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Keele University Health and Social Care Research Policy

Policy Reference Number:	HSCR-POL-01		
Author	Dr Tracy Nevatte, Head of Project Assurance		
Approver	University Senate Committee	**Date**	02-July-2020
Version Number	2.2	**Version date**	02-July-2020
Implementation	This policy will be implemented directly after its approval date.		

Printed versions of this document are uncontrolled and cannot be assured as the current version. Always check that the most up to date version is being used by only accessing via the web link.

Once approved by the University's Research Committee, the latest version of this policy will be found at https://www.keele.ac.uk/policyzone/
Any superseded versions of this document need to be promptly withdrawn from use.

Equality issues have been taken into account during the development of this document/policy/review and all protected characteristics have been considered as part of the Equality Analysis undertaken.

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Contents

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1. Summary

This Policy applies to all Keele University staff members, Keele University honorary contract holders and others within Keele University who are actively involved in health and social care research. ***Health and social care research*** is research that falls under the UK Policy Framework for Health and Social Care Research. This means research which is concerned with the protection and promotion of public health, research undertaken in or by the Department of Health, its non-Departmental Public Bodies and the NHS, and research undertaken within social care agencies. It includes clinical and non-clinical research undertaken within the health and social care systems that might have an impact on the quality of those services.

All staff members within Keele University involved in health and social care research must adhere to this policy, in addition to other relevant university policies. By reading this document, anybody conducting research in this setting should be aware of what is expected of them.

2. Background

A key objective of health and social care research at Keele is to improve the health and welfare of individuals with health conditions by producing world-leading research that impacts across the field, ranging from the laboratory investigation of cellular mechanisms to developing and testing innovative clinical interventions. Keele is committed to supporting and conducting research to the standards set by the **UK Policy Framework for Health and Social Care Research**.

To ensure a positive research environment and standardisation of practice, Keele University has set up a Health and Social Care Research Quality Management System (HSCR QMS), of which this policy forms part. The Quality Management System is a suite of documented procedures, training provision and quality control/quality assurance processes, which ensures legislative compliance across all aspects of health and social care research managed and conducted by Keele University as well as meeting the expectations of funders, collaborators and participants.

The Quality Management System serves as a training tool as well as a framework so that any staff member following the Quality Management System can be assured that the safety and wellbeing of participants are protected, data integrity is maintained and that the research is conducted in compliance with Good Clinical Practice, regulations, national standards and University policies.

3. Policy on research legislation and frameworks

Research is governed by regulatory requirements, internationally accepted standards and governance frameworks, all with the ultimate aim to ensure participant safety and data quality. Any researcher involved in health and social care research must identify, familiarise themselves with and adhere to any applicable regulations, standards and governance frameworks.

The key regulatory frameworks are summarised below:

Any health and social care researcher is expected to follow the principles captured in the **Declaration of Helsinki (World Medical Association, 2008)**. This sets ethical principles for medical research involving human subjects, including research on identifiable human material and data.

In addition, the **UK Policy Framework for Health and Social Care Research** must be adhered to. The **UK Policy Framework for Health and Social Care Research** includes clinical and non-clinical research, research undertaken by NHS or social care staff using the resources of health and social care organisations, and any research undertaken by industry, charities, research councils and universities within the health and social care systems that might have an impact on the quality of those services. The **UK Policy Framework for Health and Social Care Research** requires any research to have a designated ***sponsor***, this being defined as the individual, organisation or partnership that takes on overall responsibility for proportionate, effective arrangements being in place to set up, run and report a research project.

Some of the ***International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Guidelines*** (ICH, 2012) have been adopted into European and UK law, in particular, the guidelines on the principles of **Good Clinical Practice ('ICH-Good Clinical Practice')**.

In addition, in 2004 the **European Union Clinical Trials Directive** became effective, which applies to all clinical trials using an **Investigational Medicinal Product** (IMP); these clinical trials are referred to as 'CTIMPs'. An IMP is defined as 'a pharmaceutical form of an active substance or placebo being tested or used as a reference in a clinical trial, including products already with a marketing authorisation but used or assembled (formulated or packaged) in a way different from the authorised form, or when used for an unauthorised indication, or when used to gain further information about the authorised form'. The Clinical Trials Directive and any other related directives and guidelines can be found in Eudralex Volume 10 (European Committee, 2012). In the UK, the Clinical Trials Directive is embedded in national law via **The Medicines for Human Use (Clinical Trials) Regulations 2004** (SI 1031) (as amended).

