAG = Therapy Advisory Group; QSG = Quality & Safety Group

05 February 2024

Appendix 7b: Determining Generalisability and Transferability

One of the key questions in the HRA decision tool: Is my study research? (hra-decisiontools.org.uk) is: *Is your study designed to produce generalisable or transferable findings?*, which researchers may find difficult to answer. The following guidance is intended to help researchers conducting St Andrew's-sponsored projects answer this question.

When determining whether findings are going to be generalisable or transferable, you should base your decision on the intent and design of your project, as well as how you plan to present and interpret the results. Here are some key points to consider:

1. **Intent and Design**
   - If your project is designed to test a hypothesis and generate broadly applicable knowledge, it is considered research.
   - If your project is designed to assess and improve specific services within St Andrew's without the intent to generalise findings, it is considered a service evaluation. The same applies to the evaluation of an intervention or approach throughout.

2. **Methodology**
   - Research projects typically use rigorous, systematic methodologies that are designed to produce findings applicable to wider contexts.
   - Service evaluations/evaluations focus on specific contexts and may use methodologies suited for internal improvement rather than broad application.

3. **Publication and Presentation**
   - If you intend to publish your findings in an academic journal with a focus on generalisability or transferability, then your project is research.
   - If your intention is to improve practice at St Andrew's, i.e. internal use, then your project is likely a service evaluation or evaluation even if you publish the findings. Any external use by others is secondary and based on their interpretation (see the recommendation, below, for using a disclaimer).

4. **Generalisability and Transferability**
   - If the primary goal is to produce findings that you explicitly intend to be applicable and beneficial to other settings or organisations, your project is likely research. This includes designing the study with the intent that others will adopt or adapt the findings.
   - If the primary goal is to improve or evaluate services or interventions/approaches within St Andrew's, without the explicit intent to promote the findings for use in other settings, your project is likely a service evaluation. Even if findings might be useful elsewhere, the original intent is focused on internal improvement.

Researcher Responsibility

You must be clear about your intent and the scope of your projects from the outset. Including an explicit statement in any publications about the scope and intended use of findings can help support your decision about a project's classification and subsequent approach to research ethics. If findings from a service evaluation are published, including a clear disclaimer can help manage expectations about generalisability – see Service evaluation disclaimer.

Appendix 8: SERAC Terms of Reference

Terms of reference and meeting dates are available from: Peer review (sharepoint.com).

Appendix 9: Project Application Review Form

Please access the latest version of the review form via the online folder: templates.

Appendix 10: Grants: pre- and post-award management

The Principal Investigator (PI) is responsible for preparing grant applications and managing any funding that is awarded.

Bid Development
Protocol development is undertaken according to the roles and responsibilities agreed within the specific project team. The protocol will be submitted for approval via SERAC at the appropriate time, ahead of project start. Where funding deadlines permit, the protocol will be submitted to SERAC prior to bid submission.

Costings that are required for inclusion in the bid are based on a method of calculation agreed that has been agreed with the Finance Business Partner (FBP). The PI must provide the final figures to the FBP for comment, ahead of submission.

Where appropriate, the Business Development Team should be involved.

Bid Submission
St Andrew's approval to enter into a contract is necessary prior to submitting a bid, as per the Financial and Contractual Authorisations Policy. In the case of a two-stage funding process, notifying the Legal Team, Business Development Team, and CFO about the intention to submit a bid is sufficient at that stage. If the bid is successful, formal approval to proceed with the contract should be obtained from both the Legal and Finance Teams before the second-stage submission.

Documentation and Requirements
The PI must share contract terms and conditions with the Legal Team at the earliest opportunity.

Post-Award Tracking and Reporting
Grant tracking, project reporting and delivery must be conducted in line with funder requirements and are the responsibility of the PI.

St Andrew's financial reporting is done in liaison with FBP, as per usual St Andrew's procedures.

The Research Centre is available to provide support to PIs in the above areas, subject to capacity. PIs may ask for the Research Centre support in as much or as little as required. If PIs do not require support from the Research Centre, the expectation is that they will adhere to the grant requirements and St Andrew's policies.

Appendix 11: The Research Centre

The Research Centre team comprises a Head of Research & Development (R&D), Senior R&D Project Manager and Research Administrator.

In addition to governance functions, the Research Centre offers general research-related support across the Charity. This includes managing research placements, overseeing research equipment and software, and providing various services to Principal Investigators. These services encompass project planning, recruitment of researchers, external funding bid submissions, research communications, and facilitating research implementation. The level of support provided by the Research Centre is contingent on capacity and prioritised based on St Andrew's strategy, with requirements to be discussed with the Head of R&I.

The Research Centre is responsible for:

- Conducting research
- Supporting staff and patients to conduct research
- Supporting with pre- and post-award grant management – see Appendix 10: Grants: pre- and post-award management)
- Leading on several key collaborations; including providing a supervisory role for collaborative PhD studentships
- Supporting with Legal Agreements
- Supporting with Research Placements
- Managing the research misconduct process
- Conducting pre-assessments of project applications
- Providing administrative support to SERAC
- Overseeing critical governance aspects of research at St Andrew's, including the Charity's role as both a research Sponsor and research site
- Ensuring compliance with regulatory standards
- Arranging RiO training for researchers and requesting access to electronic health records via the Health Records Team
- Monitoring project progress – see Project Progress Reporting
- Participating in various ad hoc activities, such as representing St Andrew's at research forums and coordinating research events and conferences
- Collecting and recording project progress information provided by Principal Investigators
- Producing a Research Centre report
- Reporting adverse events, near miss, incident reporting, deviations and violations and misconduct associated with research projects and service evaluations and reporting them on a quarterly basis to SERAC
- Developing research communications to promote the research that is being carried out at St Andrew's
- Maintaining a database of all projects covered by the *Code of Practice for Conducting Research*, referred to as the Project Master List, on behalf of the Charity. This resource is kept as an Excel spreadsheet and is used to monitor the progress of projects undertaken in the Charity and generate portfolio reporting
- Reporting on research for Quality Accounts purposes on behalf of the Charity
- Maintaining an up-to-date list of all publications on St Andrew's external website: Our research » St Andrew's Healthcare (stah.org) on behalf of the Charity. See Publications

Support is subject to expertise and capacity; Principal Investigators are encouraged to discuss requirements with the Head of Research & Development at the earliest

opportunity. Support requirements may require the Principal Investigator to provide additional funding.

For delegated governance activities, the Research Centre operates under the St Andrew's Healthcare logo. For certain Research Centre projects, the team may deem that the Research Centre logo is appropriate to use.

Key internal collaborators

Appendix 12: Table of assurance processes

Key standards	Assurance Method	Recording and Monitoring Method	Team responsible for monitoring	Frequency of monitoring
Compliance with Ethics Requirements	i) Pre-assessment ii) SERAC review of application form	i) Recorded in management team notes ii) Recorded in project master log iii) Monitored via audit	Research Centre	i) Ad hoc (usually weekly) ii) Ad hoc iii) Annual
Regulatory Compliance	Completion of GCP and CV requested with external applications (regulatory compliance requires for clinical trial *only*; St Andrew's follows similar good practice for all projects)	Audit	Research Centre	Annual
Legal Agreements	Collaboration with Legal Team	Recorded in project folder	Research Centre	Yearly
Finance: i) Contracts ii) Investment by Charity iii) Bid submission	i) Authority Matrix ii) External peer review & SERAC review iii) SERAC review	i) Recorded in project folder ii) Monitored by review of individual projects	Research Centre	Annual
Research Protocol Review and Approval	SERAC review of application form	i) Recorded in project master log ii) Monitored via audit	Research Centre	Annual
Informed Consent Processes	SERAC review of application form	Review of individual project	Research Centre	At each project review
Study Documentation	SERAC review of application form	Audit	Research Centre	At each project review
Data Management and Security	i) SERAC approval ii) DPIA process, where required iii) Honorary contract terms & conditions	Review of individual project	Research Centre	At each project review
Data retention and destruction	i) Data destruction process undertaken by the Research Centre when engaged to do so	Review of individual project	Research Centre	Annual
Conflict of Interest Management	SERAC terms of reference	Review of SERAC notes	Research Centre	Annual report to EMD
Research Output and Impact	SERAC delivery assessment	i) Recorded in project master log ii) Monitored via audit	Research Centre	Annual
Adverse Event, Near Miss, Incident Reporting	Reviewed via Datix process	i) As per Datix policy ii) Review of individual project	i) As per Datix policy ii) Research Centre	i) As per Datix policy ii) Quarterly report to SERAC
Research Misconduct	Via Research Misconduct process	Review of incident	Research	Quarterly report to SERAC

Appendix 13: Procedure for the Investigation of Research Misconduct

Introduction

St Andrew's is committed to supporting the highest standards of integrity, ethics and compliance in the conduct and delivery of research and non-research projects, such as service evaluations.