Where the clinical trial involves the use of a non-CE marked medical device, then the provisions of the **Medical Devices Regulations 2002,** (as amended) and any subsequent amendments thereof, apply.

In the UK the **Mental Capacity Act (HM Government, 2005)** has been set up to help facilitate research involving adults lacking mental capacity. The Act provides a framework allowing their inclusion in research (other than CTIMPs) that may benefit those with disorders whilst safeguarding this vulnerable group when they do participate in research.

When working in health research, other guidelines and laws have to be adhered to, for example the Data Protection Act, Equality Act, Freedom of Information Act, Human Tissue Act, legislation specific to children and vulnerable adults, any other professional codes of conduct and local University and NHS Trust policies.

4. Policy on Quality Management and Compliance

The **Project Assurance Research Integrity** Team (PARI; see section 6.4) is responsible for the management and development of the Keele Health and Social Care Research Quality Management System (HSCR QMS) covering key processes that must be followed when conducting health and social care research. The **Health Research Oversight Committee** (HROC; also see section 6.3) have oversight of this Quality Management System.

University research teams and units may have their own Standard Operating Procedures (SOPs), or equivalent, covering local activities. If local procedures are in place, these must meet the minimum standards set out within the Health and Social Care Research Quality Management System Standard Operating Procedures and a local staff member (or group) should take responsibility for ensuring that local processes meet the standards required by the Keele HSCR QMS and ensure that local procedures remain compliant with University requirements.

Where Keele University sponsors research that is to be (partially) managed outside the University (e.g. research managed by an external United Kingdom Clinical Research Collaboration registered Clinical Trials Unit (CTU)), their Quality Management System must be assessed as meeting the same standards (or higher) than Keele University's Health and Social Care Research Quality Management System. The Project Assurance Research Integrity team (or their delegate) will review the external QMS for compliance with applicable standards, guidelines and regulations relating to health and social care research.

5. Policy on Keele University Approval of Clinical Research

Given the complexity of health and social care research, Keele University as an institution is involved in the review and approval of research that are either (co-)sponsored or hosted by Keele University.

5.1 Keele University as the Sponsor

Keele University is prepared to act as sponsor for research under the **UK Policy Framework for Health and Social Care Research** and the **Medicines for Human Use (Clinical Trials) Regulations**, provided that the criteria listed in its Quality Management System in regards to sponsorship are met. As the sponsor, Keele University takes responsibility for the initiation, management and financing (or arranging the financing) of the research. In order to undertake this role, Keele University must therefore satisfy itself that the research meets the relevant standards and ensure that arrangements are put and kept in place for management, monitoring and reporting. The **Project Assurance Research Integrity** Team makes the initial decision on sponsorship through a triage process outlined in the QMS, and will liaise with the Chief Investigator if any of the criteria listed are not met, with the aim to resolve any issues and may refer any issues to other experts, e.g. Health Research Oversight Committee, Pharmacists, Statisticians or Clinical Trials Unit staff.

Only individuals listed in the **Delegation of Sponsor Signatories** document are authorised to confirm sponsorship. No other individuals have the authority to do so.

As sponsor, Keele University may formally delegate one or more of the elements of sponsorship, but it remains accountable for all aspects of sponsorship whether delegated or not.

Where Keele University accepts the role as sponsor, the Chief Investigator will confirm their acceptance of Chief Investigator responsibilities and sponsor duties delegated to the Chief Investigator via a **Delegation of Sponsor Functions Agreement**. It is expected that sponsor functions delegated to the Chief Investigator may be further delegated to suitably qualified / trained staff members within Keele University but may also be delegated externally where appropriate.

For Keele University sponsored studies, the University will confirm approval of protocols by authorisation of IRAS forms for submission of research documentation to the regulatory body, Health Research Authority (HRA) and/or NHS research ethics committee (REC). The sponsor must be notified of all amendments to the protocol, both substantial and non-substantial. Review and authorisation of amendments by the sponsor will act as the confirmation that the sponsor confirms approval of the amended protocol and / or associated research documents.

If Keele University agrees to act as sponsor, full sponsorship will be confirmed in writing, with a clear documented audit trail where conditions of sponsorship have been set and (where necessary) fulfilled.