Misconduct in research can have wide-ranging and damaging consequences, harming the integrity of research, bringing the individuals involved and the organisation into disrepute and causing harm to those involved. This holds true for non-research projects, such as service evaluations. It is therefore important that organisations have robust procedures to investigate alleged misconduct fully and fairly.

It is the responsibility of all persons authorised to undertake research at St Andrew's or using St Andrew's sourced data to be aware of their responsibilities and obligations in carrying out research.

Purpose and scope

This procedure covers allegations of research misconduct brought forward by a Complainant against an individual authorised to conduct any activities that are in scope of *Code of Practice for Conducting Research*. St Andrew's views all instances of misconduct with seriousness and has the authority to propose significant penalties for those found guilty of research-related misconduct. Determining whether an allegation of misconduct qualifies as research misconduct, falls under another institutional process, requires referral to an external organisation, relates to poor practice and requires informal resolution or is dismissed will be determined by the Head of Research & Development (R&D).

Definitions

Research misconduct encompasses behaviours or actions that deviate from the code of conduct detailed in the *Code of Practice for Conducting Research*, standards of ethics, research, and scholarship, posing risks to individuals, the environment, and the integrity of research outcomes. Examples include:

- Fabrication: such as making up results, other outputs (for example, artefacts) or aspects of research, including documentation and participant consent, and presenting and/or recording them as if they were real
- Falsification: such as inappropriately manipulating and/or selecting research processes, materials, equipment, data, imagery and/or consents
- Plagiarism: using other people's ideas, intellectual property or work (written or otherwise) without acknowledgement or permission
- Failure to meet legal, ethical, and professional obligations: such as not getting appropriate ethical approval, misusing personal data, inappropriate disclosures of participants, failure to declare conflicts of interest, misappropriation of material
- Misrepresentation: such as of results, inappropriate claims of authorship
- Improper dealing with allegations of misconduct: such as failing to address possible infringements
- Deviation from the requirements listed in the *Conduct of Research at St Andrew's Healthcare*

Honest errors and differences in, for example, research methodology or interpretations, do not constitute research misconduct. Additionally, minor infractions or honest errors, especially by less experienced researchers, can often be addressed informally through mentoring and education.

An investigation of misconduct is not, itself, a disciplinary process, though that may follow if it establishes that misconduct in research took place. When allegations of research misconduct are upheld, in full or in part, this may result in action being taken under St Andrew's Healthcare's disciplinary procedures.

Researcher refers to any person authorised to undertake research including a postgraduate student, a member of staff and persons not employed by St Andrew's, but who is carrying out research under the auspices of the Charity or on Charity premises.

Other definitions are contained within Misconduct Investigation Procedure - UK Research Integrity Office (ukrio.org)

Key principles

St Andrew's adopts the Procedure for the Investigation of Misconduct in Research (UK Research Integrity Office). The latest version of the procedure is available from their website: https://ukrio.org/ukrio-resources/publications/misconduct-investigation-procedure/

- The Head of R&D is responsible for receiving any allegations of misconduct in all in scope activities, initiating and supervising the procedure, maintaining a record of information during the investigation, and taking decisions at key stages of the procedure; the Chair of SERAC will act as Research Integrity Officer
- If allegations concern misconduct by a staff member while on St Andrew's premises or while using data collected from St Andrew's for a project undertaken as a student at a university, they will be addressed according to St Andrew's disciplinary procedures; the university, likely the research sponsor, will be notified and may wish to follow their own procedures alongside
- **Researchers** will**:**
    - Act in good faith and cooperate in investigations
    - Report misconduct promptly to appropriate authorities
    - Manage conflicts of interest transparently
- **St Andrew's as an employer of researchers** will:
    - Establish clear, confidential channels for reporting research misconduct allegations.
    - Implement fair investigation processes with independent members and clear appeal routes.
    - Ensure all staff know how to report misconduct and protect whistleblowers from reprisal.
    - Resolve issues found during investigations, including imposing sanctions and correcting research records.
    - Protect the reputation of individuals found innocent of misconduct.
    - Inform funders, regulatory bodies, and professional organisations about misconduct investigations.