5.2 Keele University as a Co-Sponsor

Exceptionally, Keele University may share the sponsor responsibilities with another institution, where Keele University and the co-sponsor each take responsibilities for certain aspects of a research project. In this case a co-sponsorship arrangement will be put in place specifying the responsibilities for each co-sponsor. Situations where co-sponsorship may be considered are:

- The design of the research has been led by one party, but coordination will be by the other
- A collaborating partner is better resourced to conduct a specific aspect of a project
- The Chief Investigator is based at another institution (see below)

Co-sponsorship will not usually be undertaken, but may be considered only when based on a clear and robust risk assessment.

Where Keele University acts as a co-sponsor, the University (through its Project Assurance Team or other delegation) will maintain contact with the external co-sponsor to ensure appropriate oversight is maintained.

Keele University will not take on a joint sponsorship role, as this arrangement will not allow for a clear division of responsibilities.

5.3 Delegation of Sponsor Functions

Where another institution is to take on a significant area of operational duties for a research project this will be by way of formal delegation of sponsor functions through a legally-binding contract or similar signed on behalf of the University.

Where a United Kingdom Clinical Research Collaboration registered Clinical Trials Unit external to Keele University takes on the trial management of the trial, it is expected that the contractual agreement between Keele University and the external registered Clinical Trials Unit will clearly explain the following -

- A clear description of the division of responsibilities and duties between the Sponsor, Chief Investigator and the Clinical Trials Unit

- A clear agreement as to which Quality Management System is going to be adhered to. Where the external Quality Management System is to be used, the Project Assurance Research Integrity team, the Chief Investigator and the research team must satisfy themselves that the proposed Quality Management System meets (or exceeds) the standards required by Keele University as described in its Health and Social Care Research Quality Management System. This assessment will be documented and kept on file in the (Study) Master File by the Chief Investigator (or their delegate) and by the Project Assurance Research Integrity team in their Sponsor File.

The Chief Investigator and their team are responsible for overseeing that the terms in the contractual agreement are met.

5.4 Withdrawal of Sponsorship

Where in the view of the Head of Project Assurance, circumstances represent an inability for Keele University to execute its responsibilities fully as sponsor or an unacceptable risk to Keele University or research participants, they may recommend action to the Director of Research, Innovation and Engagement (or their delegate). The Director of Research Innovation and Engagement (or their delegate), without limitation, may mandate, the temporarily halt, suspension or termination of the research or seek to transfer sponsorship to another organisation or any other appropriate action to protect participants or the University.

Where the Chief Investigator plans to leave the employment of Keele University, or take a period of prolonged absence, the following options are available:

- Transfer sponsorship of the research to the Chief Investigator's future employer, with their consent
- Retain sponsorship with contractual agreement with the Chief Investigator's future employer
- Retain sponsorship and appoint an alternative Chief Investigator based at Keele University
- Early termination of the research

The most appropriate option will be recommended by the Head of Project Assurance and ratified by the Director of Research, Innovation and Engagement (or their delegate).

5.5 Keele University as Host

In many cases, Keele University takes on the role of managing and coordinating health and social care research or conducting discrete bodies of work in the analysis of research material on behalf of or in collaboration with an external Sponsor. This means that Keele University undertakes delegated duties for management and/or local conduct of the research as a hosted duty as agreed with the Sponsor

Examples, though not exhaustive, would be providing the services of a Clinical Trials Unit, and/or undertaking one or more individual tasks such as monitoring, pharmacovigilance, Investigational Medicinal Product supply, database development, data management and statistical expertise.

A contract must be in place at the start of the research to describe what tasks are delegated to Keele University. Where Keele University undertakes specific tasks, it is responsible for ensuring those tasks are conducted as expected and in line with the relevant Quality Management System. The Academic Lead at Keele is responsible for ensuring that the standard of procedures that they are required to work to (where not Keele's) meet or exceed those as described within Keele's QMS.

5.6 Keele University as a Research Site

A research site is defined by the HRA as an organisation or unit responsible for conducting any of the research procedures at a particular locality. This is limited to research activity which has direct interaction with research participants. Keele University will not normally act as a non-NHS site for Clinical Trials of Investigational Medicinal Products, device trials or other trials altering patient care. No participants will receive interventions for clinical trials requiring clinical trial authorisations on Keele University premises. While exceptions may occasionally be made, where an exception is made this will be documented in writing and authorised by the Head of Project Assurance.

5.7 Global Health and Social Care Research

Where a health and social care research project is to be delivered outside of the UK and Keele are the lead organisation for the research, the Project Assurance Research Integrity team will assess the most appropriate sponsorship arrangements. All global health research partners and projects must go through the University's due diligence process. Actions relating to the outcomes of the due diligence and risk assessment process will be overseen by the Head of Project Assurance or their delegate. Where required, issues may be escalated to the Health Research Oversight Committee (HROC).