- Support researchers in providing required information to professional and statutory bodies.
- Designate a confidential liaison for whistleblowers or concerned parties.

Reporting Procedure[3]

Any individual who suspects research misconduct is encouraged to report the concern promptly, adhering to the following steps:

1. Reports should be promptly submitted to the Head of Research & Development (R&D), providing detailed descriptions of alleged misconduct.
2. Anonymous reporting is accepted in accordance with the Charity's freedom to speak up policy.
3. Detailed descriptions of the alleged misconduct should include relevant dates, individuals involved, and any supporting documentation. Providing contact information can assist in the investigation.

Investigation Process

The Head of R&D will oversee the initial assessment, adhering to the following steps:

1. An initial assessment of the reported misconduct will be conducted to determine whether what has been raised falls within the remit of the procedure. If it does not, for example because what is alleged is not classified as research misconduct or it relates to research not conducted at the institution, then the Head of R&D will explain to the Complainant why it cannot be investigated under this procedure and recommend an alternative course of action where appropriate.
2. If the alleged misconduct does fall within the auspices of the procedure, then the person or people against whom the allegations have been made (typically known as the Respondent) will be informed.
3. An initial assessment of the information available and investigation will be carried out to determine whether there is sufficient evidence of research misconduct to warrant a full investigation or whether alternative action should be taken. Alternative action may be referral to another organisation, that the matter can be addressed by education or training, or that the matter should be dismissed. The Respondent will be given the opportunity to respond to the concerns raised.
4. If the initial investigation shows that there is sufficient cause for concern, then:
    a. For live projects, the Head of R&D will decide whether the project needs to be formally halted
    b. The Executive Medical Director will be informed; additionally, in cases with financial or contractual implications, the Chief Finance Officer and Legal Director will be notified; in cases involving St Andrew's employees, HR will be informed
    c. An investigation panel or named investigating manager will be appointed to conduct a full investigation
5. The panel/investigating manager will seek to determine whether there is evidence that research misconduct occurred, by whom and its level of intent and seriousness. It may also make recommendations on how to correct the record, for example if there have been publications that have been plagiarised from elsewhere or which include flawed, falsified, or fraudulent data. Alternatively, it may find that there is no substance to the allegations or evidence to support it, and that they were mistaken or

[3] Procedure informed by: Procedure for the Investigation of Misconduct in Research (ukrio.org)

malicious. Unsubstantiated allegations that are deemed to be malicious are considered an act of misconduct, in line with St Andrew's Disciplinary Policy

6. The panel/investigator will produce a report of findings that will be sent to the Head of R&D. The Head of R&D will seek to correct the published record of the research in question, informing any funders or other bodies that need to be informed. Where no substance to the allegations is found, they may take action to ensure the reputation of the individual against whom the allegations are made is preserved.
7. Based on the investigation findings, appropriate action will be taken, which may include corrective measures, disciplinary actions (in line with the Charity's Disciplinary Policy for misconduct committed by an employee of St Andrew's), or referral to external authorities, where appropriate.
8. Individuals' right to appeal are as outlined in St Andrew's Disciplinary Policy.

Confidentiality will be maintained throughout the investigative process, in accordance with legal requirements. Only individuals directly involved in the investigation will be informed. Relevant parties, including the respondent, will be kept informed of the investigation and its findings at appropriate stages, while maintaining confidentiality.

Misconduct Involving External Researchers

In cases involving external researchers holding honorary contracts:

- The individual's substantive employer will be informed of the intention to pursue an investigation
- If alleged misconduct took place at another organisation, they will be responsible for conducting the investigation. In this instance, as much information will be gathered at St Andrew's and forwarded to the external organisation
- It is the responsibility of the substantive employer to undertake any further disciplinary action

Misconduct By a Member of SERAC

There are some nuanced definitions of misconduct for individuals acting in the capacity of SERAC, which are detailed in the SERAC terms of reference.

Additional Actions

Where appropriate, the Head of R&D may take the following actions:

- Revoke honorary contracts with immediate effect, with researchers involved in proven misconduct risking future employment at St Andrew's
- Report misconduct to regulatory and approval bodies (such as MHRA, HTA, HRA, GMC)

Monitoring Misconduct

Instances of misconduct will be shared with SERAC on a regular basis, who will report into Research Committee.