6. Policy on Research Oversight

Keele University in its role as sponsor and host for health and social care research has set up an infrastructure for maintaining appropriate oversight and uses a number of committees, groups and individuals that are fully committed to research oversight.

6.1 Senate

The Senate is the academic governing body of Keele University. Its responsibility is to direct academic policy in relation to teaching and research, and to assure itself that Keele University's academic standards are properly observed.

6.2 Research Committee

The Research Committee is one of the Senate committees, and is responsible for all matters concerning the management of, and support for, Keele University research.

6.3 Health Research Oversight Committee (HROC)

The Health Research Oversight Committee is coordinated by Project Assurance Research Integrity and the minutes/reports are made available to the Research Committee. The Terms of Reference include (but are not limited to):

- Oversight of the framework for, and implementation of, sponsorship arrangements for health and social care research
- Oversight of the development, management and scope of the Quality Management System documentation
- Oversight of Keele University's health and social care research audit programme, its delivery, findings, their resolution and escalation
- To review the outcomes of external audits and inspections of the University's portfolio of clinical research and to monitor the implementation of agreed audit or inspection recommendations
- Oversight of the development and delivery of Keele University training in relation to the roles and responsibilities undertaken by University staff for health and social care research
- Ensuring that all health and social care research is carried out in line with applicable legislation and best practice
- Provision of expert input on health and social care management processes
- Assessment of situations requiring Keele University to consider its role as sponsor

6.4 Project Assurance Research Integrity Office

Project Assurance Research Integrity is responsible for the day-to-day management of Keele University's sponsor oversight systems.

Project Assurance Research Integrity coordinates:

- Sponsor level quality control functions, including sponsor review of research documentation.
- Peer review for clinical research that has not otherwise received adequate peer review as part of a grant awarding body, funder review process or research development process.
- Development and management of the University's Health and Social Care Quality Management System.
- Research audits across Keele University, focussing on the controls that faculties have put in place to ensure appropriate governance, risk management, quality and adherence to regulations, the Quality Management System, and University policies and processes.

- The University's training in relation to health and social care research where not provided on a local level.
- Oversight of external inspections, assessments or visits including resolution and escalation as necessary.

6.5 Keele Clinical Trials Unit

Keele Clinical Trials Unit reports into the Faculty of Medicine and Health Sciences at Keele University. Keele Clinical Trials Unit holds full registration status with the UK Clinical Research Collaboration (UKCRC) Network (Clinical Trials Unit registration number 36), and receives funding from the National Institute for Health Research core funding and research grant income. The Clinical Trials Unit has processes in place to support the development of new clinical research studies, including clinical trials, and a process of requesting Keele Clinical Trials Unit collaboration prior to research grant submission.

Where research has been adopted by Keele Clinical Trials Unit, the Unit holds accountability for the day to day management of the research delegated to it by the Sponsor. Any risks identified within the Clinical Trials Unit are escalated to Clinical Trials Unit Operations group, the Clinical Trials Unit Leadership group, the Faculty Research Committee, Health Research Oversight Committee and/or Sponsor (as deemed necessary).

Any risks identified within the Clinical Trials Unit are escalated through Clinical Trials Unit operational pathways to the host Faculty and ultimately the Research Committee.

The CTU manages activities relating to United Kingdom Clinical Research Collaborative registration of Keele Clinical Trials Unit as they relate to the Quality Management System, with the support of the PARI team.

6.6 Organogram of Keele University oversight in Health and Social Care Research

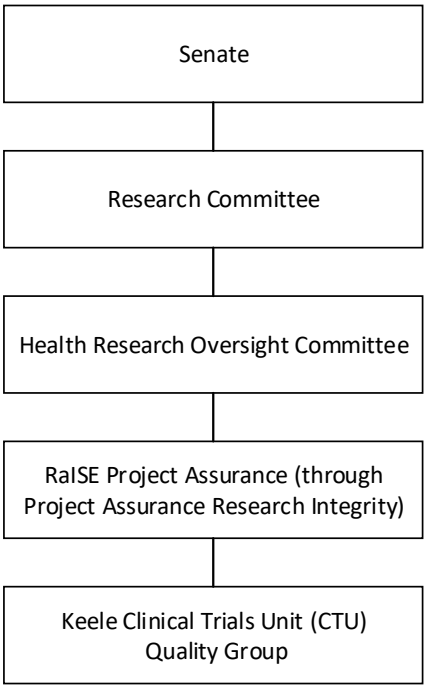

Figure 1 - Overview of Research Governance Structure

7. Policy on Research Staff

7.1 The Chief Investigator

The **Chief Investigator** is the researcher who takes primary responsibility for the conduct of the research.

The University follows the guidance of the Health Research Authority (HRA) when agreeing who can be the Chief Investigator for a research project. A researcher must be qualified by education, training and experience and have a contract with Keele University to take on the role of Chief Investigator. By doing so, they take on responsibilities as assigned to the Chief Investigator in the UK Policy Framework for Health and Social Care Research. For a Clinical Trial of an Investigational Medicinal Product, the Chief Investigator must also be an **authorised, registered health professional (specifically either a doctor, dentist or pharmacist),** and the Chief Investigator takes on the Chief Investigator responsibilities as described in the UK Policy Framework for Health and Social Care Research and the Medicines for Human Use (Clinical Trials) Regulations. Keele University has developed a 'Delegation of Sponsor Functions Agreement' which summarises these responsibilities. The Chief Investigator must sign this declaration, thereby confirming they will take on the responsibilities assigned to them.

Where the research is externally sponsored, the Chief Investigator must inform Project Assurance Research Integrity of their role in the research so appropriate insurance cover for the Chief Investigator can be put in place.

7.2 The Principal Investigator, Local Collaborator or Associate Investigator

A Principal Investigator is a person responsible for the conduct of research at a research site. The Principal Investigator may take on the responsibility individually or acting as a leader of multiple departments within the site. For a Clinical Trial of an Investigational Medicinal Product, a principal investigator at a clinical site must be an authorised, registered health professional.

Where the activities at the site are minimal and the Chief Investigator will undertake most activities, a Principal Investigator may not be required but a Local Collaborator based at the site must be identified. The **Local Collaborator** is defined as a person undertaking certain types of straightforward research procedure, not requiring the appointment of a Principal Investigator. Local collaborators at NHS sites must seek NHS permission. This will usually be the individual with whom the Chief Investigator has negotiated access to the site or the head of the department where the research will take place.

For research where the Chief Investigator is not employed by or holds no honorary contract with Keele University, there is a need for a local lead. The **Associate Investigator** is a member of staff who takes responsibility for the conduct and delivery of those parts of the research which are either carried out at or managed/overseen by Keele University. Normally this would be a member of academic staff, but in some cases it may be a senior member of Keele Clinical Trials Unit staff.

Members of Keele staff tasked with leading for discrete activities under a Keele Chief Investigator may also be named as an **Associate Investigator** within the research team. Examples include but are not limited to Associate Investigator for laboratory analysis or Associate Investigator for a clinical trial.

7.3 The Grant Holder(s)

Normally, the principal grant holder for the research will be expected to act as Chief Investigator. However, where the principal grant holder is not appropriately qualified to act as Chief Investigator (e.g. member of the CTIMP team who is not a doctor, dentist or pharmacist) then an appropriately qualified individual must be identified to act as Chief Investigator.

7.4 Other Research Staff

Any researchers conducting activity within NHS bodies or other non-Keele University sites may require access approval prior to the activity taking place.

Keele University uses the Department of Health's Research Passport as the means of undertaking necessary pre-engagement checks and manage the receipt of letters of access or honorary contracts to cover activity within NHS bodies.

Any researcher requiring a letter of access or an honorary contract is responsible for following the Research Passport process and complying with the limitations of any letter of access or honorary contract while conducting research.

Keele University will facilitate sharing of information about staff members through the appropriate channels outlined in the Research Passport resource pack and maintain up-to-date records of researchers conducting research activity external to Keele University. Keele University will also ensure researchers are aware of their responsibilities when conducting research within premises external to Keele University.

8. Framework for Quality Systems

Keele University maintains a suite of policies and procedures to ensure standards and legislative requirements are met. This section provides an overview of these policies as relevant to Health and Social Care research. This overview must be read in conjunction with these other policies and quality management systems. It does not replace these requirements and the specific policies referred to will provide more detailed information not contained in this document.

Where necessary the University's Health and Social Care Quality Management System provides additional detail of the standards expected. The University will assess, identify and document requirements on a research specific basis through quality control mechanisms and risk assessments.

8.1 Training

Any staff involved in health and social care research must be appropriately qualified by education, training and experience to take on their respective task(s) in the research. Any relevant training or education must be documented, and readily available e.g. for quality review.

Staff members who are involved in the day to day (site) management of a CTIMP (e.g. chief investigator, research nurse, trial coordinator) are required to have completed accredited Good Clinical Practice training (recognised by the MHRA). In addition, staff members have to ensure (and be able to evidence) they stay up to date with their knowledge of Good Clinical Practice and applicable regulations, for example through

completing Good Clinical Practice refresher courses every 3 years. For all other research it is recommended that staff have completed Good Clinical Practice training relevant to their role.

8.2 Pharmacovigilance and Safety

All Keele University staff involved in research projects are expected to adhere to applicable regulations and guidance documents. For clinical research Keele University, as sponsor, via its Project Assurance Research Integrity Office (delegated to Keele Clinical Trials Unit where applicable) will take on the role of ensuring:

- Processes are in place to ensure Serious Adverse Events (SAEs) are reported in accordance with the regulations, ethical approval requirements and manufacturer requirements
- Protocols include clear mechanisms for safety reporting, relevant safety sections around interventions and/or a safety plan where the research requires it
- Where necessary, studies have appropriate Data Monitoring Committees
- There are processes in place to action urgent safety measures
- There are processes in place to action serious breaches of the protocol and / or GCP

Additionally, for CTIMPS:

- That safety issues relating to a specific investigational medicinal product are reported to any other trial team of a University-sponsored trial using the same investigational medicinal product
- Mechanisms for acting on safety signals, both clinical and non-clinical, are in place where required
- There are processes in place to ensure the accuracy, quality and timely submission of development safety update reports

8.3 Data Protection

All staff must ensure they are aware of Keele University policies for information governance and their responsibilities to work in accordance with the Data Protection Act and have completed an appropriate level of training in Information Governance. Keele University is registered with the Information Commissioner's office (Registration Number: Z5571818) for the purposes of processing personal information for research.

Keele University will process personal information for research without participant consent where the Confidentiality Advisory Group of the Health Research Authority has considered a proposal meets the necessary requirements, is fully supported by the Confidentiality Advisory Group and the processing has been reviewed by the Caldicott Guardian, reported to the Data Protection Officer and an Information Guardian has been identified.

8.4 Information Technology

Keele University staff must ensure that all research data is stored appropriately for their research. The data should be secure and protected from inadvertent use. The data should also be resilient and backed up to prevent loss in the event of a disaster.

All staff members will have access to their specialty file servers where they can store a fixed amount of data. These data are backed up on a daily basis. Data retention durations are in accordance with Keele University **Records Retention Schedule**.

8.5 Document storage and archiving

Universities have a legal responsibility to maintain records safely and securely in accordance with the Data Protection Act 2018. Staff are responsible for making sure that all records are periodically and routinely appraised to determine what can be transferred to Keele University archive sites.

Research-related documentation is archived in accordance with the University's Record Retention Schedule or otherwise in accordance with the applicable regulations or instruction from the sponsor.

8.6 Quality Assurance

Keele University undertakes audit of health and social care research in accordance with its Audit Programme. This audit programme is designed to help minimise the risk of poor quality research, adverse incidents, research misconduct and fraud. Findings are resolved primarily by research teams and are reported to Keele University's committee structure (see Figure 1) and escalated in accordance with risk.

Individual faculties may instigate additional audit programmes, for example the Clinical Trials Unit, which will also inform the Project Assurance Research Integrity audit programme.

Keele University may undertake audit of partner sites, vendors or overseas bodies conducting activity for Keele University sponsored research.

8.7 External Review

Keele University may seek external review or consultation of any aspect of the Keele Research Health and Social Care Quality Management System, including this policy. Review bodies may include but are not limited to other UK Universities, NHS Trusts and relevant regulatory or advisory bodies.

9. Version History

Version	Date	Reason for change
1.0	10-APR-2017	Rewrite of clinical trials policy to cover all health and social care research and not limited to sponsorship of CTIMPs.
2.0	29-APR-2020	3 year review. Update of policy in light of changes to research support, including formation of the RaISE team. Clarity added for co-sponsorship.
2.1	27-MAY-2020	Updated organogram as Research Governance and Integrity Committee no longer exists, Research Committee now serves the function of that committee.
2.2	02-Jul-2020	Removal of section and references to RGIC which had been left in in error.